UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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 001-40384

TOURMALINE BIO, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	83-2377352
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
27 West 24th Street, Suite 702 New York, NY	**10010**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (646) 481-9832

Not Applicable
(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, $0.0001 par value per share	TRML	The Nasdaq Global 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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

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 Act). Yes ☐ No ☒

The registrant had outstanding 20,336,741 shares of common stock, $0.0001 par value per share, as of November 10, 2023.

EXPLANATORY NOTE

On October 19, 2023, the Delaware corporation formerly known as “Talaris Therapeutics, Inc.” completed its previously announced merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger, dated as of June 22, 2023 (the “Merger Agreement”), by and among Talaris Therapeutics, Inc. (“Talaris”), Tourmaline Bio, Inc. (“Legacy Tourmaline”) and Terrain Merger Sub, Inc., a direct wholly owned subsidiary of Talaris (“Merger Sub”), pursuant to which Merger Sub merged with and into Legacy Tourmaline, with Legacy Tourmaline surviving as a direct wholly owned subsidiary of Talaris and the surviving corporation of the merger (the “Merger”). Additionally, as a result of the Merger, (i) Legacy Tourmaline changed its name from “Tourmaline Bio, Inc.” to “Tourmaline Sub, Inc.”, and (ii) Talaris changed its name from “Talaris Therapeutics, Inc.” to “Tourmaline Bio, Inc.” (the “Company”).

On October 19, 2023, in connection with the transactions contemplated by the Merger Agreement, Talaris filed a Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation effecting a 1-for-10 reverse stock split of Talaris’ common stock (the “Reverse Stock Split”). As a result of the Reverse Stock Split, the number of issued and outstanding shares of Talaris’ common stock immediately prior to the Reverse Stock Split was reduced such that every 10 shares of Talaris’ common stock held by a stockholder immediately prior to the Reverse Stock Split were combined and reclassified into one share of common stock after the Reverse Stock Split. Except where otherwise indicated, the information in this Quarterly Report on Form 10-Q as of and for the periods prior to the effective time of the Merger gives effect to the Reverse Stock Split.

Because the Merger was consummated after the period covered by the financial statements included in this Quarterly Report on Form 10-Q, the historical financial information included in this Quarterly Report on Form 10-Q, including as of and for the nine months ended September 30, 2023, unless otherwise indicated or as the context otherwise requires, is that of Talaris prior to the Merger.

In this Quarterly Report on Form 10-Q, unless the context indicates otherwise, the terms “Company,” “we,” “us,” and “our” refer to (i) Talaris Therapeutics, Inc., for periods prior to the effectiveness of the Merger and (ii) Tourmaline Bio, Inc. (as a combined company) for periods following the effectiveness of the Merger.

This Quarterly Report on Form 10-Q contains references to trademarks belonging to other entities, which are the property of their respective holders. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

TOURMALINE BIO, INC.

FORM 10-Q

TABLE OF CONTENTS

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials and results thereof, research and development costs, planned regulatory submissions, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “continue” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the success, cost and timing of our development activities, non-clinical studies and clinical trials;
- the timing and outcome of our current and future clinical trials, and the reporting of data from those trials;
- the therapeutic potential of TOUR006 and future product candidates;
- the ability to obtain funding for our operations, including funding necessary to develop and commercialize our current and future product candidates, subject to regulatory approvals:
- our ability to extend our operating capital;
- the potential of our technologies and our ability to execute on our corporate strategy;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our reliance on third parties to manufacture and conduct preclinical studies and clinical trials of our current and future product candidates;
- the success of competing therapies that are or may become available;
- our ability to obtain regulatory approval for our product candidates and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- the strength and breadth of our patent portfolio;
- our ability to obtain and adequately protect intellectual property rights for our product candidates;
- potential claims relating to our intellectual property;
- our financial performance;
- our ability to develop and maintain our corporate infrastructure, including our ability to design and maintain an effective system of internal controls;
- our ability to remediate the existing material weaknesses in our internal control over financial reporting;
- our ability to attract and retain key scientific, medical, commercial and management personnel;
- our ability to continue to satisfy the listing requirements of The Nasdaq Stock Market and have our stock continue to trade thereon; and
- the effects of macroeconomic and geopolitical conditions and unforeseeable events, such as the war in Ukraine and hostilities in the Middle East, potential bank failures and the COVID-19 pandemic.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in such statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein after we distribute this Quarterly Report on Form 10-Q, whether as a result of any new information, future events or otherwise.

In addition, “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon them.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TOURMALINE BIO, INC.

BALANCE SHEETS
(in thousands, except share and per share amounts)
(unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 67,083	$ 13,670
Marketable securities	79,941	167,612
Prepaid and other current assets	4,023	4,331
Total current assets	151,047	185,613
Property and equipment, net	—	5,348
Assets held for sale	14	—
Right-of-use assets	—	2,643
Other assets	—	111
Total assets	$ 151,061	$ 193,715
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 136	$ 3,887
Accrued expenses	7,288	6,665
Lease liability, current	634	910
Other current liabilities	47	—
Total current liabilities	8,105	11,462
Share repurchase liability	82	208
Other liabilities	—	16
Lease liability, net of current	—	1,974
Total liabilities	8,187	13,660
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock, $0.0001 par value, 140,000,000 shares authorized and 4,282,848 issued and outstanding and 10,000,000 non-voting shares authorized as of September 30, 2023 and 140,000,000 shares authorized and 4,162,942 issued and outstanding and 10,000,000 non-voting shares authorized as of December 31, 2022	—	—
Additional paid-in-capital	351,980	345,517
Accumulated deficit	(208,991)	(164,741)
Accumulated other comprehensive loss	(115)	(721)
Total stockholders' equity	142,874	180,055
Total liabilities and stockholders' equity	$ 151,061	$ 193,715

The accompanying notes are an integral part of these financial statements.

TOURMALINE BIO, INC.

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	$ 267	$ 14,981	$ 17,770	$ 42,364
General and administrative	9,114	4,842	21,322	14,288
Restructuring costs	89	—	10,958	—
Total operating expenses	9,470	19,823	50,050	56,652
Gain on asset sales	538	—	538	—
Loss from operations	(8,932)	(19,823)	(49,512)	(56,652)
Interest and other income (expense), net	1,917	812	5,262	1,286
Net loss	$ (7,015)	$ (19,011)	$ (44,250)	$ (55,366)
Unrealized gain (loss) on marketable securities	99	(79)	606	(1,144)
Total comprehensive loss	$ (6,916)	$ (19,090)	$ (43,644)	$ (56,510)
Net loss	$ (7,015)	$ (19,011)	$ (44,250)	$ (55,366)
Net loss per common share, basic and diluted	(1.64)	(4.59)	(10.48)	(13.45)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	4,271,920	4,137,553	4,221,205	4,114,939

The accompanying notes are an integral part of these financial statements.

TOURMALINE BIO, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)
(unaudited)

	Common Stock		Additional		Accumulated Other	Total
	Outstanding Shares	Amount	Paid-in Capital	Accumulated Deficit	Comprehensive Income (Loss)	Stockholders' Equity (Deficit)
Balance at December 31, 2021	4,091,304	$ —	$333,734	$ (90,847)	$ (78)	242,809
Issuance of common stock upon exercise of stock options	11,081	—	131	—	—	131
Stock-based compensation expense	—	—	2,197	—	—	2,197
Net loss	—	—	—	(18,259)	—	(18,259)
Unrealized gain on marketable securities	—	—	—	—	(848)	(848)
Balance at March 31, 2022	4,102,385	—	336,062	(109,106)	(926)	226,030
Issuance of common stock upon exercise of stock options	10,185	—	102	—	—	102
Issuance of common stock under 2021 employee stock purchase plan	2,016	—	77	—	—	77
Stock-based compensation expense	—	—	2,846	—	—	2,846
Net loss	—	—	—	(18,096)	—	(18,096)
Unrealized gain on marketable securities	—	—	—	—	(217)	(217)
Balance at June 30, 2022	4,114,586	$ —	$339,087	$ (127,202)	$ (1,143)	$ 210,742
Issuance of common stock upon exercise of stock options	18,164	—	174	—	—	174
Vesting of restricted stock units	15,438	—	—	—	—	—
Stock-based compensation expense	—	—	3,041	—	—	3,041
Net loss	—	—	—	(19,011)	—	(19,011)
Unrealized gain on marketable securities	—	—	—	—	(79)	(79)
Balance at September 30, 2022	4,148,188	$ —	$342,302	$ (146,213)	$ (1,222)	$ 194,867
Balance at December 31, 2022	4,162,942	$ —	$345,517	$ (164,741)	$ (721)	$ 180,055
Issuance of common stock upon exercise of stock options	8,778	—	92	—	—	92
Vesting of restricted stock units	19,283	—		—	—	—
Stock-based compensation expense	—	—	3,659	—	—	3,659
Net loss	—	—	—	(22,497)	—	(22,497)
Unrealized loss on marketable securities	—	—	—	—	422	422
Balance at March 31, 2023	4,191,003	—	349,268	(187,238)	(299)	161,731
Issuance of common stock upon exercise of stock options	17,975	—	177	—	—	177
Vesting of restricted stock units	45,748	—	—	—	—	—
Issuance of common stock under 2021 employee stock purchase plan	322	—	3	—	—	3
Stock-based compensation expense	—	—	1,174	—	—	1,174
Net loss	—	—	—	(14,738)	—	(14,738)
Unrealized loss on marketable securities	—	—	—	—	85	85
Balance at June 30, 2023	4,255,048	—	350,622	(201,976)	(214)	148,432
Issuance of common stock upon exercise of stock options	10,985	—	111	—	—	111
Vesting of restricted stock units	11,531	—	—	—	—	—
Stock-based compensation expense	—	—	1,247	—	—	1,247
Net loss	—	—	—	(7,015)	—	(7,015)
Unrealized loss on marketable securities	—	—	—	—	99	99
Balance at September 30, 2023	4,277,564	$ —	$351,980	$ (208,991)	$ (115)	$ 142,874

The accompanying notes are an integral part of these financial statements.

TOURMALINE BIO, INC.

STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine months ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	$ (44,250)	$ (55,366)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	494	1,029
Accretion and amortization of marketable securities, net	(3,872)	(621)
Amortization of right-of-use assets	644	580
Stock-based compensation expense	6,081	8,084
Asset impairment	3,614	235
Right-of-use asset impairment	469	—
Gain on asset sales	(538)	—
Loss on disposal of assets	129	—
Changes in operating assets and liabilities:		
Prepaid and other current assets	1,658	(1,634)
Other assets	111	(7)
Accounts payable	(3,626)	(215)
Accrued expenses	635	1,260
Other current liabilities	47	—
Operating lease liability	(682)	(423)
Other liabilities	(16)	91
Net cash used in operating activities	(39,102)	(46,987)
Cash flows from investing activities:		
Purchases of property and equipment	(541)	(2,774)
Proceeds from asset sales	650	—
Purchases of marketable securities	(85,154)	(140,588)
Maturities of marketable securities	177,303	190,021
Net cash provided by investing activities	92,258	46,659
Cash flows from financing activities:		
Proceeds from exercise of stock options	259	105
Payment for repurchase of forfeited restricted stock	(5)	—
Proceeds from issuance of common stock under 2021 employee stock purchase plan	3	77
Net cash provided by financing activities	257	182
Net increase in cash, cash equivalents and restricted cash	53,413	(146)
Cash and cash equivalents at beginning of period	13,670	18,614
Cash and cash equivalents at end of period	$ 67,083	$ 18,468
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment additions included in accounts payable and accrued expenses	$ —	$ 178
Deferred issuance costs included in accounts payable and accrued expenses	$ —	$ 81
Decrease in right-of-use asset and operating lease liabilities due to remeasurement	$ 1,388	$ —
Decrease in right-of-use asset and operating lease liabilities due to termination	$ 142	$ —
Proceeds for asset sales included in other current assets	$ 1,350	$ —

The accompanying notes are an integral part of these financial statements.

TOURMALINE BIO, INC.

NOTES TO FINANCIAL STATEMENTS
(unaudited)

1. Nature of Business and Liquidity

Talaris Therapeutics, Inc. ("Talaris") was a cell therapy company focused on developing an innovative method of allogeneic hematopoietic stem cell transplantation ("allo-HSCT") to transform the standard of care in solid organ transplantation, certain severe autoimmune diseases and certain severe blood, immune and metabolic disorders. Talaris' lead product candidate was FCR001. On October 19, 2023, Talaris completed its previously announced merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger, dated as of June 22, 2023 (the "Merger Agreement"), by and among Talaris, Tourmaline Sub, Inc. (formerly known as Tourmaline Bio, Inc., "Legacy Tourmaline") and Terrain Merger Sub, Inc., a direct wholly owned subsidiary of Talaris ("Merger Sub"), pursuant to which Merger Sub merged with and into Legacy Tourmaline, with Legacy Tourmaline surviving as a direct wholly owned subsidiary of Talaris and the surviving corporation of the merger (the "Merger"). On October 19, 2023, in connection with and prior to the completion of the Merger, Talaris effected a 1-for-10 reverse stock split of its common stock (the "Reverse Stock Split"). Upon the completion of the Merger, Legacy Tourmaline changed its name from "Tourmaline Bio, Inc." to "Tourmaline Sub, Inc.", and Talaris changed its name from "Talaris Therapeutics, Inc." to "Tourmaline Bio, Inc." (the "Company"). The Merger and the Reverse Stock Split are further described below in Note 15. *Subsequent Events*.

Following the completion of the Merger, the business conducted by the Company became primarily the business conducted by Legacy Tourmaline, which is a late-stage clinical biotechnology company developing transformative medicines that dramatically improve the lives of patients with life-altering immune diseases. The Company's lead product candidate is TOUR006, a fully human monoclonal antibody that selectively binds to interleukin-6, a key proinflammatory cytokine involved in the pathogenesis of many autoimmune and inflammatory disorders. Founded on September 17, 2021, the Company is headquartered in New York City.

Prior to the Merger, in February 2023, Talaris announced the discontinuation of its FREEDOM-1 and FREEDOM-2 clinical trials evaluating FCR001's ability to induce durable tolerance in living donor kidney transplant recipients. This decision was primarily attributable to the pace of enrollment and the associated timeline to critical milestones. Talaris also announced a restructuring plan that resulted in the reduction in its workforce by 33% (the "Initial Reduction in Force") and a comprehensive review of strategic alternatives focused on maximizing shareholder value, including, but not limited to, a reverse merger and/or a divestiture of its cell therapy chemistry, manufacturing and controls ("CMC") capabilities.

In March 2023, pending the outcome of its review of strategic alternatives, Talaris voluntarily paused enrollment in the FREEDOM-3 Phase 2 clinical trial evaluating FCR001's ability to induce tolerance in diffuse systemic scleroderma, a severe autoimmune disease, while continuing to evaluate patients for potential future enrollment.

In April 2023, Talaris' Board of Directors approved, and Talaris announced, a further reduction in force (the "April Reduction in Force") that resulted in the termination of approximately 80 additional employees, or approximately 95% of its remaining workforce. The April Reduction in Force was substantially completed in the second quarter of 2023.

In June 2023, following a comprehensive review of strategic alternatives, Talaris entered into the Merger Agreement with Legacy Tourmaline (see Note 15).

In July 2023, Talaris entered into an asset purchase agreement with ImmunoFree, Inc. ("ImmunoFree"), pursuant to which it sold certain clinical data and intellectual property related to FCR001 for approximately $2.2 million, including a combination of cash consideration, reimbursement of certain expenses and assumption of all current and future clinical wind-down liabilities (see Note 5).

In September 2023, Talaris sold certain long-lived assets primarily used in its CMC operations (see Note 5).

On October 19, 2023, Talaris completed the Merger with Legacy Tourmaline pursuant to the Merger Agreement as described in Note 15. *Subsequent Events*. The Reverse Stock Split has been retroactively applied to the accompanying financial statements and notes to the financial statements (see Note 15). In connection with the Merger, a special dividend of $64.7 million was paid to eligible pre-Merger Talaris stockholders (see Note 15).

The financial information included in the accompanying interim financial statements is that of Talaris prior to the Merger because the Merger was consummated after the period covered by these financial statements. Unless the context indicates otherwise, the term "Company" as used hereinafter refers to (i) Talaris Therapeutics, Inc., for periods prior to the effectiveness of the Merger, and (ii) Tourmaline Bio, Inc. (as a combined company) for periods following the effectiveness of the Merger.

Liquidity

The accompanying interim financial statements have been prepared assuming that the Company will continue as a going concern. Management has evaluated whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. Since its inception, the Company has incurred net losses and negative cash flows from operations. During the nine months ended September 30, 2023 and the year ended December 31, 2022, the Company incurred a net loss of $44.3 million and $73.9 million, respectively, and used $39.1 million and $60.9 million in cash for operations, respectively. In addition, as of September 30, 2023, the Company had an accumulated deficit of $209.0 million. The Company expects to continue to generate operating losses and negative cash flows for the foreseeable future. The Company currently expects its post-merger cash, cash equivalents, and marketable securities of $218.2 million will be sufficient to fund its operating expenses and capital requirements for more than twelve months from the date the financial statements are available to be issued.

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, assumptions, and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of financial statements, and the reported amounts of income and expense during the reporting period. The most significant estimates relate to the determination of the fair value of stock option grants and estimates related to the amount of prepaid and accrued research and development expenses as of the balance sheet date. Management evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors, including the current economic environment, and makes adjustments when the facts and circumstances dictate. These estimates are based on information available as of the date of the financial statements; therefore, actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. As of September 30, 2023 and December 31, 2022, cash and cash equivalents consisted primarily of checking and savings deposits, money market fund holdings, and commercial paper.

Marketable Securities

The Company classifies its marketable securities as available-for-sale securities, which are carried at their fair value based on the quoted market prices of the securities. Unrealized gains and losses are reported as accumulated other comprehensive loss, a separate component of stockholders' deficit. Realized gains and losses on available-for-sale securities are included in net loss in the period earned or incurred.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset. Equipment and furniture and fixtures are depreciated over five or seven year lives. Leasehold improvements are amortized over the shorter of the lease term or the five-year estimated useful life of the asset. Computer equipment and computer software are depreciated over three years. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are expensed as incurred.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, which consist primarily of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. During the three and nine months ended September 30, 2023, the Company recorded non-cash impairment charges of $0.2 million and $3.6 million, respectively. For additional disclosures regarding the $3.6 million non-cash impairment charge and accompanying analysis, refer to Note 7. During the year three and nine months ended September 30, 2022, the company recorded non-cash impairment charges of $0.2 million.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company's investment policy includes guidelines regarding the quality of the financial institutions and financial instruments and defines allowable investments that it believes minimizes the exposure to concentration of credit risk. The Company may invest in money market funds (minimum of $1 billion in assets), U.S. Treasury securities, corporate debt, bank debt, U.S. government-related agency securities, other sovereign debt, municipal debt and commercial paper. These deposits may exceed federally insured limits. The Company has not experienced any losses historically in these accounts and believes that it is not exposed to significant credit risk as its deposits are held at financial institutions that management believes to be of high credit quality.

On March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation ("FDIC") was appointed as receiver. On March 27, 2023, SVB was acquired by First-Citizen BancShares, Inc ("First-Citizen"). Similarly, on May 1, 2023, First Republic Bank ("FRB") was closed by the California Department of Financial Protection and Innovation and the FDIC was appointed as receiver. JPMorgan Chase Bank, National Association (N.A.) acquired all of FRB's deposit accounts and substantially all of its assets. The Company historically did not and currently does not have banking relationships with SVB or FRB.

Fair Value of Financial Instruments

Fair value is defined as the price that the Company would receive to sell an investment in a timely transaction or pay to transfer a liability in a timely transaction with an independent buyer in the principal market, or in the absence of a principal market, the most advantageous market for the investment or liability. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 investments) and the lowest priority to unobservable inputs (Level 3 investments).

The three levels of the fair value hierarchy are as follows:

- ***Level 1 inputs:*** Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- ***Level 2 inputs:*** Quoted prices in markets that are not considered to be active or financial instrument valuations for which all significant inputs are observable, either directly or indirectly; and

- ***Level 3 inputs***: Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

Financial instruments are categorized in their entirety based on the lowest level of input that is significant to the fair value measurement. The assessment of the significance of a particular input to the fair value measurement requires judgment and considers factors specific to the investment.

The Company's money market funds and marketable securities are carried at fair value determined according to the fair value hierarchy described above (Level 1 and Level 2, respectively).

Research and Development Expenses

Research and development expenses include (i) employee-related expenses, including salaries, benefits, travel and stock-based compensation expense; (ii) external research and development expenses incurred under arrangements with third parties, such as contract research organization agreements, investigational sites, and consultants; (iii) the cost of acquiring, developing, and manufacturing clinical study materials; (iv) costs associated with preclinical and clinical activities and regulatory operations; (v) costs incurred in development of intellectual property; and (vi) an allocated portion of facilities and other infrastructure costs associated with research and development activities. Costs incurred in connection with research and development activities are expensed as incurred.

The Company enters into consulting, research, and other agreements with commercial entities, researchers, universities, and others for the provision of goods and services. Such arrangements are generally cancelable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the respective vendors, including the Company's clinical sites. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company. Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved, and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees, nonemployees, and directors based on the fair value on the date of the grant and recognizes stock-based compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock option, restricted stock unit, and stock appreciation right awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company's policy is to account for forfeitures when they occur.

The Company classifies stock-based compensation expense in its statement of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company recently completed its IPO and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the US Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero because the Company has never paid cash dividends on common stock and did not expect to pay any cash dividends prior to completion of the Merger.

Prior to the Company's IPO, the Company considered the estimated fair value of the common stock as of the measurement date in determining the exercise price for options granted. The estimated fair value of the common stock was determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including convertible preferred stock), the effect of the rights and preferences of the preferred shareholders, and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, forecasted future operations of the Company, an evaluation or benchmark of the Company's competition, and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date. The fair value for options granted since the Company's IPO are based on the closing stock price on grant date.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more likely than not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions. These reserves are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. Potential interest and penalties associated with such uncertain tax positions are recorded as a component of income tax expense. The Company had no significant uncertain tax positions as of September 30, 2023 and December 31, 2022.

Basic and Diluted Net Loss Per Share

The Company calculates basic and diluted net loss per share using the two-class method. The two-class method requires income available to common stock as if all income for the period had been distributed. Accordingly, basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by dividing the net loss by the sum of the weighted average number of common shares outstanding during the period plus the dilutive effects of potentially dilutive securities outstanding during the period. Potentially dilutive securities include vested and unexercised stock options, restricted stock issued upon early exercise of stock options, convertible preferred shares and contingent stock liabilities. The dilutive effect of stock options and contingent stock liabilities are computed using the treasury stock method and the dilutive effect of convertible preferred shares is calculated using the if-converted method. The Company has generated a net loss for all periods presented, therefore diluted net loss per share is the same as basic net loss per share since the inclusion of potentially dilutive securities would be anti-dilutive.

Segments

Operating segments are defined as components of an entity for which separate financial information is made available and is regularly evaluated by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company's CODM is the chief executive officer and operations are managed as a single segment for the purposes of assessing performance and making operating decisions.

Comprehensive Loss

Comprehensive loss represents net loss for the period plus the results of certain other changes in stockholders' equity. The Company's comprehensive loss included unrealized gains related to marketable securities for the nine months ended September 30, 2023 and 2022.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), and subsequently has issued additional guidance (collectively, "ASC 842"), which requires companies to generally recognize operating and financing lease liabilities and corresponding right-of-use assets on the balance sheet. The Company adopted ASC 842 on January 1, 2022 using the modified retrospective approach, with no restatement of prior periods. Upon adoption, the Company elected the package of transitional practical expedients which allowed the Company to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. In addition, the Company made an accounting policy election to not apply the recognition requirements in the leasing standards to short-term leases, which is a lease that at commencement date has a lease term of 12 months or less and does not contain a purchase option that it is reasonably certain to exercise.

As a result of the adoption of the new leasing standards, on January 1, 2022, the Company recorded right-of-use assets of $3.4 million and operating lease liabilities of $3.5 million. The adoption did not have a material impact on the statement of operations or the statement of cash flows.

3. Fair Value of Financial Assets

The following table presents information about the Company's financial instruments that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the inputs the Company utilized to determine such fair value *(in thousands)*:

	September 30, 2023			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Money market funds (cash equivalents)	$ 66,719	$ 66,719	$ —	$ —
Marketable securities	79,941	7,826	72,115	—
Total financial assets measured at fair value	$146,660	$74,545	$72,115	$ —

	December 31, 2022			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Money market funds (cash equivalents)	$ 12,309	$ 12,309	$ —	$ —
Marketable securities	167,612	31,718	135,894	—
Total financial assets measured at fair value	$179,921	$44,027	$135,894	$ —

4. Marketable Securities

The fair value of the Company's marketable securities as of September 30, 2023 and December 31, 2022 is based on level 1 and level 2 inputs. The Company's investments consist mainly of U.S. government and agency securities, government-sponsored bond obligations and certain other corporate debt securities. Fair value is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs. There were no transfers between levels within the hierarchy during the nine months ended September 30, 2023 and the year ended December 31, 2022. The Company has assessed U.S. government treasuries as level 1 and all other marketable securities as level 2 within the fair value hierarchy of ASC 820. The Company classifies its entire investment portfolio as available-for-sale as defined in ASC 320, Debt Securities. Securities are carried at fair value with the unrealized gains (losses) reported in other comprehensive loss.

As of September 30, 2023 and December 31, 2022, none of the Company's investments were determined to be other than temporarily impaired.

The following table summarizes the Company's investments *(in thousands)*:

	September 30, 2023			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Commercial paper	$35,371	$ 1	$ (54)	$35,318
Government and agency securities	44,685	3	(65)	44,623
Total	$80,056	$ 4	$ (119)	$79,941

	December 31, 2022			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Commercial paper	$119,313	$ 19	$ (365)	$118,967
Government and agency securities	43,016	—	(368)	42,648
Corporate debt securities	6,004	—	(7)	5,997
Total	$168,333	$ 19	$ (740)	$167,612

The aggregate fair value of available-for-sale securities in an unrealized loss position as of September 30, 2023 was $61.1 million. The Company has reviewed its portfolio of available-for-sale debt securities and determined that the decline in fair value below cost did not result from credit-loss related factors. As such, no allowance for credit losses was recorded as of September 30, 2023.

5. Asset Sales

On July 7, 2023, the Company entered into an asset purchase agreement with ImmunoFree, Inc. (the "ImmunoFree APA"), effective July 1, 2023. Pursuant to the terms of the ImmunoFree APA, the Company sold certain clinical data and intellectual property related to FCR001 for cash consideration of $0.5 million, reimbursement of $0.2 million for certain expenses and assumption of all current and future clinical wind-down liabilities. In connection with this agreement, the Company relinquished its rights under the ULRF License Agreement in order to allow ImmunoFree to license such rights to FCR001 from ULRF (see Note 10). The Company recorded a gain on sale of asset of $0.5 million in the accompanying statement of operations and comprehensive loss.

On September 29, 2023, the Company entered into an asset purchase agreement with New York Blood Center, Inc. ("NYBC") (the "NYBC APA"). Pursuant to the terms of the NYBC APA, the Company sold its long-lived assets primarily used in its CMC operations for cash consideration of $1.5 million and assumption of the Company's lease obligations related to its laboratory space in Louisville, Kentucky and Houston, Texas (see Note 7).

6. Prepaid and Other Current Assets

Prepaid and other current assets consisted of the following *(in thousands)*:

	September 30, 2023	December 31, 2022
Prepaid insurance	$ 1,179	$ 1,037
Prepaid research and development expenses	—	2,426
Receivable from asset sale	1,350	—
Other current assets	1,494	868
Total prepaid and other current assets	$ 4,023	$ 4,331

7. Property and Equipment, Net and Assets Held for Sale

Property and equipment, net consisted of the following *(in thousands)*:

	September 30, 2023	December 31, 2022
Equipment	$ —	$ 6,562
Leasehold improvements	—	1,191
Computer equipment	—	859
Furniture and fixtures	—	674
Construction in progress	—	242
Total property and equipment	—	9,528
Less accumulated depreciation	—	(4,180)
Property and equipment, net	$ —	$ 5,348

Depreciation expense was immaterial and $0.5 million for the three and nine months ended September 30, 2023, respectively, and $0.4 and $1.0 million for the three and nine months ended September 30, 2022, respectively.

The Company reviewed the cumulative impact of its announcements in February, March and April of 2023 to discontinue its FREEDOM-1 and FREEDOM-2 clinical trials and initiate a reduction in force of 33% of its employees, pause enrollment in its FREEDOM-3 clinical trial and initiate a second reduction in force of 95% of its remaining employees, respectively, on the carrying value of certain of its long-lived assets. The analysis resulted in the Company determining a triggering event had occurred in relation to the long-lived assets used primarily in the Company's CMC operations The Company obtained third-party quotes to assess the current fair value of these assets and determine if an impairment had occurred. The value determined from these quotes was $2.0 million, resulting in the Company recording a non-cash impairment expense of $2.7 million for the assets, during the period ended March 31, 2023.

In April 2023, the Company committed to a plan to sell its long-lived assets used primarily in its CMC operations. The assets held for sale were reported at the lower of the carrying amount or fair value, less costs to sell. In May 2023, the Company evaluated the fair value, less costs to sell, of its assets held for sale in connection with a potential sale and determined that an impairment had occurred. The Company recorded a non-cash impairment expense of $0.5 million, during the period ended June 30, 2023. The Company completed the sale of its long-lived assets used primarily in its CMC operations in September 2023 (see Note 5).

In June 2023, the Company reviewed the impact of the ImmunoFree APA on the carrying value of certain long-lived assets (see Note 5). The analysis resulted in the Company determining a triggering event had occurred in relation to computer equipment. The Company determined the assets had no carrying value and recorded a non-cash impairment charge of $0.2 million, during the period ended June 30, 2023.

In September 2023, the Company committed to a plan to sell its remaining long-lived assets of primarily office furniture and computer equipment and therefore classified such assets as held for sale on the accompanying balance sheet as of September 30, 2023 (see Note 15). The assets held for sale were reported at the lower of the carrying amount or fair value, less costs to sell. The Company obtained third-party quotes to assess the current fair value of these assets and determine if an impairment had occurred. The value determined from these quotes was immaterial, resulting in the Company recording a non-cash impairment expense of $0.2 million for the assets during the period ended September 30, 2023.

8. Restructuring Costs

In February 2023, after a review of the Company's business, programs, resources and capabilities, including anticipated costs and timelines, the Company announced the decision to discontinue its FREEDOM-1 and FREEDOM-2 clinical trials and to conduct a comprehensive review of strategic alternatives.

The Company announced a restructuring plan that resulted in the Initial Reduction in Force and the April Reduction in Force, which were substantially completed as of September 30, 2023. During the three and nine months ended September 30, 2023, the Company recorded restructuring costs of $0.1 million and $7.5 million, respectively, related to severance, employee termination, and retention costs.

Restructuring costs also included impairment expense of zero and $3.4 million for the three and nine months ended September 30, 2023, respectively (see Note 7).

The Company's restructuring liability, which is included in accrued compensation and benefit costs (see Note 9), consisted of the following *(in thousands)*:

	Employee-Related Costs	
	Three months ended September 30, 2023	Nine months ended September 30, 2023
Accrued restructuring balance at beginning of period	$ 3,262	$ —
Expenses incurred	89	7,535
Payments	(1,993)	(6,177)
Accrued restructuring balance at September 30, 2023	$ 1,358	$ 1,358

9. Accrued Expenses

Accrued expenses consisted of the following *(in thousands)*:

	September 30, 2023	December 31, 2022
Compensation and benefit costs	$ 1,498	$ 3,566
Research and development expenses	418	1,978
Legal settlement	4,000	—
Professional fees, consulting and other	1,372	1,121
Total accrued expenses	$ 7,288	$ 6,665

10. Commitments and Contingencies

Leases

The Company had one active lease agreement for office space as of September 30, 2023. The Company's former cell processing facility lease was located on the University of Louisville campus in Louisville, Kentucky (the "Louisville Lease"). This lease had a termination date in November 2023, with an option to extend for three additional one-year renewals at the Company's discretion. In May 2020, the Company added additional office and laboratory space to the Louisville Lease. In March 2023, the Company entered into an amended lease agreement for the Louisville Lease that increased the successive one-year renewal terms from three to five and reduces the written notice period for the successive one-year renewals from six months in advance to three months in advance.

The Company reviewed the cumulative impact of its announcements in February, March and April of 2023 on its lease terms. Based on this analysis, the Company determined a triggering event had occurred and it was not reasonably certain to exercise its option to renew the Louisville Lease upon its original termination in November 2023. As a result of this determination, the Company remeasured the associated right-of-use asset and operating lease liability. The Company prospectively modified the estimated useful lives of the existing leasehold improvements. These assets were subject to the non-cash impairment disclosed in Note 7.

In September 2023, the Company, NYBC and landlord entered into an assignment, assumption, and amendment of lease and landlord consent agreement ("Louisville Lease Assignment Agreement"). Pursuant to the Louisville Lease Assignment Agreement, the Company assigned its rights and obligations under the Louisville Lease to NYBC effective September 29, 2023. The Company recorded a reduction to the associated right-of-use asset and operating lease liability. There was no impact to the accompanying statement of operations for the three and nine months ended September 30, 2023.

In September 2021, the Company entered into a sublease agreement for separate office space in Louisville, Kentucky. This sublease had a termination date in November 2023. In August 2023, the Company entered into an amended sublease agreement, effective August 1, 2023, to terminate the sublease for no cash consideration. The Company recorded a reduction to the associated right-of-use asset and operating lease liability. There was no impact to the accompanying statement of operations for the three and nine months ended September 30, 2023.

In July 2021, the Company entered into a lease agreement for laboratory space in Houston, Texas (the "Houston Lease"). The Houston Lease commenced in January 2022. The term of the lease was 36 months from the commencement date, terminating December 2024. In September 2023, the Company, NYBC and landlord entered into an assignment, assumption, and amendment of lease and landlord consent agreement ("Houston Lease Assignment Agreement"). Pursuant to the Houston Lease Assignment Agreement, the Company assigned its rights under the Houston Lease to NYBC effective September 29, 2023. The Company recorded a reduction to the associated right-of-use asset and operating lease liability. The Company recorded a minimal gain on disposal of the right-of-use asset as gain on asset sale in the accompanying statement of operations and comprehensive loss for the three and nine months ended September 30, 2023. Pursuant to the Houston Lease Assignment Agreement, the Company retained its obligations to the Houston Lease as a guarantor. The Company evaluated the conditions of its guarantee as of the balance sheet date and determine the fair value of the guarantee is de-minimus.

The Company maintained a lease for office space in Wellesley, Massachusetts (the "Boston Lease") as of September 30, 2023. The Boston Lease, that had an original termination date in March 2021. In April 2021, the Company entered into an amended lease agreement providing for temporary space from April 2021 until an expansion of the Boston Lease was complete, from which the lease term extends 39 months from the expansion completion date. The expansion was completed in June 2022, resulting in the lease term extending to September 2025. In October 2023, the Company entered into an agreement to terminate the lease (see Note 15). The Company determined a triggering event had occurred in relation to its Boston Lease and recorded a non-cash impairment expense of $0.5 million related to its right-of-use asset during the three and nine months ended September 30, 2023, included in general and administrative expenses in the accompanying statements of operations and comprehensive loss.

The future minimum rent payments relating to the Company's Boston Lease under the terms and conditions existing as of September 30, 2023, were $0.6 million for the year ending December 31, 2023. In October 2023, the Company paid $0.6 million in connection with its termination of the Boston Lease (see Note 15). Subsequent to the October payment on the Boston Lease, the Company has no remaining lease obligations.

The Company incurred rent expense of $0.2 million and $0.7 million for the three and nine months ended September 30, 2023, respectively, and $0.3 million and $0.8 million for three and nine months ended September 30, 2022, respectively.

Cash paid for amounts included in the measurement of the Company's operating lease liability was $0.3 million and $0.5 million for the three and nine months ended September 30, 2023, respectively, and $0.2 million and $0.6 million for the three and nine months ended September 30, 2022, respectively.

License Agreement

In October 2018, the Company entered an amended and restated exclusive license agreement with ULRF related to certain licensed patent rights and know-how related to human facilitating cells for its Facilitated allo-HSCT Therapy approach. Pursuant to the ULRF License Agreement, ULRF granted the Company an exclusive, worldwide license under such patents and a nonexclusive royalty-bearing, worldwide license for such know-how to research, develop, commercialize and manufacture FCR001 and products containing FCR001 in all fields, without limitation. ULRF also granted the Company the right to grant sublicenses in accordance with the ULRF License Agreement. Under the terms of the agreement, the Company is obligated to compensate ULRF three percent of net sales of all licensed products sold, one third of any non-royalty sublicensing income, and up to $1.625 million in regulatory and sales milestones on each licensed product upon the occurrence of specific events as outlined in the license agreement; and annual license maintenance fees.

In addition, upon execution of the ULRF License Agreement, the Company granted contingent equity consideration equal to 65,186 shares of common stock to ULRF. Coincident with the completion of the Company's IPO, the Company issued 48,889 shares of common stock to ULRF and provided a cash payment of approximately $0.3 million in lieu of issuing the remaining 16,297 shares of common stock.

The Company incurred $0.1 million in expense in January 2023 related to an annual maintenance fee pursuant to the ULRF License Agreement for the year ending December 31, 2023. The Company incurred $0.1 million in expense in February 2022 related to an annual maintenance fee pursuant to the license agreement for the year ended December 31, 2022.

In connection with the transaction with ImmunoFree, the ULRF License Agreement relating to FCR001 was terminated, conditioned upon the license of Talaris' rights under the ULRF License Agreement to ImmunoFree.

Legal Proceedings

At each reporting date, the Company evaluates whether a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as incurred.

The Company may be involved in litigation arising in the ordinary course of conducting business. The Company reviews all litigation on an ongoing basis when making accrual and disclosure decisions. The Company, in accordance with current accounting standards for loss contingencies and based upon information currently known by the Company, will establish reserves for litigation when it is probable that a loss associated with a claim or proceeding has been incurred and the amount of the loss or range of loss can be reasonably estimated. When no amount within the range of loss is a better estimate than any other amount, the Company will accrue the minimum amount of the estimable loss. To the extent that such litigation against the Company may have an exposure to a loss in excess of the amount accrued, the Company believes that such excess would not be material to its financial condition, results of operations, or cash flows.

In September 2023, the Company received a purported notice of material breach from ImmunoFree (the "ImmunoFree Demand Letter") alleging that the Company breached a provision of the ImmunoFree APA and that the Company fraudulently induced ImmunoFree to enter into the ImmunoFree APA. In the ImmunoFree Demand Letter, ImmunoFree alleged the Company failed to disclose certain information and costs related to a patient in the FREEDOM-1 Study and demanded that the Company indemnify ImmunoFree for the cost of treatment for this patient. During the three and nine months ended September 30, 2023, the Company recorded an expense of $4.0 million related to the ImmunoFree Demand Letter (see Note 15). This expense is included in accrued expenses in the accompanying balance sheets (see Note 9) and general and administrative expenses in the accompanying statements of operations and comprehensive loss.

In addition, three individual lawsuits have been filed against Talaris and its directors related to the Merger: Wieder v. Talaris Therapeutics, Inc., et al., No. 1:23-cv-08355 (S.D.N.Y. filed Sept. 21, 2023), Carlisle v. Talaris Therapeutics, Inc., et al., No. 1:23-cv-08520 (S.D.N.Y. filed Sept. 27, 2023), and Roberts v. Talaris Therapeutics, Inc., et al., No. 1:23-cv-01063 (D. Del. filed Sept. 27, 2023) (collectively, the "Stockholder Litigation"). The complaints named Talaris and the Board of Directors of Talaris as defendants. Legacy Tourmaline and its officers and directors were not named as defendants in the complaints. The complaints asserted claims under Section 14(a) and Section 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 14a-19 promulgated thereunder, and generally allege that the proxy statement filed by Talaris on July 20, 2023, and as amended on August 25, 2023 and September 11, 2023 (the "Proxy Statement"), misrepresents and/or omits certain purportedly material information relating to the Merger. The complaints sought a variety of equitable and injunctive relief including, among other things, an injunction enjoining the consummation of the Merger, rescission of the Merger if it is consummated, rescissory damages and costs and attorneys' fees.

Between July 25 and September 20, 2023, six purported stockholders of Talaris sent demand letters regarding the Proxy Statement (the "Demand Letters"). Based on the same core allegations as the Stockholder Litigation, the Demand Letters requested that Talaris disseminate corrective disclosures in an amendment or supplement to the Proxy Statement.

On October 10, 2023, Talaris filed a Form 8-K to update and supplement the Proxy Statement with additional disclosures relating to the Merger (the "Supplemental Disclosures"). Thereafter, plaintiffs in the Stockholder Litigation voluntarily dismissed their complaints, and opposing counsel (for the stockholders in the Stockholder Litigation and Demand Letters) requested a mootness fee in connection with the Supplemental Disclosures. The ultimate outcome of any litigation is uncertain and unfavorable outcomes could have a negative impact on the Company's results of operations and financial condition. Regardless of outcome, litigation can have an adverse impact on the Company due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

11. Common Stock

Common Stock

On April 30, 2021, the Company's stockholders approved the third amended and restated certificate of incorporation of the Company, which included the authorization of 10,000,000 shares of undesignated preferred stock with a par value of $0.0001, authorization of 140,000,000 shares of voting common stock and 10,000,000 shares of non-voting common stock. As of September 30, 2023, no undesignated preferred stock was outstanding.

Common Stock Reserved

The number of shares of common stock that have been reserved for outstanding stock-based awards granted and stock-based awards available for grant under the Company's 2021 Stock Option and Incentive Plan (the "2021 Plan") and the 2018 Equity Incentive Plan (the "2018 Plan") and shares reserved for issuance under the Company's 2021 Employee Stock Purchase Plan (the "2021 ESPP") are as follows:

	September 30, 2023	December 31, 2022
Restricted stock related to early exercise of common stock options	5,281	15,815
Restricted stock units outstanding	60,478	114,461
Outstanding common stock options	533,900	626,373
Outstanding stock appreciation rights	100,000	—
Shares reserved for issuance under equity incentive plans	227,602	75,843
Shares reserved for issuance under the 2021 Employee Stock Purchase Plan	158,109	116,644
Total	1,085,370	949,136

12. Stock-Based Compensation

2021 Employee *Stock Purchase Plan*

On January 1, 2023, an additional 41,787 shares were added to the 2021 ESPP, representing 1% of total common shares outstanding at December 31, 2022, pursuant to the terms of the plan. The expense incurred under this plan for the nine months ended September 30, 2023 and 2022 was immaterial to the financial statements. The amounts have been included in the total stock-based compensation line items in the accompanying financial statements and disclosures.

Equity Incentive Plans

On January 1, 2023 an additional 208,937 shares were added to the 2021 Plan, representing 5% of total common shares outstanding at December 31, 2022, pursuant to the terms of the plan.

As of September 30, 2023, 227,602 shares remained available for future grant under the 2021 Plan. 694,378 stock-based award units were outstanding under the 2021 Plan and 2018 Plan as of September 30, 2023.

The Company's 2021 Plan provides for the Company to sell or issue common stock or restricted common stock or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, nonemployees and members of the board of directors of the Company. The 2021 Plan is administered by the board of directors or at the discretion of the board of directors by the compensation committee of the board. The exercise prices, vesting periods, and other restrictions are determined at the discretion of the compensation committee of the board of directors, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the contractual term of stock option may not be greater than 10 years. Stock options granted to date typically vest over four years.

Stock Option Valuation

The assumptions used to determine the fair values of stock options granted to employees and directors are presented as follows:

	Nine months ended September 30,	
	2023	2022
Fair value of common stock	$17.30 - $25.40	$23.00 - $165.60
Dividend yield	—%	—%
Volatility	90.36% - 91.64%	82.29% - 88.41%
Risk-free interest rate	3.46% - 3.98%	1.46% - 3.38%
Expected term (years)	5.50 - 6.25	5.38 - 6.25

Summary of Option Activity

The Company's stock option activity regarding employees, directors, and nonemployees is summarized as follows (*in thousands excepts share and per share amounts)*:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate intrinsic value
Options outstanding—December 31, 2022	626,373	$ 69.20	8.43	$ 42
Granted	118,450	18.56		
Exercised	(27,686)	9.34		
Cancelled	(55,348)	84.53		
Forfeited	(127,789)	69.67		
Other	(100)	59.58		
Options outstanding—September 30, 2023	533,900	$ 60.20	8.02	$ 1,506
Options exercisable—September 30, 2023	240,475	$ 59.13	7.65	

Additional information with regard to stock option activity involving employees and directors is as follows (*in thousands except per share amounts)*:

	Nine months ended September 30,	
	2023	2022
Weighted-average grant-date fair value per option of total options granted	$ 13.73	$ 60.40
Aggregate intrinsic value of stock options exercised	489	286

As of September 30, 2023, total unrecognized compensation cost related to the unvested awards to employees, directors, and nonemployees is $2.5 million, which is expected to be recognized in October 2023 as a result of the Company's merger (see Note 15).

Summary of Restricted Stock Unit Activity

The fair values of restricted stock units ("RSUs") are based on the fair market value of the Company's common stock on the date of grant. Each RSU represents a contingent right to receive one share of the Company's common stock upon vesting. In general, RSUs vest (i) annually in four equal installments on the grant anniversary or (ii) incrementally over two years. The following table summarizes the Company's RSU activity for the three months ended September 30, 2023:

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2022	114,461	$ 67.64
Granted	141,900	17.30
Vested	(76,482)	38.95
Forfeited	(119,271)	38.92
Other	(130)	55.10
Outstanding at September 30, 2023	60,478	$ 42.39

As of September 30, 2023, total unrecognized compensation cost related to the unvested awards to employees is $0.3 million, which is expected to be recognized in October 2023 as a result of the Company's merger (see Note 15).

Stock Appreciation Rights Valuation

The fair values of stock appreciation rights ("SARs") are based on the fair market value of the Company's common stock on the date of grant. Each SAR represents a contingent right to receive shares of the Company's common stock equal to the increase in fair value from the date of grant upon exercise. In general, SARs vest incrementally over 18 months and have a contractual term of 10 years. The assumptions used to determine the fair values of SARs granted to employees and directors under the 2021 Plan are presented as follows:

	Nine months ended September 30, 2023
Fair value of common stock	$ 17.30
Dividend yield	— %
Volatility	90.83%
Risk-free interest rate	3.46%
Expected term (years)	4.0

Summary of Stock Appreciation Rights Activity

The Company's SAR grant activity regarding employees is summarized as follows (*in thousands excepts share and per share amounts)*:

	Number of SARs	Weighted-Average Exercise Price per SAR	Weighted-Average Remaining Contractual Life (in years)	Aggregate intrinsic value
Outstanding—January 1, 2023	—	$ —	—	$ —
Granted	100,000	17.30		
Exercised	—	—		
Forfeited	—	—		
Outstanding—September 30, 2023	100,000	$ 17.30	9.35	$ 1,080
Exercisable—September 30, 2023	33,332	$ 17.30	9.35	

As of September 30, 2023, total unrecognized compensation cost related to unvested awards to employees is $0.2 million, which is expected to be recognized in October 2023 as a result of the Company's merger (see Note 15).

Stock-Based Compensation

The Company recorded stock-based compensation expense regarding its employees, directors, and nonemployees as follows *(in thousands)*:

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Research and development expense	$ 40	$ 1,742	$1,856	$4,722
General and administrative expense	1,207	1,299	4,224	3,362
Total	$ 1,247	$ 3,041	$6,080	$8,084

13. Net Loss Per Share Attributable to Common Stockholders

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company *(in thousands except share and per share amounts*).

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Net loss and net loss attributable to common stockholders	$ (7,015)	$ (19,011)	$ (44,250)	$ (55,366)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.64)	$ (4.59)	$ (10.48)	$ (13.45)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	4,271,920	4,137,553	4,221,205	4,114,939

The Company's potential dilutive securities, which include convertible preferred stock, contingent stock liabilities, restricted stock related to early exercise of common stock options and common stock options, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following potential dilutive securities, presented on an as converted basis, were excluded from the calculation of net loss per share due to their anti-dilutive effect:

	Nine months ended September 30,	
	2023	2022
Options to purchase common stock	533,900	623,298
Restricted stock units	60,478	112,701
Restricted stock related to early exercise of options to purchase common stock	5,281	23,792
Stock appreciation rights	100,000	—
	599,659	759,791

14. Defined Contribution Plan

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. Current Company match contributions to the plan are made to employees who meet minimum service requirements in the amount of 100% of the first 3%, and 50% of the next 2% of employee contributions, subject to certain limitations. Contributions made by the Company were immaterial and $0.3 million for the three and nine months ended September 30, 2023, respectively, and $0.1 million and $0.4 million for the three and nine months ended September 30, 2022, respectively.

15. Subsequent Events

The Company has evaluated subsequent events through November 14, 2023, the date the financial statements were available to be issued. The Company has concluded no subsequent events have occurred that require disclosure, except for those referenced below.

ImmunoFree Demand Letter

On October 6, 2023, the Company and ImmunoFree executed a binding settlement agreement (the "Settlement Agreement") pursuant to which the Company paid ImmunoFree $4.0 million and ImmunoFree and the Company mutually released each other from any and all claims, liabilities and/or losses relating to the ImmunoFree APA, the FREEDOM-1 Study, and the ImmunoFree Demand Letter and the allegations therein. As set forth in the Settlement Agreement, the Company denies any and all liability with respect to this matter, and has resolved it solely to avoid the risks and costs associated with litigating this matter and any risk to the consummation of the Merger Agreement.

Lease Termination

On October 4, 2023, the Company entered into a lease termination agreement related to its Boston Lease. Pursuant to the terms of the lease termination agreement, the Company agreed to pay a termination fee of $0.7 million, consisting of a payment of $0.6 million in cash and $0.1 million non-cash consideration for its security deposit. These amounts are included in lease liability, current and other current assets in the accompanying balance sheets as of September 30, 2023. In connection with the lease termination, the Company sold its remaining long-lived assets held for sale, primarily office furniture and computer equipment.

Reverse Stock Split

Immediately prior to the effective time of the Merger, the Company effected a 1-for-10 Reverse Stock Split of its shares of common stock. As a result of the Reverse Stock Split, every 10 shares of the Company's common stock held by a stockholder immediately prior to the Reverse Stock Split were combined and reclassified into one share of the Company's common stock. No fractional shares were issued in connection with the Reverse Stock Split. Any fractional shares resulting from the Reverse Stock Split were rounded down to the nearest whole number, and each Company stockholder who would otherwise be entitled to a fraction of a share of common stock upon the Reverse Stock Split (after aggregating all fractions of a share to which such stockholder would otherwise be entitled) was entitled to receive a cash payment in lieu thereof at a price equal to the fraction to which the stockholder would otherwise be entitled multiplied by the closing price of the Company's common stock on October 19, 2023. No fractional shares of Company common stock were issuable to Legacy Tourmaline stockholders pursuant to the Merger, and no certificates or scrip for any such fractional shares were issued, with no cash being paid for any fractional share eliminated by such rounding.

Merger Agreement and Financing Transaction

On October 19, 2023, the Company completed the Merger with Legacy Tourmaline.

In connection with the Merger, the Company declared a special cash dividend to its stockholders on October 6, 2023 (the "Special Dividend"). The Special Dividend was $15.118 per share of Company common stock, payable in cash. The ex-dividend date in respect to the Special Dividend was before market open on October 20, 2023, and only pre-Merger stockholders of record as of October 16, 2023, record date for the Special Dividend, that continued to hold their eligible shares of the Company until market open on October 20, 2023 were entitled to the dividend payment. The Special Dividend was $64.7 million ($67.5 million less the Aggregate Cash Amount (as defined in the Merger Agreement)) and was contingent upon closing of the Merger.

Subject to the terms of the Merger Agreement, immediately prior to effective time of the Merger, (a) all unexpired and unvested Company stock options, stock appreciation rights, and restricted stock units were accelerated, (b) all outstanding Company restricted stock units and all outstanding and in-the-money Company stock options and stock appreciation rights were settled for consideration equal to (i) 55% of each award's value in shares of Company common stock and (ii) 45% of each award's value in cash, and (c) all out-of-the-money outstanding Company stock options and stock appreciation rights were cancelled for no consideration. As a result, the Company issued 176,835 shares of Company common stock and paid an Aggregate Cash Amount (as defined in the Merger Agreement) of $2.8 million to certain pre-Merger holders of Company stock options, stock appreciation rights and restricted stock units.

Subject to the terms of the Merger Agreement, immediately prior to the effective time of the Merger, (a) certain new and current investors of Legacy Tourmaline purchased an aggregate of $75.0 million of common stock of Legacy Tourmaline (the "Pre-Merger Financing Transaction") and (b) each share of Legacy Tourmaline's preferred stock was converted into one share of Legacy Tourmaline's common stock. At the effective time of the Merger, the Company issued an aggregate of approximately 15,877,090 shares of its common stock to Legacy Tourmaline's stockholders, based on an exchange ratio of 0.7977 (without giving effect to the Reverse Stock Split) shares of the Company's common stock for each share of Legacy Tourmaline common stock outstanding immediately prior to the Merger, including those shares of common stock issued upon the conversion of Legacy Tourmaline preferred stock and those shares of Legacy Tourmaline common stock issued in the Pre-Merger Financing Transaction (but excluding shares canceled pursuant to the Merger Agreement and excluding any dissenting shares). The issuance of the shares of the Company's common stock issued to the former stockholders of Legacy Tourmaline was registered with the Securities and Exchange Commission on the Company's Registration Statement on Form S-4 (File No. 333-273335), as amended.

Immediately following the effective time of the Merger, 20,336,741 shares of the Company's common stock were issued and outstanding. Company securityholders as of immediately prior to the Merger owned approximately 21.9% of the outstanding shares of the Company and former Legacy Tourmaline securityholders, including those who purchased shares in the Pre-Merger Financing Transaction, owned approximately 78.1% of the outstanding shares of the Company.

In connection with the Merger, the Company paid an estimated $6.2 million for transaction-related expenses contingent on the Merger, including payments to certain former Talaris employees.

The Company is still evaluating the accounting impact of the Merger.

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 and the unaudited interim condensed financial statements and related notes included in this Quarterly Report on Form 10-Q should be read in conjunction with (i) Talaris' audited financial statements and the related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the Securities and Exchange Commission (the "SEC") on March 31, 2023, (ii) Legacy Tourmaline's audited financial statements and the related notes for the year ended December 31, 2022 and the period from September 17, 2021 (inception) to December 31, 2021 included in the proxy statement/prospectus (the "Proxy Statement/Prospectus") filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Securities Act"), with the SEC on September 15, 2023 and (iii) the unaudited pro forma condensed combined financial statements for the six months ended June 30, 2023 and for the year ended December 31, 2022 included in the Proxy Statement/Prospectus.

This discussion and analysis and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. See also the section titled "Special Note Regarding Forward-Looking Statements."

Recent Developments

On October 19, 2023, Tourmaline Bio, Inc., formerly known as Talaris Therapeutics, Inc. (the "Company"), completed its previously announced merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger, dated as of June 22, 2023 (the "Merger Agreement"), by and among the Company, Tourmaline Bio, Inc. ("Legacy Tourmaline") and Terrain Merger Sub, Inc., a direct wholly owned subsidiary of the Company ("Merger Sub"), pursuant to which Merger Sub merged with and into Legacy Tourmaline, with Legacy Tourmaline surviving as a direct wholly owned subsidiary of the Company and the surviving corporation of the merger (the "Merger"). Following the completion of the Merger, the business conducted by the Company became primarily the business conducted by Tourmaline, which is a late-stage clinical biotechnology company developing transformative medicines that dramatically improve the lives of patients with life-altering immune diseases.

On October 19, 2023, in connection with and prior to the completion of the Merger, the Company effected a 1-for-10 reverse stock split of its common stock (the "Reverse Stock Split"), Legacy Tourmaline changed its name from "Tourmaline Bio, Inc." to "Tourmaline Sub, Inc.", and the Company changed its name from "Talaris Therapeutics, Inc." to "Tourmaline Bio, Inc.".

Under the terms of the Merger Agreement, immediately prior to the effective time of the Merger, each share of Legacy Tourmaline's preferred stock was converted into one share of Legacy Tourmaline's common stock. At the effective time of the Merger, the Company issued an aggregate of approximately 15,877,090 shares of its common stock to Legacy Tourmaline's stockholders, based on an exchange ratio of 0.7977 (without giving effect to the Reverse Stock Split) shares of the Company's common stock for each share of Legacy Tourmaline common stock outstanding immediately prior to the Merger, including those shares of common stock issued upon conversion of the Legacy Tourmaline preferred stock and those shares of Legacy Tourmaline common stock issued in the Legacy Tourmaline pre-closing financing transaction (the "Pre-Merger Financing Transaction") which closed on October 19, 2023, immediately prior to the closing of the Merger (but excluding shares to be canceled pursuant to the Merger Agreement and excluding any dissenting shares).

The issuance of the shares of the Company's common stock issued to the former stockholders of Legacy Tourmaline was registered with the Securities and Exchange Commission on the Company's Registration Statement on Form S-4 (File No. 333-273335), as amended.

The shares of the Company's common stock listed on The Nasdaq Global Market, previously trading through the close of business on Thursday, October 19, 2023 under the ticker symbol "TALS," is expected to commence trading on The Nasdaq Global Market on a post-Reverse Stock Split adjusted basis under the ticker symbol "TRML" on October 20, 2023.

The financial information included in this Management's Discussion and Analysis of Financial Condition and Results of Operations is that of the Company (referred to in this Management's Discussion and Analysis of Financial Condition and Results of Operations as "Talaris" in order to avoid confusion) prior to the Merger because the Merger was consummated after the period covered by the financial statements included in this Quarterly Report. Accordingly, the historical financial information included in this Quarterly Report, unless otherwise indicated or as the context otherwise requires, is that of Talaris prior to the Merger.

Talaris Overview

As a result of the Merger, our historic business operations ceased and our going forward operations will be those of Legacy Tourmaline. Accordingly, the results of operations reported for the three and nine months ended September 30, 2023 and 2022 in this Management's Discussion and Analysis are not indicative of the results of operations expected in the fiscal year ended December 31, 2023 and future years due to the termination of our historic business operations.

Prior to the Merger, Talaris was a cell therapy company that was focused on developing an innovative method of allogeneic hematopoietic stem cell transplantation ("allo-HSCT") to transform the standard of care in solid organ transplantation, certain severe autoimmune diseases and certain severe blood, immune and metabolic disorders. Talaris' lead product candidate was FCR001.

Prior to the Merger, in February 2023, Talaris announced the discontinuation of its FREEDOM-1 and FREEDOM-2 clinical trials evaluating FCR001's ability to induce durable tolerance in living donor kidney transplant ("LDKT") recipients. This decision was primarily attributable to the pace of enrollment and the associated timelines to critical milestones.

In February 2023, Talaris also announced a comprehensive review of strategic alternatives focused on maximizing stockholder value. In March 2023, pending the outcome of its review of strategic alternatives, Talaris voluntarily paused enrollment in its FREEDOM-3 Phase 2 clinical trial, while continuing to evaluate patients for potential future enrollment.

In connection with the evaluation of strategic alternatives and in order to extend our resources, Talaris implemented a restructuring plan that included reducing our workforce by approximately one-third (the "Initial Reduction in Force"), with remaining employees primarily focused on maintaining its cell therapy chemistry, manufacturing and controls ("CMC") capabilities and executing FREEDOM-3. In April 2023, Talaris announced the April Reduction in Force, which resulted in the termination of approximately 95% of Talaris' remaining workforce. The workforce reductions were substantially completed as of June 30, 2023.

On June 22, 2023, Talaris entered into the Merger Agreement.

Concurrently with the execution of the Merger Agreement, Legacy Tourmaline consummated the Pre-Merger Financing Transaction, pursuant to which certain new and existing investors of Legacy Tourmaline purchased $75.0 million of Legacy Tourmaline common stock.

Prior to the effective time of the Merger, Talaris declared a cash dividend to the pre-Merger Talaris stockholders. The aggregate amount of the special cash dividend was $64.7 million.

On July 1, 2023, Talaris entered into an asset purchase agreement with ImmunoFree, pursuant to which it sold certain clinical data and intellectual property related to FCR001 for approximately $2.2 million, including a combination of cash consideration, reimbursement of certain expenses and assumption of all current and future clinical wind-down liabilities. See Note 15 in the accompanying financial statements.

Prior to the Merger, Talaris did not generate any revenue and has primarily financed its operations through private placements of convertible preferred stock, payments under a former research collaboration with Novartis, Inc., research grants and its initial public offering, or IPO, completed in May 2021.

Prior to the Merger, Talaris had received net proceeds of $186.2 million from sales of its convertible preferred stock and net proceeds of $137.2 million from its IPO.

Talaris has never been profitable and has incurred net losses in each year since inception. Prior to the Merger, Talaris had an accumulated deficit of $209.0 million and Talaris' net loss for the three months ended September 30, 2023 and year ended December 31, 2022 were $7.0 million and $73.9 million, respectively. As of September 30, 2023, Talaris had approximately $67.1 million of cash and cash equivalents and $79.9 million of marketable securities.

Components of Our Results of Operations

Revenue

Talaris has not generated any revenue since its inception and does not expect to generate any revenue from the sale of products in the future, if at all.

Operating Expenses

Research and Development Expenses

Research and development expenses consisted primarily of costs incurred in connection with the development and research of Talaris' novel cell therapy, as well as unrelated discovery program expenses. Talaris expensed research and development costs as incurred. These expenses included:

- employee-related expenses, including salaries, related benefits and stock-based compensation expense, for employees engaged in research and development functions;
- external research and development expenses incurred under arrangements with third parties, such as CROs, investigational sites, and consultants;
- the cost of acquiring, developing, and manufacturing clinical study materials;
- costs associated with preclinical and clinical activities and regulatory operations;
- costs incurred in development of intellectual property; and
- an allocated portion of facilities and other infrastructure costs associated with its research and development activities.

Talaris entered into consulting, research, and other agreements with commercial entities, researchers, universities, and others for the provision of goods and services. Such arrangements were generally cancelable upon reasonable notice and payment of costs incurred. Costs were considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the respective vendors, including its clinical sites. These costs consisted of direct and indirect costs associated with specific projects, as well as fees paid to various entities that performed certain research on behalf of it. Depending upon the timing of payments to the service providers, Talaris recognized prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved, and experience with similar contracts. Talaris monitored each of these factors and adjusted estimates accordingly.

Talaris historically used its personnel and infrastructure resources across multiple research and development programs directed toward identifying and developing product candidates. Its direct research and development expenses were historically tracked on a program-by-program basis and consisted primarily of external costs, including fees paid to consultants, contractors and CROs in connection with its development activities and the cost of acquiring, developing, and manufacturing clinical study materials. Talaris did not fully allocate personnel costs to individual programs as many of its personnel were deployed across multiple programs.

General and Administrative Expenses

General and administrative expenses consisted primarily of salaries and related costs for personnel in executive, finance, corporate and business development, human resources and administrative functions. General and administrative expenses also included legal fees relating to patent and corporate matters, professional fees for accounting, auditing, tax and administrative consulting services, insurance costs and other operating costs, including an allocated portion of facilities and other infrastructure costs associated with its general and administrative activities.

Restructuring Costs

Restructuring costs consisted of severance, employee termination costs and asset impairment related to Talaris' long-lived assets used primarily in its CMC operations.

Other Income (Expense), Net

Other income (expense), net was comprised of interest income earned on cash reserves in Talaris' operating account and on its marketable securities and amortization expense and accretion income on its marketable securities.

Results of Operations

Comparison of Three Months Ended September 30, 2023 and 2022

The following table summarizes Talaris' results of operations for the three months ended September 30, 2023 and 2022:

	Three months ended September 30,		
	2023	2022	Change
		(in thousands)	
Operating expenses			
Research and development	$ 267	$ 14,981	$(14,714)
General and administrative	9,114	4,842	4,272
Restructuring costs	89	—	89
Total operating expenses	9,470	19,823	(10,353)
Gain on asset sale	538	—	538
Loss from operations	(8,932)	(19,823)	10,891
Interest and other income (expense), net	1,917	812	1,105
Net loss	$ (7,015)	$ (19,011)	$ 11,996

Research and development expenses

	Three months ended September 30,		
	2023	2022	Change
		(in thousands)	
Direct research and development program expense:			
FCR001 clinical and pre-clinical programs	$(324)	$ 4,294	$ (4,618)
Indirect research and development expenses:			
Personnel related (including stock-based compensation)	48	7,301	(7,253)
Facilities and other operating costs	543	3,386	(2,843)
Total research and development expenses	$ 267	$ 14,981	$(14,714)

Research and development expenses were $0.3 million for the three months ended September 30, 2023, compared to $15.0 million for the three months ended September 30, 2022. The decrease of $14.7 million was primarily due to:

- a decrease of $7.3 million in personnel costs primarily due to a decrease in headcount as a result of the Initial Reduction in Force and April Reduction in Force. Personnel costs for the three months ended September 30, 2023 included immaterial stock-based compensation expense. Personnel costs for the three months ended September 30, 2022 included stock-based compensation expense of $1.7 million;
- a decrease of $4.6 million in FCR001 external clinical program expenses related to the discontinuation of Talaris' FREEDOM-1, FREEDOM-2, and FREEDOM-3 clinical trials in the first quarter of 2023. Costs incurred in the third quarter of 2023 related to the close-out of these clinical trials; and

- a decrease of $2.8 million in other costs primarily due to a decrease in consulting, research collaborations, and other services related to the discontinuation of the FREEDOM-1, FREEDOM-2 and FREEDOM-3 clinical trials, and pre-clinical activities in the first quarter of 2023.

General and Administrative Expenses

The following table summarizes Talaris' general and administrative expenses to support its business activities for the three months ended September 30, 2023 and 2022:

	Three months ended September 30,		
	2023	2022	Change
		(in thousands)	
Personnel related (including stock-based compensation)	$1,621	$ 2,699	$(1,078)
Professional and consulting fees	5,851	817	5,034
Facility-related and other	1,642	1,326	316
Total general and administrative expenses	$9,114	$ 4,842	$ 4,272

General and administrative expenses were $9.1 million for the three months ended September 30, 2023 compared to $4.8 million for the three months ended September 30, 2022. The increase in general and administrative costs of $4.3 million was primarily due to:

- an increase of $5.0 million in professional and consulting fees primarily due to $4.0 million in legal settlement reserve as a result of the ImmunoFree Demand Letter (see Note 15 of the accompanying financial statements) and an increase in legal and consulting fees in connection with the Merger and evaluation of strategic alternatives; and
- a decrease of $1.1 million in personnel costs primarily due to a decrease in headcount and a decrease in stock-based compensation as a result of the Initial Reduction in Force and April Reduction in Force; and
- an increase of $0.3 million in facility-related and other expenses primarily due to non-cash impairment expense related to its Wellesley lease and long-lived assets offset by a decrease in its director and officer insurance premiums in 2023.

Restructuring Costs

Restructuring costs for the three months ended September 30, 2023 were comprised of $0.1 million in employee termination costs related to the April Reduction in Force. Talaris did not incur any restructuring costs in the three months ended September 30, 2022.

Other Income, Net

Other income, net in the three months ended September 30, 2023 was comprised of $1.2 million of net accretion income on Talaris' marketable securities and $0.7 million in interest income from its marketable securities and operating cash balance. Other income, net in the three months ended September 30, 2022 was comprised of $0.2 million in interest income from its marketable securities and operating cash balance and $0.6 million of net accretion income on its marketable securities.

Comparison of Nine Months Ended September 30, 2023 and 2022

The following table summarizes Talaris' results of operations for the three months ended September 30, 2023 and 2022:

	Nine months ended September 30,		
	2023	2022	Change
		(in thousands)	
Operating expenses			
Research and development	$ 17,770	$ 42,364	$ (24,594)
General and administrative	21,322	14,288	7,034
Restructuring costs	10,958	—	10,958
Total operating expenses	50,050	56,652	(6,602)
Gain on asset sale	538	—	538
Loss from operations	(49,512)	(56,652)	7,140
Interest and other income (expense), net	5,262	1,286	3,976
Net loss	$ (44,250)	$ (55,366)	$ 11,116

Research and development expenses

	Nine months ended September 30,		
	2023	2022	Change
		(in thousands)	
Direct research and development program expense:			
FCR001 clinical and pre-clinical programs	$ 5,054	$ 11,405	$ (6,351)
Indirect research and development expenses:			
Personnel related (including stock-based compensation)	8,564	21,366	(12,802)
Facilities and other operating costs	4,152	9,593	(5,441)
Total research and development expenses	$17,770	$ 42,364	$(24,594)

Research and development expenses were $17.8 million for the nine months ended September 30, 2023, compared to $42.4 million for the nine months ended September 30, 2022. The decrease of $24.6 million was primarily due to:

- a decrease of $12.8 million in personnel costs primarily due to a decrease in headcount as a result of the Initial Reduction in Force and April Reduction in Force. Personnel costs for the nine months ended September 30, 2023 and 2022 include stock-based compensation expense of $1.8 million and $3.0 million, respectively;
- a decrease of $6.4 million in FCR001 external clinical program expenses related to the discontinuation of Talaris' FREEDOM-1, FREEDOM-2 and FREEDOM-3 clinical trials in the first quarter of 2023; and
- a decrease of $5.4 million in other operating costs primarily due to a decrease in consulting, research collaborations, and other services related to the discontinuation of the FREEDOM-1 and FREEDOM-2 clinical trials in the first quarter of 2023.

General and Administrative Expenses

The following table summarizes Talaris' general and administrative expenses to support its business activities for the three months ended September 30, 2023 and 2022:

	Nine months ended September 30,		
	2023	2022	Change
		(in thousands)	
Personnel related (including stock-based compensation)	$ 6,468	$ 7,418	$ (950)
Professional and consulting fees	10,293	2,187	8,106
Facility-related and other	4,561	4,683	(122)
Total general and administrative expenses	$21,322	$ 14,288	$7,034

General and administrative expenses were $21.3 million for the nine months ended September 30, 2023, compared to $14.3 million for the nine months ended September 30, 2022. The increase in general and administrative costs of $7.0 million was primarily due to:

- an increase of $8.1 million in professional and consulting fees related to $4.0 million legal settlement reserve as a result of the ImmunoFree Demand Letter and an increase in legal and consulting fees in connection with the Merger and evaluating strategic alternatives;
- a decrease of $1.0 million in personnel costs primarily due to a decrease in headcount as a result of the Initial Reduction in Force and April Reduction in Force, offset by an increase in stock based compensation; and
- a decrease of $0.1 million in facility-related and other expenses primarily due to a decrease in Talaris' director and officer insurance premiums.

Restructuring Costs

Restructuring costs in the nine months ended September 30, 2023 were comprised of $7.5 million in severance and employee termination costs related to the Initial Reductions in Force and the April Reduction in Force and $3.4 million non-cash asset impairment primarily related to long-lived assets used primarily in Talaris' CMC operations. Talaris did not incur any restructuring costs in the nine months ended September 30, 2022.

Other Income, Net

Other income, net in the nine months ended September 30, 2023 was comprised of $3.9 million of net accretion income on Talaris' marketable securities and $1.4 million in interest income from its marketable securities and operating cash balance. Other income, net in the nine months ended September 30, 2022 was comprised of $0.6 million in interest income from its marketable securities and operating cash balance and $0.7 million of net accretion income on its marketable securities.

Liquidity and Capital Resources

Since Talaris' inception, it incurred significant operating losses. It did not commercialize any products and it will not generate revenue from sales of products in the future. Since 2018, Talaris financed its operations primarily with proceeds from the sale of its convertible preferred stock and its IPO in May 2021. Through September 30, 2023, it had received net proceeds of $186.2 million from sales of its convertible preferred stock and net proceeds of $137.2 million from its IPO, after deducting underwriting discounts and commissions and other expenses.

Cash in excess of immediate requirements was invested in accordance with Talaris' investment policy, primarily with a view to liquidity and capital preservation. Talaris' primary use of cash was to fund operating expenses, which consisted primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses were impacted by the timing of when it paid these expenses, as reflected in the change in its outstanding accounts payable and accrued expenses. As of September 30, 2023, Talaris had cash and cash equivalents of $67.1 million and marketable securities of $79.9 million.

Prior to the effective time of the Merger, Talaris declared a cash dividend to the pre-Merger Talaris stockholders. The aggregate amount of the special cash was $64.7 million. In connection with the Merger, Legacy Tourmaline consummated the Pre-Merger Financing Transaction, raising gross proceeds of $75.0 million, before deducting transaction-related expenses. Upon the consummation of the Merger and the Pre-Merger Financing Transaction, the post-merger combined company had cash, cash equivalents, and marketable securities of approximately $218.2 million.

The Company expects there will be no further material cash expenditures related to Talaris' FCR001 clinical trials. From the date of the Merger, the activities of the Company will become those of Legacy Tourmaline.

The Company is in the business of developing biopharmaceuticals, and it has no current or near-term revenues. The Company is incurring substantial clinical and other costs in its drug development efforts. The Company expects it will need to raise additional capital in order to fully realize management's plans.

After the consummation of the Merger, the Company believes that its current financial resources are sufficient to fund its operations for its operating expenses and capital expenditure requirements through 2026.

Cash Flows

The following table summarizes Talaris' sources and uses of cash for each of the periods presented:

	Nine months ended September 30,		
	2023	2022	Change
	(in thousands)		
Net cash used in operating activities	$ (39,102)	$ (46,987)	$ 7,885
Net cash provided by investing activities	92,258	46,659	45,599
Net cash provided by financing activities	257	182	75
Net increase in cash and cash equivalents and restricted cash	$ 53,413	$ (146)	$53,559

Cash Flow from Operating Activities

During the nine months ended September 30, 2023, operating activities used $39.1 million of cash, due to Talaris' net loss of $44.3 million and $1.9 million of cash used from changes in its operating assets and liabilities, partially offset by non-cash charges of $7.0 million. Net cash used from changes in its operating assets and liabilities primarily consisted of a $3.0 million decrease in accounts payable and accrued expenses related to payment of accrued compensation arrangements and a $0.7 million decrease in its operating lease liability. These were offset by a $1.7 million decrease in prepaids and other current assets driven by amortization of annual subscriptions and director and officer insurance premiums. Non-cash charges primarily consisted of $6.1 million of stock-based compensation expense, $3.6 million long-lived asset impairment, $0.5 million right-of-use asset impairment and $0.1 million in loss on disposal of assets, offset by a net $2.7 million of depreciation on fixed assets, accretion of marketable securities and amortization of right-of-use assets and $0.5 million gain on asset sale.

During the nine months ended September 30, 2022, operating activities used $47.0 million of cash, due to Talaris' net loss of $55.4 million and $0.9 million of cash used from changes in its operating assets and liabilities, partially offset by non-cash charges of $9.3 million. Net cash used from changes in its operating assets and liabilities primarily consisted of a $1.7 million increase in prepaids and other current assets driven by annual director and officer insurance premiums, timing of CRO prepaids, and deferred offering costs related to its registration statement on Form S-3 and a $0.4 million decrease in operating lease liability driven by lease payments. These were offset by a $0.6 million increase in accounts payable and accrued expenses driven by compensation related accruals and $0.1 million increase in other liabilities. Non-cash charges primarily consisted of $8.1 million of stock-based compensation expense, $0.4 million of depreciation on fixed assets and amortization of marketable securities, $0.6 million of amortization of right-of-use assets, and $0.2 million of asset impairment.

Cash Flow from Investing Activities

During the nine months ended September 30, 2023, investing activities provided $92.3 million of cash, due to maturities of marketable securities of $177.3 million, partially offset by purchases of marketable securities of $85.2 million and purchases of property and equipment of $0.5 million.

During the nine months ended September 30, 2022, investing activities provided $46.7 million of cash, due to maturities of marketable securities of $190.0 million, partially offset by purchases of marketable securities of $140.6 million and purchases of property and equipment of $2.8 million.

Cash Flow from Financing Activities

During the nine months ended September 30, 2023, net cash provided by financing activities was $0.3 million primarily consisting of proceeds from exercise of stock options.

During the nine months ended September 30, 2022, net cash provided by financing activities was $0.2 million primarily consisting of proceeds from ESPP share issuances and exercise of stock options.

Future Funding Requirements

Since inception, the Company has not generated any revenue from product sales. Management does not expect to generate any meaningful product revenue unless and until Tourmaline obtains regulatory approval of and commercializes its product candidate and any future product candidates, and management does not know when, or if, that will occur. Until the Company can generate significant revenue from product sales, if ever, it will continue to require substantial additional capital to develop its product candidate and any future product candidates and fund operations for the foreseeable future. Management expects the Company's expenses to increase in connection with its ongoing activities as described in greater detail below. The Company is subject to all the risks incident in the development of new biopharmaceutical products, and it may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may harm the Company's business.

In order to complete the development of TOUR006 and any future product candidates and to build the sales, marketing and distribution infrastructure that management believes will be necessary to commercialize product candidates, if approved, the Company will require substantial additional capital. Accordingly, until such time that the Company can generate a sufficient amount of revenue from product sales or other sources, if ever, management expects to seek to raise any necessary additional capital through private or public equity or debt financings, loans or other capital sources, which could include income from collaborations, partnerships or other marketing, distribution, licensing or other strategic arrangements with third parties, or from grants. To the extent that the Company raises additional capital through equity financings or convertible debt securities, the ownership interest of its 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 its common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting the Company's ability to take specific actions, including restricting its operations and limiting its ability to incur liens, issue additional debt, pay dividends, repurchase its own common stock, make certain investments or engage in merger, consolidation, licensing, or asset sale transactions. If the Company raises capital through collaborations, partnerships, and other similar arrangements with third parties, it may be required to grant rights to develop and market product candidates that the Company would otherwise prefer to develop and market themselves. The Company may be unable to raise additional capital from these sources on favorable terms, or at all. the Company's ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from recent bank failures, other general macroeconomic conditions and otherwise. The failure to obtain sufficient capital on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations or financial condition, including requiring the Company to delay, reduce or curtail its research, product development or future commercialization efforts. The Company may also be required to license rights to product candidates at an earlier stage of development or on less favorable terms than the Company would otherwise choose. Management cannot provide assurance that the Company will ever generate positive cash flow from operating activities.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, the Company is unable to estimate the exact amount and timing of its capital requirements. The Company's future funding requirements will depend on many factors, including:

- the scope, timing, progress, results, and costs of researching and developing TOUR006, and conducting larger and later-stage clinical trials;
- the scope, timing, progress, results, and costs of researching and developing other product candidates that the Company may pursue;
- the costs, timing, and outcome of regulatory review of TOUR006 and any future product candidates;

- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, for TOUR006 and any future product candidates for which it receives marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of Tourmaline's products, should any of its product candidate and any future product candidates receive marketing approval;
- the cost and timing of attracting, hiring, and retaining skilled personnel to support Tourmaline's operations and continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing Tourmaline's intellectual property rights and defending intellectual property-related claims;
- Tourmaline's ability to establish, maintain, and derive value from collaborations, partnerships or other marketing, distribution, licensing, or other strategic arrangements with third parties on favorable terms, if at all;
- the extent to which the profile of marketed or development stage competing products affects the clinical and commercial potential of Tourmaline's products;
- the extent to which Tourmaline acquires or in-licenses other product candidates and technologies, if any; and
- the costs associated with operating as a public company.

A change in the outcome of any of these or other factors with respect to the development of TOUR006 and any of Tourmaline's future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, Tourmaline's operating plans may change in the future, and Tourmaline may need additional capital to meet the capital requirements associated with such operating plans.

Critical Accounting Policies and Estimates

Talaris' management's discussion and analysis of financial condition and results of operations is based on its financial statements, which were prepared in accordance with generally accepted accounting principles ("GAAP") in the United States. The preparation of Talaris' financial statements and related disclosures required it to make estimates and judgments that affected the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in its financial statements. Talaris based its estimates on historical experience, known trends and events and various other factors that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Talaris evaluated its estimates and assumptions on an ongoing basis. Its actual results could differ from these estimates under different assumptions or conditions.

While Talaris' significant accounting policies are described in more detail in Note 2 to its accompanying financial statements, it believes that the following accounting policies are those most critical to the judgments and estimates used in the preparation of its financial statements.

Research and Development Contract Costs and Accruals

As part of the process of preparing Talaris' financial statements, it was required to estimate its accrued research and development expenses. This process involved reviewing open contracts and purchase orders, communicating with its applicable personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when it has not yet been invoiced or otherwise notified of actual costs. The majority of Talaris' service providers invoiced it in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some required advance payments. Talaris

made estimates of its accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to it at that time. Talaris periodically confirmed the accuracy of these estimates with the service providers and made adjustments, if necessary. Examples of estimated accrued research and development expenses included fees paid to vendors in connection with clinical development activities and CROs and investigative sites in connection with pre-clinical, non-clinical, and human clinical trials.

Talaris based the expense recorded related to external research and development on its estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that supplied, conducted and managed clinical trials on its behalf. The financial terms of these agreements were subject to negotiation, varied from contract to contract and may have resulted in uneven payment flows. There were instances in which payments made to its vendors exceeded the level of services provided and resulted in a prepayment of the expense. In accruing service fees, Talaris estimated the time period over which services were performed and the level of effort expended in each period. If the actual timing of the performance of services or the level of effort varied from the estimate, Talaris adjusted the accrual or the amount of prepaid expenses accordingly. Although Talaris does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to Talaris' prior estimates of accrued research and development expenses. There have been no changes to its process of determining external research and development expense accruals during the nine months ended September 30, 2023.

Stock Based Compensation Expense

Talaris measured stock-based awards granted to employees, directors, and nonemployees based on their fair value on the date of the grant and recognized compensation expense for those awards over the requisite service period, which was generally the vesting period of the respective award. For stock-based awards with service-based vesting conditions, Talaris recognized compensation expense using the straight-line method. The fair value of each stock option grant was estimated on the date of grant using the Black-Scholes option-pricing model, which required inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and Talaris' expected dividend yield. The fair value of each option to purchase common stock award was estimated on the date of grant based on the fair value of its common stock on that same date.

As there was no public market for Talaris common stock prior to the closing of its IPO, the estimated fair value of its common stock was determined by its board of directors as of the date of each option grant with input from management, considering its most recently available third-party valuations of common stock, and its board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These independent third-party valuations of Talaris equity instruments were performed contemporaneously with identified value inflection points. Talaris common stock valuation was prepared using the option-pricing method ("OPM"), which used a market approach to estimate its enterprise value, as well as the probability-weighted expected return method ("PWERM") and the hybrid method, a combination of OPM and PWERM.

For all stock-based awards granted ended after the closing of Talaris' IPO, it did not have to estimate the fair value of its common stock as it was determined based on the quoted market price of Talaris' common stock. For the nine months ended September 30, 2023, the quoted market price of Talaris' common stock was used in determining the fair value of its stock-based compensation awards, and no other significant estimates were used in determining those amounts.

Emerging Growth Company and Smaller Reporting Status

In April 2012, the Jumpstart Our Business Startups Act of 2012 ("JOBS Act") was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" ("EGC") can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended ("Securities Act"), for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. Talaris has elected to use the extended transition period for new or revised accounting standards during the period in which it remains an emerging growth company; however, it may adopt certain new or revised accounting standards early to the extent allowed by the standard.

The Company will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which it has more than $1.235 billion in annual revenue; (ii) the date it qualifies as a “large accelerated filer,” with at least $700.0 million of equity securities held by non-affiliates; (iii) the date on which it has issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of its initial public offering.

The Company is also a “smaller reporting company” meaning that the market value of its stock held by non-affiliates is less than $700 million and its annual revenue was less than $100 million during the most recently completed fiscal year. The Company may continue to be a smaller reporting company if either (i) the market value of its stock held by non-affiliates is less than $250 million or (ii) its annual revenue was less than $100 million during the most recently completed fiscal year and the market value of its stock held by non-affiliates is less than $700 million. If the Company is a smaller reporting company at the time it ceases to be an emerging growth company, it may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company it may choose to present only the two most recent fiscal years of audited financial statements in its Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact Talaris’ financial position and results of operations is disclosed in Note 2 to its financial statements appearing at the beginning of this Quarterly Report.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and are not required to provide the information specified under this item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Interim Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2023, the end of the period covered by this Quarterly Report on Form 10-Q. Disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Based on their evaluation, the Chief Executive Officer and Interim Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of September 30, 2023 because of the material weaknesses in our internal control over financial reporting described below.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

We identified material weaknesses in the design and operating effectiveness of our internal control over financial reporting primarily related to limited staffing levels within the finance and accounting departments that were not commensurate with our financial accounting and reporting requirements. We had to rely increasingly on outsourced service providers and specialists, without adequate resources to monitor such work and did not maintain appropriate segregation of duties. Based on this, we did not fully implement components of the COSO framework, resulting in material weaknesses either individually, or in the aggregate, in the control environment, risk assessment, control activities, information and communication, and monitoring components.

As discussed above, the unaudited interim financial statements included in the Quarterly Report on Form 10-Q are those of the Company prior to the Merger because the Merger was consummated after the period covered by the unaudited interim financial statements. There were no adjustments that resulted from the above material weaknesses. However, these material weaknesses could, in the future, result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

Remediation Plans

We have taken and will continue to take certain measures to remediate the material weaknesses described above.

As of September 30, 2023, we have continued with the remediation steps that were initiated in the third quarter of 2023, including, but not limited to, hiring additional accounting personnel with expertise commensurate with our financial accounting and reporting requirements and that have the requisite experience to oversee outsourced service providers and specialists, upgrading our financial systems and implementing information technology general controls, establishing controls to identify, assess, and respond to the risks of material misstatement, and establishing controls to identify and account for certain non-routine, unusual or complex transactions in a timely fashion.

The elements of our remediation plans can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects. As management continues to evaluate and work to improve our internal control over financial reporting, management may determine it is necessary to take additional measures to address the material weaknesses. These material weaknesses will not be considered remediated unless and until

such time as management designs and implements effective controls that operate for a sufficient period of time and concludes, through testing, that these controls are effective. Until the controls have been operating for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively, the material weaknesses described above will continue to exist. Management is monitoring the progress of the remediation plan and reporting regularly to the audit committee of the board of directors on the progress and results of the remediation plan, including the identification, status and resolution of internal control deficiencies. We can provide no assurance that the measures we have taken and plan to take in the future will remediate the material weaknesses identified or that any additional material weakness or restatements of financial results will not arise in the future due to a failure to implement and maintain adequate internal control over financial reporting or circumvention of these controls. In addition, even if we are successful in strengthening our controls and procedures, in the future these controls and procedures may not be adequate to prevent or identify irregularities or errors or to facilitate the fair presentation of our financial statements.

Changes in Internal Control over Financial Reporting

For the three months ended September 30, 2023, other than the remediation efforts described above, there have been no other changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may become involved in legal proceedings arising from the ordinary course of business. For additional information regarding legal proceedings, if any, see Note 10 “Commitments and Contingencies—Legal Proceedings” to our unaudited interim financial statements included elsewhere in this Quarterly Report on Form 10-Q. We believe there are currently no pending legal proceedings to which we or our property are subject that could have a material adverse effect on our financial position, results of operations or cash flows.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding to invest in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

Summary Risk Factors

An investment in our common stock involves various risks, and prospective investors are urged to carefully consider the matters discussed in the section titled “Risk Factors” prior to making an investment in our common stock. These risks include, but are not limited to, the following:

- We have incurred net losses every year since our inception and have no source of product revenue. We expect to continue to incur significant operating losses and may never become profitable.
- Our business is highly dependent on the success of TOUR006 as well as any other potential future product candidates. If we are unable to successfully complete clinical development of, obtain regulatory approval for, or commercialize, TOUR006 or any other potential future product candidates, or if we experience delays in doing so, our business will be materially harmed.
- We will need significant additional capital to proceed with development and commercialization of TOUR006 and any potential future product candidates and our other operations. We may not be able to access sufficient capital on acceptable terms, if at all, and, as a result, we may be required to delay, scale back or discontinue development of such product candidates or other operations.
- We have a limited operating history and no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.
- We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations appliable to public companies.
- We may not be able to obtain and maintain the relationships with third parties that are necessary to develop, commercialize and manufacture TOUR006 and any potential future product candidates.
- We rely completely on contract development and manufacturing organization (“CDMOs”) for the manufacture and testing of TOUR006 and any potential future product candidates under current good manufacturing practices (“cGMP”), and we are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of any potential product candidates and any future products.
- Our manufacturing and testing of bulk drug substance for TOUR006 currently takes place in China through a global CDMO with facilities in China and around the world. A significant disruption in the operation of the manufacturing facility in China, a trade war or political unrest could materially adversely affect our business, financial condition and results of operations.

- We may seek to establish business development arrangements ("BD Arrangements"), and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.
- TOUR006 and any other of our future product candidates must undergo rigorous clinical trials before seeking regulatory approvals, and clinical trials may be delayed, suspended or terminated at any time for many reasons, any of which could delay or prevent regulatory approval and, if approval is granted, commercialization of our product candidates.
- If clinical trials of TOUR006 or any potential future product candidates fail to initiate, complete, or produce positive results or fail to demonstrate safety and efficacy to the satisfaction of the Food and Drug Administration (the "FDA") or comparable health authorities or sufficiently to demonstrate differentiation from other approved therapies or therapies in development, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, development of TOUR006, or any potential future product candidates, may be delayed or prevented, which would have a material adverse effect on our business.
- Even if we obtain approval to market TOUR006 or other potential future product candidates, these products may become subject to unfavorable pricing regulations, reimbursement practices from third-party payors or healthcare reform initiatives in the United States ("U.S.") and abroad, which could harm our business.
- We expect to expand our clinical development, manufacturing and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.
- Healthcare reform may negatively impact our ability to profitably sell TOUR006 and any potential future product candidates, if approved.
- Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the U.S.
- Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.
- Our relationships with healthcare providers, customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.
- Our business could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics.
- Our ability to use our US net operating loss carryforwards and certain other U.S. tax attributes may be limited.
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

- Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes-Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, could have a material adverse effect on our business and share price.

Risks Related to Our Financial Condition and Capital Needs

We have a limited operating history and no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.

We are a biotechnology company with a limited operating history and a single product candidate, TOUR006, in development to date. Legacy Tourmaline was formed in 2021 and commenced operations in 2022. To date, we have not yet demonstrated our ability to successfully complete pivotal clinical trials, obtain regulatory approvals, manufacture a product on a commercial scale or arrange for a third-party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization, and we may not be successful in doing so in the future. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, technical or regulatory challenges, or unanticipated delays in development timelines. We will eventually need to transition from a company with a clinical development focus to a company, if TOUR006 or any potential future product candidates are approved, capable of supporting commercial activities. We may not be successful in such a transition.

We have incurred net losses every year since our inception and have no source of product revenue. We expect to continue to incur significant operating losses and may never become profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. Legacy Tourmaline has incurred losses in each year since it commenced operations.

We expect to continue to incur significant research and development ("R&D") costs and other expenses related to our ongoing operations for the foreseeable future, particularly to fund R&D of, and seek regulatory approvals for, TOUR006 and any potential future product candidates. Legacy Tourmaline expects to continue to incur significant operating losses in 2023 and over the next several years as our research, development, manufacturing, preclinical study, clinical trial and related activities grow. We expect our accumulated deficit will also increase in future periods. The size of our future net losses will depend, in part, on the amount of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our stockholders' deficit and working capital.

In addition, we will not be able to generate product revenue unless and until TOUR006 or any potential future product candidates successfully completes clinical trials, receives regulatory approval and is successfully commercialized or generates revenues through business development activities. We do not expect to receive product revenue from our product candidates for a number of years, if ever.

Our ability to generate any product revenue from TOUR006 and any potential future product candidates also depends on a number of additional factors, including our ability, or the ability of any potential future third-party partner, to successfully:

- complete research and clinical development of current and future product candidates and obtain regulatory approval for those product candidates;
- establish and maintain supply and manufacturing relationships, and ensure adequate, scaled up and legally compliant manufacturing of bulk drug substances and drug products to maintain sufficient supply;

- launch and commercialize TOUR006 or any potential future product candidates for which marketing approval is obtained, if any, and, if launched independently by us without a partner, successfully establish a sales force and marketing and distribution infrastructure;
- demonstrate the necessary safety data (and, if accelerated approval is obtained, verify the clinical benefit) post-approval to ensure continued regulatory approval;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors, for any approved products;
- achieve market acceptance for any approved products;
- enter into collaboration, partnering, licensing, or other similar arrangements on economically favorable terms;
- establish, maintain, protect and enforce our intellectual property rights; and/or
- attract, hire and retain qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, including that TOUR006 and any potential future product candidates may not advance through development or be approved for commercial sale, we are unable to predict if or when we will generate product revenue or achieve or maintain profitability.

Even if we successfully complete development and obtain health authority approval for commercialization for any product candidates that we take forward, we anticipate incurring significant costs associated with launching and commercializing any products. If we fail to become profitable or do not sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or cease operations.

Our business is highly dependent on the success of TOUR006 as well as any other potential future product candidates. If we are unable to successfully complete clinical development of, obtain regulatory approval for, or commercialize, TOUR006 or any other potential future product candidates, or if we experience delays in doing so, our business will be materially harmed.

Our future success and ability to generate revenue from TOUR006 or any potential future product candidates, which we do not expect will occur for several years, if ever, is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more product candidates. We have identified thyroid eye disease (“TED”) as the lead indication for TOUR006. We submitted an investigational new drug application (“IND”) in the U.S. to support initiation of a Phase 2b trial of TOUR006 in first-line TED, which IND was cleared by the FDA in August 2023. In September, 2023, we initiated this study. In addition, our plans to initiate an open-label basket study in additional TED patient cohorts to further inform the utility of TOUR006 for the treatment of additional TED subpopulations. If TOUR006 encounters undesirable safety signals, insufficient efficacy results, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

Our second indication for TOUR006 is expected to be atherosclerotic cardiovascular disease (“ASCVD”). TOUR006 for ASCVD is in an earlier stage of development and will require substantial additional investment for clinical development, regulatory review and approval in one or more jurisdictions.

We will need significant additional capital to proceed with the development and commercialization of TOUR006 and any potential future product candidates and our other operations. We may not be able to access sufficient capital on acceptable terms, if at all, and, as a result, we may be required to delay, scale back or discontinue development of such product candidates or other operations.

Our operations have consumed substantial amounts of cash since inception, and we will require substantial additional capital to finance our operations and pursue our product development strategy both in the short- and the long-term, and the amount of funding we will need depends on many factors, including:

- the rate of progress in the development of TOUR006 and our other potential future product candidates;
- the initiation, progress, timing, delays, costs and results of preclinical studies and clinical trials for TOUR006 and any potential future product candidates;
- the number and development requirements of product candidates that we may pursue;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign health authorities, including the potential for such authorities to require that we perform more studies than those that we currently expect;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the cost and timing of selecting and auditing a manufacturing site for later-stage clinical and commercial-scale manufacturing;
- the cost and timing of performing manufacturing process validation sufficient to meet regulatory expectations and requirements;
- the effect of products that may compete with TOUR006 and any potential future product candidates or other market developments;
- market acceptance of any approved product candidates, including product pricing and product reimbursement by third-party payors;
- the cost of potentially acquiring, licensing or investing in additional businesses, products, product candidates and technologies; and
- the cost of establishing sales, marketing and distribution capabilities for TOUR006 and any potential future product candidates for which we may receive regulatory approval and that we decide to commercialize ourselves or in collaboration with partners.

We believe that our working capital will be sufficient to fund our operating expenses and capital expenditure requirements for more than twelve months from the date of issuance of this Quarterly Report on Form 10-Q. Moreover, based on our current development plans and related assumptions, we believe our cash position is sufficient to fund our key programs through 2026. We have based these estimates on plans and assumptions that may prove to be insufficient or inaccurate (for example, with respect to anticipated costs, timing or success of certain activities), and we could utilize our available capital resources sooner than we currently expect. In addition, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially as a result of a number of factors.

We plan to finance our future cash needs through public or private equity or debt offerings, BD Arrangements or a combination of these potential financing sources. For example, we may seek BD Arrangements in the future to facilitate clinical development that requires significantly more capital and resources that may otherwise not be available to us on acceptable terms or at all, such as large cardiovascular outcome trials of TOUR006 in patients with

ASCVD. Additional capital may not be available in sufficient amounts, on reasonable terms or when we need it, if at all. In addition, our ability to obtain financing may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from geopolitical tensions, such as the ongoing war in Ukraine and hostilities in the Middle East, global pandemics, inflation, rising interest rates, and liquidity concerns at, and failures of, banks and other financial institutions. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in economic growth, increases in inflation rates, higher interest rates and uncertainty about economic stability. If the financial market disruptions and economic slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our financial condition and our ability to pursue our business strategy.

If adequate funds are not available from public or private equity or debt offerings, or BD Arrangements on acceptable terms when needed, in order to continue the development of TOUR006 or any of our potential future product candidates we may need to:

- seek strategic alliances for R&D programs when we otherwise would not, at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or
- enter into BD Arrangements that could require us to relinquish, or license, on potentially unfavorable terms, our rights to intellectual property, product candidates or products that we otherwise would develop or seek to commercialize ourselves.

We may not be able to raise adequate additional capital on a timely basis, on acceptable terms or at all. If we are unable to do so, we may need to significantly delay, scale back or discontinue development of or abandon TOUR006 or any potential future product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects, or we may be required to cease operations altogether.

We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations appliable to public companies.

We will incur significant legal, accounting and other expenses as a public company that we did not incur as a private company, including costs associated with public company reporting obligations under the Exchange Act. Our management team consists of the executive officers of Legacy Tourmaline prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or onboard committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Once we are no longer an emerging growth company, a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.

We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. However, as an emerging growth company we may take advantage of exemptions from various requirements such as an exemption from the requirement to have our independent auditors attest to our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 as well as an exemption from the "say on pay" voting requirements pursuant to the Dodd-Frank Act. After we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which may allow us to take advantage of some of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced

disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Even after we no longer qualify as an emerging growth company, we expect to still qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, in at least the near term, which will allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in periodic reports and proxy statements. Once we are no longer an emerging growth company, a smaller reporting company or otherwise qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Risks Related to Our Dependence on Third Parties

We may not be able to obtain and maintain the relationships with third parties that are necessary to develop, commercialize and manufacture TOUR006 and any potential future product candidates.

We expect to depend on third parties, including contract research organizations ("CROs"), clinical data management organizations, clinical investigators, and CDMOs and other third-party partners and service providers to support our development efforts, to conduct our clinical trials and certain aspects of our research and preclinical studies, to manufacture clinical and commercial-scale quantities of our drug substances and drug products under cGMP and to market, sell and distribute any products we successfully develop and for which we obtain regulatory approval. Any problems we experience with any of these third parties could delay the development, manufacturing or commercialization of TOUR006 or any potential future product candidates, which could harm our results of operations.

We cannot guarantee that we or, as applicable, any of our partners will be able to successfully negotiate agreements for, and maintain relationships with, third-party partners and service providers on favorable terms, if at all. If we or any of our partners are unable to obtain and maintain these agreements, we may not be able to clinically develop, manufacture, obtain regulatory approvals for or commercialize TOUR006 or any potential future product candidates, which will, in turn, adversely affect our business. If we or any of our partners need to enter into alternative arrangements, it could delay our product development and, if applicable, commercialization activities and such alternative arrangements may not be available on terms acceptable to us.

We expect to continue to expend substantial time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, our reliance on these third parties for development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that our clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and we remain responsible for ensuring that manufacturing activities are conducted under cGMP. However, we cannot control the amount or timing of resources our partners will devote to our programs, TOUR006 or potential future product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct their clinical trials or other R&D activities in accordance with regulatory requirements, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for TOUR006 or any potential future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize any approved products. In addition, we base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf and, if their estimates are not accurate, it could negatively affect the accuracy of our financial statements.

Any agreements we have or may enter into with third-party partners and service providers may give rise to disputes regarding the rights and obligations of the parties. Disagreements could develop over contract interpretation, rights to ownership or use of intellectual property, the scope and direction of our programs, the approach for regulatory approvals or commercialization strategy. Any disputes or commercial conflicts could lead to the termination of our agreements, delay progress of our product development programs, compromise our ability to renew agreements or obtain future agreements, lead to the loss of intellectual property rights, result in increased financial obligations for us or result in costly and time-consuming arbitration or litigation.

We rely completely on CDMOs for the manufacture and testing of TOUR006 and any potential future product candidates under cGMP, and we are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of any potential product candidates and any future products.

We require the services of third-party CDMOs to provide process development, analytical method development, formulation development, and manufacturing. We do not have, and do not currently plan to acquire or develop, the facilities or capabilities to manufacture and test bulk drug substance or filled drug product for use in clinical trials or commercialization. As a result, we rely completely on CDMOs, which entails risks to which we would not be subject if we manufactured TOUR006 or any potential future product candidates or products ourselves, including risks related to reliance on third parties for availability of drug product to use in our clinical trials and for regulatory compliance and quality assurance with respect to such drug product, the possibility of breach of the manufacturing agreement by third parties because of factors beyond our control (including a failure to manufacture TOUR006 and any potential future product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of agreements by third parties, based on their own business priorities, at a time that is costly or damaging to us.

TOUR006 is a biologic, and the manufacture and testing of biologic products is complex, highly regulated and requires significant expertise and capital investment, including the development of advanced manufacturing techniques, process controls, and advanced analytical testing capability. As a result, the manufacture and testing of our product candidate is subject to many risks, including the following, some of which we may experience:

- product loss or other negative consequences due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, shortages of qualified personnel or improper delivery or storage conditions;
- difficulties with product yields, quality control release testing, including challenges related to analytical method development and the qualification and implementation of those methods for release testing, which can delay availability of clinical trial materials;
- challenges with long-term stability of our product candidate and products at reasonable and expected storage conditions;
- challenges with comparability of product made following changes in the manufacturing process such as a change in the manufacturing facility, scale-up, changes in the storage container used for drug product, or other changes;
- the negative consequences of failure to comply with strictly enforced federal, state and foreign regulations;
- major deviations from normal manufacturing processes, which may result in reduced production yields, product defects and other supply disruptions;
- the presence of microbial, viral or other contaminants discovered in our product candidate or in the manufacturing facilities in which it is made, which can necessitate closure of facilities for an extended period of time to investigate and eliminate the contamination;
- the negative consequences of our CDMOs' failure to be approved for commercial production following an audit by regulatory authorities, by us or by our partners;
- Our CDMOs' changing strategies and business priorities, which can affect the availability of facilities where we intend to manufacture our product candidate; and

- Our CDMOs' manufacturing facilities being adversely affected by labor, raw material and component shortages, turnover of qualified staff or financial difficulties of their owners or operators, including as a result of natural disasters, power failures, local political unrest or other factors.

We cannot ensure that issues relating to the manufacture or testing of our product candidates, such as those described above, will not occur or continue to occur in the future. If we or our CDMOs experience any such issues there could be a shortage of drug substance or drug product for use in our clinical trials, which could delay clinical and regulatory timelines significantly and have an adverse effect on our business.

In addition, to date, TOUR006 has been manufactured and tested by our drug substance and drug product CDMOs solely for clinical trials. We intend to continue to use CDMOs for these purposes, and also for the supply of larger quantities that may be required to conduct accelerated or expanded early clinical trials or larger, later clinical trials and for commercialization if we advance any of our product candidates through regulatory approval and to commercialization. These manufacturers may not have sufficient manufacturing capacity and may not be able to scale up the production of drug substance or drug product in the quantities we need and at the level of quality required in a timely or effective manner, or at all. In particular, there is increased competition in the biotechnology industry for CDMO manufacturing slots and other capabilities generally, which has had, and may continue to have, a negative impact on the availability of manufacturing capacity and therefore our ability to supply clinical trial materials for planned, ongoing or expanded clinical trials or commercialization.

The scale up and validation of the manufacturing processes in the CDMOs' facilities to manufacture larger quantities or different formats such as a pre-filled syringe involve complex activities and coordination. Scale up and process validation activities entail risks such as process reproducibility and robustness, stability of in-process intermediates, product quality consistency and other technical challenges. We may be unable to scale up or validate our manufacturing processes, which can be expensive and time-consuming and could delay the initiation or completion of our clinical trials.

Similarly, we or our CDMOs may make changes to our manufacturing processes at various points in product development for many reasons, including changing manufacturing facilities, scaling up, facility fit, raw material or component availability, improving process robustness and reproducibility, decreasing processing times, changing the storage container, or others. In some circumstances, we may fail to demonstrate that the product from the new process is comparable to product from the prior process and we may be required to perform additional bridging studies, animal or human studies to demonstrate that the product used in earlier clinical trials are comparable to the product we intend to use in later trials or later stages of an ongoing trial. These efforts are expensive and there is no assurance that they will be successful, which could impact our ability to continue or initiate clinical trials in a timely manner, or at all, and could require the conduct of additional clinical trials.

Any future adverse developments affecting manufacturing operations or the scale up or validation of manufacturing processes for TOUR006 or any of our future product candidates may result in shipment delays, lot failures, clinical trial delays or discontinuations, or, if we are commercializing products, inventory shortages, product withdrawals or recalls or other interruptions in supply. We may also have to record inventory write-offs and incur other charges and expenses for drug substance or drug product that fail to meet specifications or cannot be used before its expiration date. In addition, for out of specification materials, we may need to undertake costly remediation efforts or manufacture new batches at considerable cost and time delays or, in the longer run, seek more expensive manufacturing alternatives.

We currently have a single source of supply for our drug substance and for our drug product. Single sourcing minimizes our leverage with our CDMOs, who may take advantage of our reliance on them to increase the pricing of their manufacturing services or require us to change our intended manufacturing plans based on their strategies and priorities. Single sourcing also imposes a risk of interruption or delays in supply in the event of manufacturing, quality or compliance difficulties and/or other difficulties in timely supplying us with materials. We do not currently have arrangements in place for redundant supply for drug substance or drug product. If one of our suppliers fails or refuses to supply us for any reason or we otherwise choose to engage a new supplier for TOUR006 or any of our future product candidates, including a second-source supplier to mitigate the risks of single-source supply, it may take a significant amount of time and cost to implement and execute the necessary technology transfer to, and qualification of, a new supplier. The FDA or comparable foreign health authority must approve manufacturers of commercial drug substance and drug product. If there are any delays in qualifying new suppliers or facilities or a new supplier is unable to meet the requirements of the FDA or comparable foreign health authority for approval of production of our commercial supply, there could be a shortage of drug substance or drug product with respect to the affected product candidates.

If our CDMOs are unable to source certain raw materials and components from their supplier and if they must obtain such materials from a different supplier, additional testing, and regulatory approvals, may be required, which may negatively impact manufacturing timelines. Any significant delay in the acquisition or decrease in the availability of these materials, components or other items, or failure to successfully qualify alternative materials or components, could considerably delay the manufacture of our product candidates, which could adversely impact the timing or completion of any ongoing and planned trials or the timing of regulatory approvals, if any, of our product candidates.

In addition, our CDMOs' facilities and operations may be adversely affected by labor, raw material and component shortages, high turnover of staff and difficulties in hiring trained and qualified replacement staff and the operations of our CDMOs may be requisitioned, diverted or allocated by U.S. or foreign government orders such as under emergency, disaster and civil defense declarations. Changes in economic conditions, supply chain constraints, labor, raw material and component shortages and steps taken by governments and central banks could also lead to higher inflation than previously experienced or expected, which could, in turn, lead to an increase in costs.

If any CDMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CDMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We would also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of our product candidate that such CDMO owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another CDMO manufacture our product candidates.

Our manufacturing and testing of bulk drug substance for TOUR006 currently takes place in China through a global CDMO with facilities in China and around the world. A significant disruption in the operation of the manufacturing facility in China, a trade war or political unrest could materially adversely affect our business, financial condition and results of operations.

We currently contract manufacturing operations to third parties. TOUR006 bulk drug substance is manufactured by a third-party facility in China. TOUR006 drug product is manufactured in Austria and packaged in Germany. Any disruption in production or inability of our manufacturers in those countries to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue development of our product candidates. Furthermore, since bulk drug substance is produced in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or unstable economic conditions in China. Any of these matters could materially and adversely affect our business and results of operations. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. Furthermore, any recall of the manufacturing lots or similar action regarding our product candidates used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currencies. Future appreciation of the local currencies could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in such countries.

We may seek to establish BD Arrangements, and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of TOUR006 or any of our future product candidates will require substantial additional cash to fund expenses. For TOUR006 or any of our future product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a BD Arrangement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's own evaluation of a potential collaboration. Such factors a potential collaborator will use to evaluate a BD Arrangement may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a BD Arrangement could be more attractive than one with us for our product candidate. The terms of any additional BD Arrangements or other arrangements that we may establish may not be favorable to us.

We may in the future be restricted under our current BD Arrangements from entering into potential future BD Arrangements on certain terms with potential collaborators. BD Arrangements are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate BD Arrangements on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

In addition, any future BD Arrangements that we enter into may not be successful. The success of our BD Arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a BD Arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the BD Arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. BD Arrangements with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

We have no experience in sales, marketing and distribution and may have to enter into agreements with third parties to perform these functions, which could prevent us from successfully commercializing TOUR006 or any potential future product candidates.

We currently have no sales, marketing or distribution capabilities. To commercialize TOUR006 or any potential future product candidates we must either develop our own sales, marketing and distribution capabilities or make arrangements with third parties to perform these services for us. If we decide to market or distribute any of our products on our own, we will have to commit significant resources to developing a marketing and sales force and supporting

distribution capabilities. If we decide to enter into arrangements with third parties for performance of these services, we may find that they are not available on terms acceptable to us, or at all. If we are not able to establish and maintain successful arrangements with third parties or build our own sales and marketing infrastructure, we may not be able to commercialize our product candidates, which would adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Discovery, Development and Regulatory Approval of Our Product Candidates

TOUR006 and any other of our future product candidates must undergo rigorous clinical trials before seeking regulatory approvals, and clinical trials may be delayed, suspended or terminated at any time for many reasons, any of which could delay or prevent regulatory approval and, if approval is granted, commercialization of our product candidates.

TOUR006 and any other product candidates we might develop are subject to rigorous and extensive clinical trials before we can seek regulatory approval from the FDA and comparable foreign health authorities such as the European Medicines Authority. Clinical trials may be delayed, altered, suspended or terminated at any time for reasons including but not limited to:

- ongoing discussions with the FDA or comparable foreign health authorities regarding the scope or design of our clinical trials;
- delays in obtaining, or the inability to obtain, required approvals from institutional review boards ("IRBs") and ethics committees or other governing entities at clinical trial sites selected for participation in our clinical trials;
- delays in reaching agreement on acceptable terms with clinical trial sites on clinical budgets and/or clinical trial agreements;
- lack and/or loss of personnel at clinical trial sites to conduct our trials, including patient screening, patient visits and/or assessments, data entry of patient data into the clinical database and/or processing of patient samples;
- institutional policies related to in-person patient visits resulting in delays to treatments or assessments being conducted, CRO and/or sponsor visits to conduct monitoring visits to verify data and/or site adherence to regulatory requirements;
- delays in patient enrollment and other key trial activities;
- delays in reaching agreement on acceptable terms with prospective CROs;
- the failure of CROs, testing laboratories and other third parties to satisfy their contractual duties to us or meet expected deadlines;
- deviations from the trial protocol by clinical trial sites and investigators, or failures to conduct the trial in accordance with regulatory requirements;
- alterations in the size and scope of the trial;
- lower than anticipated retention rates of participants in clinical trials, including patients dropping out due to protocol non-compliance, side effects or disease progression;
- missing or incomplete data;
- failure of enrolled patients to complete treatment or to return for post-treatment follow-up;

- for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected patients and test any patient samples;
- implementation of new, or changes to, guidance or interpretations from the FDA or comparable foreign health authorities with respect to approval pathways for TOUR006 and any potential future product candidates we are pursuing;
- the need to repeat or conduct additional clinical trials as a result of inconclusive or negative results, poorly executed testing or changes in required endpoints or other changes to the trial or analysis;
- insufficient supply or deficient quality of drug substance, drug product or other clinical trial material necessary to conduct our clinical trials, as well as delays in the testing, validation, manufacturing and delivery to clinical trial sites of such material;
- withdrawal of clinical trial sites or investigators from our clinical trials for any reason, including as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- unfavorable FDA or comparable foreign health authority inspection or review of a clinical trial site or records of any clinical or preclinical investigation;
- drug-related adverse effects or tolerability issues experienced by participants in our clinical trials;
- changes in government regulations or administrative actions;
- lack of adequate funding to continue the clinical trials;
- ability to hire and retain key R&D personnel; or
- the placement of a clinical hold on a trial by the FDA or comparable foreign health authorities.

We cannot guarantee that we will be able to successfully obtain FDA or other global health authority clearance to proceed with any planned clinical investigations of TOUR006 or any potential future product candidates or to accomplish required regulatory and/or manufacturing activities or all of the other activities necessary to initiate and complete clinical trials in a timely fashion, if at all. As a result, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approvals or successfully commercialize our products. In addition, we have only limited experience in conducting late-stage clinical trials required to obtain regulatory approval. In any event, we do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all.

Our product development costs will increase if we experience delays in clinical testing. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects. We or our partners' inability to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenue or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

If clinical trials of TOUR006 or any potential future product candidates fail to initiate, complete, or produce positive results or to demonstrate safety and efficacy to the satisfaction of the FDA or comparable health authorities or sufficient to demonstrate differentiation from other approved therapies or therapies in development, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from health authorities for the sale of TOUR006 or any potential future product candidates, we or our partners must conduct extensive preclinical studies and clinical trials to demonstrate its safety and efficacy in humans. Preclinical studies and clinical trials are expensive, take several years to complete and may not yield results that support further clinical development or product approvals. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. There is a high failure rate for drugs and biologic products proceeding through clinical trials and failure can occur at any stage of testing. Because we have limited experience designing clinical trials, we may be unable to design and execute a clinical trial to support regulatory approval.

We may also not be successful in generating clinical data sufficient to differentiate TOUR006 from other products in the same therapeutic area. If our competitors' products are, or are perceived to be, more effective, more convenient, less costly or safer than TOUR006, or we are unable to demonstrate differentiation in any of those factors, we may not be able to achieve a competitive position in the market.

In addition, data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In any event, it is impossible to predict when or if any of our product candidates will prove safe and effective in humans or will receive regulatory approval. If we are unable to successfully discover, develop or enable our partners to develop drugs that regulatory authorities deem effective and safe in humans, we will not have a viable business.

We may not be able to file INDs, IND amendments, or clinical trial applications ("CTAs") to commence clinical trials on the timelines we expect, and even if we are able to, the FDA or comparable health authorities may not permit us to proceed.

We may not be able to file INDs or CTAs for TOUR006 or any future product candidates on the timelines we expect, if at all. For example, we may experience, or our partners may experience, manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND or CTA will result in the FDA or comparable health authority allowing initial or later-stage clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or CTA, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND or CTAs. Any failure to file INDs and CTAs on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

If we experience delays or difficulties in the enrollment of patients in clinical trials, development of TOUR006, or any potential future product candidates, may be delayed or prevented, which would have a material adverse effect on our business.

We may not be able to initiate or continue clinical trials for our product candidate if we, or a potential future sponsor, are unable to locate and enroll a sufficient number of eligible patients to participate in these continuing trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, at clinical trial sites participating in our clinical trials, or at clinical trial sites not participating in our clinical trials and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment may also be affected by other factors, including:

- size and nature of the patient population;

- severity of the disease under investigation;
- patient eligibility criteria for the trial in question;
- nature of the trial protocol;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- perceived risks and benefits of the product candidate under study;
- the occurrence of adverse events attributable to our lead product candidate;
- efforts to facilitate timely enrollment in clinical trials;
- the number and nature of competing products or product candidates and ongoing clinical trials of competing product candidates for the same indication at clinical trial sites participating in our clinical trials, or at clinical trial sites not participating in our clinical trials;
- patient referral practices of physicians;
- risk that enrolled subjects will drop out or die before completion;
- competition for patients from other clinical trials at clinical trial sites participating in our clinical trials, or at clinical trial sites not participating in our clinical trials;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- continued enrollment of prospective patients by clinical trial sites.

Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than expected, the development costs for our product candidates may increase and the completion of our trials may be delayed or our trials could become too expensive to complete. Any delays in completing our clinical trials will increase costs, delay or prevent product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any delays in completing our clinical studies for our product candidates may also decrease the period of commercial exclusivity. Any of these occurrences may significantly harm our business, financial condition, results of operations, and prospects.

Success in preclinical studies or earlier-stage clinical trials for TOUR006, or evidence from published observations, clinical studies, or other literature for other anti-IL-6 or anti-IL-6 receptor agents, may not be indicative of such results in future or ongoing clinical trials for TOUR006.

To date, the data supporting our drug discovery and development programs are derived in part from laboratory and preclinical studies and earlier-stage clinical trials conducted by Pfizer. Owing in part to the complexity of biological pathways, when used to treat human patients, as well as differences in the design or conduct of clinical trials, TOUR006 might not demonstrate the biochemical and pharmacological properties we anticipate based on laboratory studies or earlier-stage clinical trials, and it may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. Success in preclinical studies and earlier-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate or positive data to demonstrate the effectiveness and safety of our current and potential future product candidates. In this regard, the data supporting our drug discovery and development programs are derived from laboratory and preclinical studies, and future clinical trials in humans may show that one or more of our product candidates are not safe and effective, in which event we may need to abandon development of such product candidates. In fact, many companies in the pharmaceutical and

biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical studies and earlier-stage clinical trials. Similarly, preliminary data and interim results from clinical trials may not be predictive of final results. As a general matter, there is also a substantial risk that Phase 3 trials with larger numbers of patients and/or longer durations of therapy will fail to replicate efficacy and safety results observed in earlier clinical trials. The impact of such differences may lead to a clinical trial(s) of TOUR006 failing to reproduce any positive efficacy, safety, or other findings from laboratory and preclinical studies and earlier-stage clinical trials for TOUR006.

In addition, the rationale supporting our drug discovery and development programs is also based upon published articles describing positive results from clinical trial(s) and/or the clinical experience of physicians using tocilizumab (and other inhibitors of IL-6 or IL-6 receptor) in various diseases. For example, part of the rationale supporting the development and investigation for TOUR006 in TED is from published articles describing the off-label use of tocilizumab in TED, which report observations of positive efficacy and safety results.

Results from our future or ongoing clinical trials of TOUR006 may differ significantly from those from published articles in the literature of other molecules in the anti-IL-6 or anti-IL-6R class. For example, differences in clinical results may arise from differences between drug targets or between molecules that inhibit the same drug target. In addition, there may be substantial differences, even if the same disease or indication, between clinical trial(s) of TOUR006 and published literature (e.g., case series or reports, clinical trials, etc.) for other molecules in the anti-IL-6 or anti-IL-6R class based upon factors such as the clinical use setting, patient population being treated or investigated, assessments (e.g., efficacy, safety, pharmacodynamics, etc.), data collection and handling, analysis, study conduct, or other factors. Bias may have also been introduced in the published clinical reports that led to an incorrect determination or overestimate of the efficacy and safety results for TOUR006 because of the open-label nature and lack of controls or other robustness measures in these case series and uncontrolled clinical studies. There also can be publication bias, if only examples of successful cases of the clinical use of an anti-IL-6 or anti-IL-6R molecule (e.g., tocilizumab, satralizumab, sarilumab, siltuximab, ziltivekimab, etc.) may have been published, while treatment experiences for such molecules that were unsuccessful and/or associated with adverse safety outcomes were not published.

The impact of such differences may lead to a clinical trial(s) of TOUR006 failing to reproduce any positive efficacy, safety, or other findings in relation to inhibition of IL-6 or the IL-6 receptor that were reported in publications of other molecules. If such an event was to occur, there is a risk that the TOUR006 development program in a particular indication(s) or all indications is terminated, longer or more expensive development programs (including larger, longer, and/or costlier clinical trials) may be required to investigate TOUR006, TOUR006 is not approved by the FDA or other regulatory authorities, TOUR006 is not reimbursed by payors or other similar bodies, or there is limited or no success achieved in the commercialization of TOUR006.

Preliminary, initial, or interim results from clinical trials that we announce, present, or publish from time to time may change as more data and information become available (or are updated based upon audit, validation and verification procedures of the data/information commonly performed for clinical trials) that could result in material changes in the final trial results.

From time to time, we may announce, present or publish preliminary, initial, or interim data or other information from our clinical trials. Any such data and other results from our clinical trials may materially change as more patient data and information become available. Such data and information may also undergo significant change following subsequent auditing, validation and/or verification procedures that are commonly conducted in clinical trials. Thus, any preliminary, initial, or interim data or other information may not be predictive of final results from the clinical trial and should be viewed with caution until the final data are available. We may also arrive at different conclusions, or other determinations that may qualify such results, once we have received and fully evaluated the additional data. Differences between preliminary, initial or interim results and final results could lead to significantly different interpretations or conclusions of the trial outcomes.

Further, others, including regulatory authorities and collaboration or regional partners, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of TOUR006, the approvability or commercialization of TOUR006 or any future product candidates, and us in general. In addition, the information we choose to publicly disclose regarding a particular clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the preliminary, initial or interim data that our reports differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, TOUR006 may be harmed, which could significantly harm our business, financial condition, results of operations and prospects.

TOUR006 may cause undesirable side effects or adverse events or have other properties or safety risks, which could terminate further development of this product candidate, result in a lack of product approval by the FDA or other regulatory authorities, delay the timing (and/or increase the cost) of a product approval by the FDA or other regulatory authorities, lead to a restrictive product label that significantly limits prescribing of an approved product, delay or preclude reimbursement by payors, or significantly limit or preclude the commercialization of TOUR006.

A concerning safety signal (such as that involving serious adverse events, life-threatening adverse events, or deaths, or a nonserious adverse event that may occur at a high or concerning frequency and/or severity or if rare, leads to a significant safety concern), tolerability concern (e.g., undesirable side effects that cannot be tolerated by patients, require suboptimal dosing alterations require additional monitoring and/or lead to patients missing or delaying doses) or other safety issue caused by TOUR006 may be observed in any future or ongoing clinical trial of TOUR006. For example, dosing in the 200 mg arm of the prior Phase 2 trial of TOUR006 in systemic lupus erythematosus was stopped for safety concerns based on an unblinded data review and recommendation from the internal review committee for that study. Prior safety (clinical and nonclinical) data for TOUR006, safety data and observations for other molecules in the anti-IL-6 and anti-IL-6R classes, and published safety data and observations for other molecules in the anti-IL-6 and anti-IL-6R classes used in the same disease or indication as that being investigated in TOUR006 clinical trial(s) may not be indicative of similar safety and tolerability results or profile for TOUR006 in future or ongoing clinical trials. For example, some potential therapeutics developed in the biopharmaceutical industry that initially showed therapeutic promise in early-stage trials have later been found to have a problematic safety or tolerability profile that prevented their further development.

In addition, TOUR006 is a recombinant protein. Recombinant proteins can sometimes induce host immune responses that can cause the production of anti-drug antibodies (“ADAs”). ADAs may neutralize the effectiveness of the product candidate, can require that higher doses be used to obtain a therapeutic effect or can cross react with substances naturally occurring in a subject’s body, which can cause unintended effects, including potential impacts on efficacy and adverse events. For example, the ADAs may prevent the drug from offering a therapeutic benefit or lead to a less efficacious effect. ADAs may also cause hypersensitivity reactions (including anaphylaxis) that may require patients to stop taking that drug or can, in some cases, be serious, life-threatening, or fatal. If we determine that ADAs are causing safety or efficacy concerns for TOUR006, we may need to delay, halt, or terminate our clinical trials and the affected product candidates. TOUR006 may never obtain regulatory approval by the FDA or other regulatory authorities. We cannot provide assurance that the detection of ADAs will not occur at a higher rate than what we have observed historically or that ADA will not lead to meaningful impacts upon efficacy or safety, or that the detection of ADAs will not otherwise result in TOUR006 not being approved by the FDA or other regulatory authorities.

If a safety signal, tolerability concern, ADA concern, or other safety issue emerges from any future or ongoing clinical trial for TOUR006, or any other IL-6 inhibitor product candidate, this could result in:

- slowing of patient enrollment in our clinical trials or inability to enroll the trials;
- a meaningful rate of patients dropping out of trials (which could lead to a delay in completing the clinical trial or adversely impact the trial’s probability of success in observing a positive efficacy result);
- a meaningful rate of patients missing or postponing their trial procedures (including but not limited to dosing, study visits and efficacy assessments) which in turn could lead to a delay in completing the clinical trial or adversely impact the trial’s probability of success in observing a positive efficacy result;
- an inability to use a dose that offers efficacy or necessitating the use of a lower dose that may offer only low or partial efficacy;

- suspension of the clinical trial by us, the FDA or other regulatory authority, or local IRB or ethics committee;
- termination of the clinical trial;
- need for additional and/or larger clinical trial(s) to further evaluate the safety profile of TOUR006;
- abandonment of the development of TOUR006 for that particular indication being evaluated by the clinical trial or for other indications or as a program altogether;
- refusal by the FDA or other regulatory authority to grant product approval;
- restrictions on the product labeling (such as a black boxed warning, warnings and precautions, limitations of use, and/or narrowed and limited indication) that may significantly limit the prescribing and usage of TOUR006;
- requirement to develop a Risk Evaluation and Mitigation Strategy ("REMS") for TOUR006 in the U.S. or a similar strategy as required by a comparable foreign regulatory authority;
- a view by healthcare professionals that TOUR006 presents an unfavorable benefit-risk profile which in turn may significantly limit the prescribing and usage of TOUR006;
- a meaningful rate of patients either choosing to not start TOUR006 treatment or to prematurely discontinue usage of TOUR006;
- use of additional monitoring by healthcare professionals, either on their own or due to the recommendations of expert panels or treatment guidelines, in the use of TOUR006 that in turn may significantly limit the prescribing and usage of TOUR006;
- a view by payors that TOUR006 presents an unfavorable benefit-risk profile which in turn may significantly limit the reimbursement of TOUR006;
- a requirement to conduct additional post-market studies, including clinical trials;
- lawsuit(s) that results in us being held liable for harm caused to trial participants or other patients; and/or
- reputational injury to us.

Any of these occurrences could materially and adversely affect our business, financial condition, results of operations and prospects.

TOUR006 is a product candidate within the IL-6 inhibitor and IL-6R inhibitor class and may be adversely impacted by results for other members in the class, which could delay, terminate or increase the cost of development of TOUR006, delay or prevent approval by the FDA or other regulatory authorities, lead to a restrictive product label that significantly limits prescribing, delay or preclude reimbursement by payors, or significantly limit or preclude the commercialization of TOUR006.

TOUR006 is a member of the IL-6 inhibitor and IL-6R inhibitor class. There are other products and product candidates within this class that are being developed or commercialized by third parties over which we have no control and for which we do not have any information beyond what is publicly available. It is possible that negative data or information may emerge from one or more of these other products or product candidates related to a limitation or failure of efficacy, safety concern, negative publicity or other issue. Such an occurrence may adversely impact TOUR006 or its perceived product profile and could terminate further development of TOUR006, result in a lack of product approval by the FDA or other regulatory authorities, delay the timing (and/or increase the cost) of a product approval, lead to a restrictive product label that significantly limits prescribing, delay or preclude reimbursement by payors, or significantly limit or preclude the commercialization of TOUR006.

We face significant competition from other biotechnology and pharmaceutical companies targeting autoimmune and cardiovascular disease indications. Our operating results will suffer if we fail to compete effectively.

The markets for autoimmune disease therapies are competitive and are characterized by significant technological development and new product introduction. For example, there are several large and small pharmaceutical companies focused on delivering therapeutics for TED or ASCVD. We anticipate that, if we obtain regulatory approval of TOUR006, we will face significant competition from other approved therapies or drugs that become available in the future for the treatment of our target indications. If approved, TOUR006 may also compete with unregulated, unapproved and off-label treatments. TOUR006 may also face biosimilar competition following loss of regulatory exclusivity and/or patent expiry. Even if an approved biosimilar product is less effective than TOUR006, a less effective biosimilar may be more quickly adopted by physicians and patients than our competing product candidate based upon cost. TOUR006 will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our product, if approved, provides an attractive alternative to existing and other new therapies to gain a share of some patients' discretionary budgets and to gain physicians' attention within their clinical practices. Some of the companies that may offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. Such competition could lead to reduced market share for our product candidate and contribute to downward pressure on the pricing of our product candidate, which could harm our business, financial condition, results of operations and prospects.

We expect to face competition from agents with different mechanisms of action in both TED and ASCVD. For example, in January 2020, the FDA approved Amgen Inc.'s (formerly Horizon Therapeutics Public Limited Company) Tepezza (teprotumumab), an anti-IGF-1R antibody, for the treatment of TED. In addition, there are multiple other agents in various stages of development for the treatment of TED, including Roche's satralizumab, an anti-IL-6R monoclonal antibody. The first line of treatment for patients with TED is generally immunosuppressive therapy, including high doses of corticosteroids. For ASCVD, several classes of therapies are routinely used, including statins, beta-blockers, ACE inhibitors, ARBs, aspirin, and other anti-platelet agents. Additionally, we are aware of two IL-6 blockers currently being developed for the treatment of ASCVD.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, as well as in obtaining regulatory approvals of those product candidates in the U.S. and in foreign countries. Many of our current and potential future competitors also have significantly more experience commercializing drugs that have been approved for marketing. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a smaller number of our competitors. Competition may reduce the number and types of patients available to us to participate in clinical trials because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

Due to varying regulatory requirements in certain foreign countries, there are many more products and procedures available for use to treat autoimmune diseases in some international markets than are approved for use in the U.S. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market their products.

Our ability to compete successfully will depend largely on our ability to:

- develop and commercialize therapies in our target indications that are competitive with other products in the market;
- demonstrate through our clinical trials that TOUR006 or any potential future product candidates is differentiated from existing and future therapies;
- attract and retain qualified scientific, product development, manufacturing and commercial personnel;
- obtain patent or other proprietary protection for TOUR006 and any potential future product candidates;

- obtain required regulatory approvals, including approvals to market TOUR006 or any potential future product candidates we develop;
- have commercial quantities of any approved product manufactured at acceptable cost and quality levels and in compliance with FDA and other regulatory requirements;
- successfully commercialize TOUR006 or any potential future product candidates, if approved;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- avoid regulatory exclusivities or patents held by competitors that may inhibit our products' entry to the market.

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we develop. The inability to compete with existing or subsequently introduced treatments would have an adverse impact on our business, financial condition, results of operations and prospects.

If the market opportunities for TOUR006 and any potential future product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, then our revenue potential and ability to achieve profitability will be adversely affected.

The total addressable market opportunity for TOUR006 and any other potential future product candidates we may develop will ultimately depend upon, among other things, the proportion of patients identified as sensitive to our treatments, acceptance by the medical community, patient access, drug and any related companion diagnostic pricing and their reimbursement.

We intend to initially seek regulatory approval of TOUR006 as therapies for patients with TED and ASCVD. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. In addition, we may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, which may prove to be the wrong choice and may adversely affect our business, financial condition, results of operations and prospects.

We may not successfully identify new product candidates to expand our development pipeline.

The success of our business over the longer term depends upon our ability to identify and validate new potential therapeutics. Efforts to identify new product candidates require substantial technical, financial and human resources, and our methodology may not successfully identify medically relevant potential therapeutics to be developed as product candidates. Moreover, our research and business development efforts may identify molecules that initially show promise yet fail to yield product candidates for clinical development for multiple reasons. For example, potential product candidates may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal drug profiles, suboptimal manufacturability or stability, or other characteristics suggesting that they are unlikely to be commercially viable products. Our inability to successfully identify additional new product candidates to advance into clinical trials could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to the Marketing and Commercialization of Our Product Candidates

Even if any of our current or future product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If TOUR006 or any of our potential future product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our current or potential future candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments, including pharmaceutical and nonpharmaceutical interventions;
- the acceptance of our product candidates as front-line treatments for various indications;
- the prevalence and severity of any side effects, in particular compared to alternative treatments;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the size of the target patient population;
- the willingness and ability of the target patient population to try new therapies and adhere or comply with taking such therapy as prescribed and of physicians to prescribe these therapies;
- our ability to offer our products for sale at competitive prices;
- our ability to protect our approved products from generic or biosimilar competition through the use of regulatory exclusivity or patents;
- the convenience and ease of administration compared to alternative treatments;
- the amount of clinical burden upon healthcare professionals or patients related to any additional monitoring or other measures needed in order for patients to initiate and/or continue receiving such products;
- the strength of marketing, sales and distribution support;
- publicity for our product candidates and competing products and treatments;
- the availability of third-party payor coverage and adequate reimbursement;
- the timing of any marketing approval in relation to other product approvals;
- support from patient advocacy groups; and
- any restrictions on the use of our products together with other medications.

Even if we obtain approval to market TOUR006 or other potential future product candidates, these products may become subject to unfavorable pricing regulations, reimbursement practices from third-party payors or healthcare reform initiatives in the U.S. and abroad, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. In many regions, including the European Union ("EU"), Japan and Canada, the pricing of prescription drugs is controlled by the government and some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after regulatory approval for the product is granted. Regulatory agencies in those countries could determine that the pricing for our products should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market our products at a premium as new drugs. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit its commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, private health insurers, health maintenance organizations and other organizations, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. In the U.S. and markets in other countries, governments and private insurers closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that will apply. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drug products. We cannot be sure that coverage and reimbursement will be available for any product that we or our partners commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or our partners obtain regulatory approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we and our partners may not be able to successfully commercialize any product candidate for which marketing approval is obtained.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign health authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including costs of research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, ability to raise capital needed to commercialize products and overall financial condition.

Even if we are able to obtain regulatory approval for TOUR006 or any of our future product candidates, we may receive an undesirable label, including, but not limited to, a black boxed warning, which could impede our ability to successfully commercialize TOUR006 or any of our future product candidates or compete successfully.

Even if we receive regulatory approval for any of our product candidates, the FDA may determine that labels for our product candidates may require safety restrictions such as a black boxed warning, warnings and precautions, limitations of use, and/or narrowed and limited indication that may significantly limit the prescribing and usage of TOUR006. Safety restrictions such as a black boxed warning may impede our ability to successfully market and commercialize our product candidates and our ability to compete successfully against our competitors.

Two approved therapies in the IL-6 class, tocilizumab (Actemra®) and sarilumab (Kevzara®) have received black boxed warning for risks of serious infections. Two approved therapies in the IL-6 class, satralizumab (Enspryng®) and siltuximab (Sylvant®) have not. We cannot guarantee or ensure that TOUR006 will not get a black boxed warning or significant safety restrictions on its product labels, if approved.

Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

Our market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates which may not prove to be accurate. Our estimates and forecasts relating to size and expected growth of our target market may prove to be inaccurate. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. Our growth is subject to many factors, including our success in implementing our business strategy, which is subject to many risks and uncertainties.

Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, the ability to gain market share and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as our estimates, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we or our partner commercializes any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for TOUR006 or any potential future product candidates, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician endorsement of our products or expand our business.

Risks Related to Government Regulation

The regulatory approval processes of the FDA and comparable foreign health authorities are lengthy and inherently unpredictable. Our inability to obtain regulatory approval for TOUR006 would substantially harm our business.

Currently, we have no product candidate that has received regulatory approval and TOUR006 or any potential future product candidates is not expected to be commercially available for several years, if at all. The time required to obtain approval from the FDA and comparable foreign health authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the health authorities. In addition, approval policies, regulations or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions. It is possible that none of our existing or future product candidates will ever obtain regulatory approval.

TOUR006 or any of our future product candidates could fail to receive regulatory approval from the FDA or a comparable foreign health authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of results of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials to support the submission and filing of a Biologics License Application ("BLA") or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies;
- unfavorable quality review or audit/inspection findings; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign health authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and commercialization, or we may decide to abandon the development program for other reasons. For example, the FDA may require us to conduct a Phase 1 trial for TOUR006 in ASCVD. If we obtain approval, regulatory authorities may approve TOUR006 or any potential future product candidates for fewer or more limited indications than we request, may grant accelerated approval or conditional marketing authorization based on a surrogate endpoint and contingent on the successful outcome of costly and time-consuming post-marketing confirmatory clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

We may seek fast track and/or breakthrough therapy designations or priority review for one or more of our product candidates, but we might not receive such designation or priority review, and even if we do, such designation or priority review may not lead to a faster development or regulatory review or approval process, and does not assure FDA approval of our product candidates. Even if a product qualifies for such designation or priority review, the FDA may later decide that the product no longer meets the conditions for qualification or may decide that the time period for FDA review or approval will not be shortened.

We may seek fast track and/or breakthrough therapy designations for one or more of our product candidates.

The FDA may issue a fast track designation to a product candidate if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic may request that the FDA designate the biologic as a fast track product at any time during the clinical development of the product. For fast track products, sponsors may have greater interactions with the FDA during product development. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. However, the FDA's PDUFA goal for reviewing a BLA fast track application under the Prescription Drug User Fee Act ("PDUFA") does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Fast track designation and breakthrough therapy designation are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for any such designation, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of such designation may expedite the development or approval process, but does not change the standards for approval. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the BLA is eligible only for standard review.

In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines ("PRIME"), scheme, which provides incentives similar to the breakthrough therapy designation in the U.S.

Sponsors that benefit from PRIME designation are potentially eligible for accelerated assessment of their marketing authorization applications, although this is not guaranteed. If a product for which PRIME designation was granted is the subject of an accelerated assessment, the product may be placed on the market in the EU before our product candidate with a similar therapeutic indication.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operation.

Our failure to obtain health authority approval in foreign jurisdictions would prevent us from marketing TOUR006 or any potential future product candidates outside the U.S.

If we or our partners succeed in developing any products, we intend to market them in the EU and other foreign jurisdictions in addition to the U.S. In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the U.S. generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the U.S., we must secure product pricing and reimbursement approvals before health authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by health authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we fail to obtain approval of TOUR006 or any potential future product candidates by health authorities in another country, we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline. In addition, failure to obtain regulatory approval in one country or region could adversely affect future regulatory approvals in other countries.

Even if TOUR006 and any potential future product candidates receive regulatory approval, they will still face extensive ongoing regulatory requirements, which may result in significant expenses, and may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign health authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. We will be subject to ongoing requirements, including submissions of safety and other post-marketing information, reports, establishment registration and product listing requirements, requirements relating to current cGMP, applicable product tracking and tracing requirements, quality control, quality assurance and corresponding maintenance of records and documents, and recordkeeping. We will also need to ensure continued compliance by it and/or any future contract manufacturing organizations and CROs for any post-approval clinical trials that we conduct. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Additionally, under the Food and Drug Omnibus Reform Act of 2022, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

Even after approval, the FDA and comparable foreign health authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign health authorities become aware of new safety information after approval of TOUR006 and any potential future product candidates, they may require labeling changes or establishment of a REMS, or similar strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Failure to comply with any related obligations may result in the suspension or withdrawal of an obtained approval and in civil and/or criminal penalties. Receipt of approval for narrower indications than sought, restrictions on marketing through a REMS or similar strategy imposed by the FDA or in an EU member state or other foreign country, or significant labeling restrictions or requirements in an approved label such as a black boxed warning could have a negative impact on our ability to recoup our R&D costs and to successfully commercialize that product, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects. In any event, if we are unable to comply with our post-marketing obligations imposed as part of the marketing approvals in the U.S., the EU, or other countries, our approval may be varied, suspended or revoked, product supply may be delayed and our sales of our products could be materially adversely affected.

In addition, manufacturers of drug substance and drug product and their facilities are subject to continual review and periodic inspections by the FDA and comparable foreign health authorities for compliance with cGMP, regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the U.S. If we or the manufacturing facilities for TOUR006 or any potential future product candidates fail to comply with applicable regulatory requirements, or if TOUR006 or any potential future product candidates are found to cause undesirable or unacceptable side effects, a regulatory agency may:

- issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labelling or marketing of such products;
- require that we conduct and complete post-marketing studies;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend marketing of, withdraw or modify regulatory approval of or initiate a recall of such product;
- suspend or modify any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or refuse to permit the import or export of products.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the U.S. will be heavily scrutinized by the FDA, DOJ, HHS, OIG, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations and civil and criminal sanctions by the government. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties. Additionally, comparable foreign health authorities, public prosecutors, industry associations, healthcare professionals and other members of the public will heavily scrutinize advertising and promotion of any product candidate outside of the U.S.

In the U.S., engaging in the impermissible promotion of our products for off-label uses can subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal FCA, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these FCA lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses involving fines in excess of $1 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of TOUR006 or any potential future product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU member state laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), as approved by the competent authorities in connection with a marketing authorization. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

Failure to comply with EU, EU member state, and other country laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of a marketing authorization, or with other applicable regulatory requirements, may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties. In addition, directives adopted at the EU level may be implemented differently by individual member states. These directives, and their differing implementations in member states, increase our legal and financial compliance costs and may make some activities more time-consuming and expensive.

Healthcare reform may negatively impact our ability to profitably sell TOUR006 and any potential future product candidates, if approved.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of TOUR006 or any potential future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

For example, on July 9, 2021, President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede generic drug and biosimilar competition.

Additionally, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA"), into law, which among other things, (1) directs the HHS, to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA includes certain exemptions to the price negotiation program, including a limited exemption for products with orphan drug designation. This exemption applies only to products with one orphan drug designation that is (i) for a rare disease or condition and (ii) is approved for indication(s) for such rare disease or condition. By limiting price negotiation exemption to products with only one orphan drug designation, the IRA may decrease our interest in pursuing orphan drug designation for our product candidates in multiple indications. The IRA also, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025 and eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. These provisions will take effect progressively starting in fiscal year 2023, although the Medicare drug pricing negotiation program is currently subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive legislation repealing the ACA, such legislation may be reintroduced. Members of Congress have introduced legislation to modify or replace certain provisions of the ACA. It is unclear how these efforts to repeal and/or replace the ACA will impact the ACA and our business. For example, the Tax Cuts and Jobs Act (the "2017 Tax Act"), repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA and IRA may be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measures may impact the ACA or IRA, increase the pressure on drug pricing or limit the availability of coverage and adequate reimbursement for TOUR006 and any potential future product candidates, which would adversely affect our business.

There has also been increasing executive, legislative and enforcement interest in the U.S. with respect to drug pricing practices. There have been U.S. congressional inquiries, presidential executive orders and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, in an executive order, the

administration of President Biden expressed its intent to pursue certain policy initiatives to reduce drug prices and, in response, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to lower drug prices. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS, Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve the quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved product and could seriously harm its future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenue from TOUR006 and any potential future product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

In many countries outside the U.S., government-sponsored healthcare systems are the primary payors for drugs. With increasing budgetary constraints and/or difficulty in understanding the value of medicines, governments and payors in many countries are applying a variety of measures to exert downward price pressure and we expect that legislators, policy makers and healthcare insurance funds in the EU Member States will continue to propose and implement cost cutting measures. These measures include mandatory price controls, price referencing, therapeutic-reference pricing, increases in mandates, incentives for generic substitution and biosimilar usage, government-mandated price cuts, limitations on coverage of target population and introduction of volume caps.

Many countries implement health technology assessment ("HTA"), procedures that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies. These assessments are increasingly implemented in established and emerging markets. In the EU, Regulation (EU) 2021/2282 on Health Technology Assessment, which will become effective on January 12, 2025, will allow EU member states to use common HTA tools, methodologies and procedures to conduct joint clinical assessments and joint scientific consultations whereby HTA authorities may provide advice to health technology developers. Each EU member state will, however, remain exclusively competent for assessing the relative effectiveness of health technologies and making pricing and reimbursement decisions. Given that the extent to which pricing and reimbursement decisions are influenced by the HTA process currently varies between EU member states, it is possible that our products may be subject to favorable pricing and reimbursement status only in certain EU countries. If we are unable to maintain favorable pricing and reimbursement status in EU member states that represent significant markets, including following periodic review, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected. Moreover, in order to obtain reimbursement for our products in some EU member states, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Efforts to generate additional data for the HTA process will involve additional expenses which may substantially increase the cost of commercializing and marketing our products in certain EU member states.

We cannot predict the likelihood, nature or extent of healthcare reform initiatives that may arise from future legislation or administrative action. However, it is possible that countries will continue taking aggressive actions to seek to reduce expenditures on drugs. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies.

If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our relationships with healthcare providers, customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we or our partner obtains marketing approval. Our arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute products for which we or our partner obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal FCA or federal civil monetary penalties;

- the FCA imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- HIPAA, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense or knowingly and willfully making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), also imposes obligations on certain covered entity healthcare providers, health plans and healthcare clearinghouses, and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security, processing and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the federal Sunshine Act, as amended, and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the HHS information related to “payments or other transfers of value” made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and local laws requiring the registration of pharmaceutical sales representatives; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or pricing; federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and state and foreign laws that govern the privacy and security and other processing of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, additional regulatory oversight, litigation, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Outside the U.S., interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of EU member states, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Legislation or other changes in U.S. tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Our ability to use our U.S. net operating loss carryforwards and certain other U.S. tax attributes may be limited.

As of December 31, 2022, we had U.S. federal net operating loss carryforwards of approximately $1.2 million. The amount of net operating loss carryforwards that we are permitted to deduct is limited to 80% of taxable income in each such taxable year to which the net operating loss carryforwards are applied. In addition, our U.S. federal net operating losses and tax credits may be subject to limitations under Sections 382 and 383 of the Code, if we have undergone or undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period. We may have experienced such ownership changes in the past and may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Our net operating losses and tax credits may also be impaired or restricted under state law. Our ability to utilize our net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the U.S. are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred frequently in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. Compliance with new accounting standards may also result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes-Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, could have a material adverse effect on our business and share price.

Our management is required to establish and maintain an adequate internal control structure and procedures for financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

Any failure to maintain effective internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins our reporting on internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements would not be prevented or detected on a timely basis.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner commensurate with the financial reporting requirements of an SEC registrant. Prior to the completion of the Merger, we were a private company and therefore had not designed or maintained internal controls over financial reporting commensurate with the financial reporting requirements of an SEC registrant.

Our management identified material weaknesses in our internal control over financial reporting primarily related to limited staffing levels within the finance and accounting departments that were not commensurate with our financial accounting and reporting requirements. We had to rely increasingly on outsourced service providers and specialists, without adequate resources to monitor such work and did not maintain appropriate segregation of duties. Based on this, we did not fully implement components of the COSO framework, resulting in material weaknesses either individually, or in the aggregate, in the control environment, risk assessment, control activities, information and communication, and monitoring components.

However, the material weaknesses described above could result in a misstatement of one or more account balances or disclosures that would result in a material misstatement to the annual or interim consolidated financial statements that would not be prevented or detected.

We are in the process of implementing measures designed to improve our internal control over financial reporting and remediate these material weaknesses. Such measures include, but are not limited to: hiring additional accounting personnel with expertise commensurate with our financial accounting and reporting requirements and that have the requisite experience to oversee outsourced service providers and specialists, upgrading our financial systems and implementing information technology general controls, establishing controls to identify, assess, and respond to the risks of material misstatement, and establishing controls to identify and account for certain non-routine, unusual or complex transactions in a timely fashion. While we are currently in the process of remediating the material weaknesses outlined above, we cannot assure you that these efforts will remediate the material weaknesses in a timely manner, or at all.

We expect to expand our clinical development, manufacturing and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of September 30, 2023, we had 28 full-time employees, including 18 who are engaged in research and development activities, and no part-time employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical product development, business development, regulatory affairs and, if TOUR006 or any potential future product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our choice to focus on multiple therapeutic areas may negatively affect our ability to develop adequately the specialized capability and expertise necessary for operations. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We must attract and retain highly skilled employees in order to succeed. If we are not able to retain our current senior management team or to continue to attract and retain qualified scientific, technical and business personnel, our business may suffer.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. An important element of our strategy is to take advantage of the R&D and other expertise of our current management. The loss of any one of our executive officers, other senior members of the leadership team, or other key personnel could result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and further commercialization of TOUR006 and any potential future product candidates.

There is intense competition for qualified personnel, including management, in the technical fields in which we operate and we may not be able to attract and retain qualified personnel necessary for the successful research, development and future commercialization, if any, of TOUR006 and any potential future product candidates.

Our Executive Severance and Change in Control Plan with certain of our executive officers may require us to pay severance benefits to any of those persons who are terminated in connection with a change in control of us, which could harm our financial condition or results.

Certain of our executive officers are parties to our Executive Severance and Change in Control Plan that contains change in control and severance provisions providing for aggregate cash payments for severance and other benefits and acceleration of vesting of stock options in the event of a termination of employment in connection with a change in control of us. The accelerated vesting of options could result in dilution to our existing stockholders and harm the market price of our common stock. The payment of these severance benefits could harm our financial condition and results. In addition, these potential severance payments may discourage or prevent third parties from seeking a business combination with us.

Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the U.S.

Our business is subject to risks associated with conducting business internationally. Some of our manufacturing and clinical trial sites are located outside of the U.S. Furthermore, if we or any future partner succeeds in developing TOUR006 or any of our potential future product candidates, we intend to market them in the EU and other jurisdictions in addition to the U.S. If approved, we or any future partner may hire sales representatives and conduct physician and patient association outreach activities outside of the U.S. Doing business internationally involves a number of challenges and risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy and data protection regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- delays or interruptions in the supply of clinical trial material resulting from any events affecting raw material or component supply or manufacturing capabilities abroad;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property rights;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits on our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of inflation and local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political, global geopolitical and economic instability, including geopolitical conflicts such as the ongoing war in Ukraine and hostilities in the Middle East, terrorism and political unrest, disease outbreaks, epidemics and pandemics; and

- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our ongoing international clinical operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

Our business could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics.

Disease outbreaks, epidemics and pandemics in regions where we may have clinical trial sites or other business operations could adversely affect our business, including by causing significant disruptions in our operations and/or in the operations of third-party manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics have negative impacts on our ability to initiate new clinical trial sites, to enroll new patients and to maintain existing patients who are participating in our clinical trials, which may include increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of TOUR006 and any potential future product candidates, if at all. Disease outbreaks, epidemics and pandemics also could adversely impact clinical trial results for TOUR006 or other future potential product candidates, such as by diminishing or eliminating their efficacy or by producing a safety concern, either through direct biological effects or through confounding of the data collection and analysis. This adverse impact could terminate further development of TOUR006, result in a lack of product approval by the FDA or other regulatory authorities, delay the timing (and/or increase the cost) of a product approval by the FDA or other regulatory authorities, lead to a restrictive product label that significantly limits prescribing of an approved product, delay or preclude reimbursement by payors, or significantly limit or preclude the commercialization of TOUR006.

General supply chain issues may be exacerbated during disease outbreaks, epidemics and pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. If our CDMOs are required to obtain an alternative source of certain raw materials and components, for example, additional testing, validation activities and regulatory approvals may be required which can also have a negative impact on timelines. Any associated delays in the manufacturing and supply of drug substance and drug product for our clinical trials could adversely affect our ability to conduct ongoing and future clinical trials of TOUR006 on our anticipated development timelines. Likewise, the operations of our third-party manufacturers may be requisitioned, diverted or allocated by U.S. or foreign government orders. If any of our CDMOs or raw materials or components suppliers become subject to acts or orders of U.S. or foreign government entities to allocate or prioritize manufacturing capacity, raw materials or components to the manufacture or distribution of vaccines or medical supplies needed to test or treat patients in a disease outbreak, epidemic or pandemic, this could delay our clinical trials, perhaps substantially, which could materially and adversely affect our business.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Political developments impacting government spending and international trade, including current or potential government-imposed sanctions, potential government shutdowns and trade disputes and tariffs, may negatively impact markets and cause weaker macro-economic conditions. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our current and future potential product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our operations are vulnerable to interruption by fire, earthquake, power loss, telecommunications failure, terrorist activity and other events beyond our control, which could harm our business.

Our facilities may experience electrical blackouts as a result of a shortage of available electrical power. Future blackouts, which may be implemented by the local electricity provider in the face of high winds and dry conditions, could disrupt our operations. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity or other disasters and do not have a comprehensive recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business.

We use and generate materials that may expose us to material liability.

Our research programs involve the use of hazardous materials, chemicals and radioactive and biological materials. We are subject to foreign, federal, state and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products. We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers' compensation, property and business interruption insurance and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

We may be exposed to increased litigation, including stockholder litigation, which could have an adverse effect on our business and operations.

We may be exposed to increased litigation from stockholders, suppliers and other third parties from time to time, including litigation due to the Merger. Such litigation may have an adverse impact on our business and results of operations or may cause disruptions to our operations. In addition, in the past, stockholders have initiated class action lawsuits against biotechnology companies following periods of volatility in the market prices of these companies' common stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty and breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Risks Related to Our Intellectual Property

Our success depends in significant part upon our ability to obtain and maintain intellectual property protection for our products and technologies.

Our success depends in significant part on our ability and the ability of our current or future licensors, licensees, partners and collaborators to establish and maintain adequate intellectual property rights covering the product candidates, products and technologies that we plan to develop. In addition to taking other steps designed to protect our intellectual property, we have applied for, and intend to continue applying for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. However, the patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees, partners or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current or future licensors, licensees, partners or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Pending and future patent applications filed by us or our current or future licensors', licensees', partners' or collaborators' may not result in patents being issued that protect our technology or product candidates, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products.

We have filed five provisional patent applications in the U.S. to obtain patent rights to our inventions, with claims directed to methods of use, combination therapy and other technologies relating to our product candidates. There can be no assurance that any of these patent applications will issue as patents or, for those applications that do mature into patents, whether the claims of the patents will exclude others from making, using or selling our product or product candidates, or products or product candidates that are substantially similar to us for the same or similar uses. In countries where we have not and do not seek patent protection, third parties may be able to manufacture and sell products that are substantially similar or identical to our products or product candidates without our permission, and we may not be able to stop them from doing so.

Similar to other biotechnology companies, our patent position is highly uncertain and involves complex legal and factual questions. In this regard, we cannot be certain that we or our current or future licensors, licensees, partners or collaborators were the first to make an invention, or the first inventors to file a patent application claiming an invention in our owned or licensed patents or pending patent applications. In addition, even if patents are issued, given the amount of time required for the development, testing and regulatory review of our product candidates, any patents protecting such candidates might expire before or shortly after the resulting products are commercialized. Moreover, the laws and regulations governing patents could change in unpredictable ways that could weaken the ability of us and our current or future licensors, licensees, partners or collaborators to obtain new patents or to enforce existing patents and patents we may obtain in the future. In any event, our patent rights and those of our current or future licensors, licensees, partners or collaborators may not effectively prevent others from commercializing competitive technologies and products.

In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees, partners or collaborators to perform these activities, which means that these patent applications may not be prosecuted or maintained, and these patents may not be enforced, in a manner consistent with the best interests of our business. If our current or future licensors, licensees, partners or collaborators fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors, licensees, partners or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

In addition, the legal protection afforded to inventors and owners of intellectual property in countries outside of the U.S. may not be as broad or effective as that in the U.S. and we may be unable to acquire and enforce intellectual property rights outside the U.S. to the same extent as in the U.S., if at all. Accordingly, our efforts, and those of our licensors, licensees, partners and collaborators, to enforce intellectual property rights around the world may be inadequate to obtain a commercial advantage from the intellectual property that we own or license.

We do not currently own or have a license to any issued patents that cover TOUR006, although this product candidate is disclosed and its use claimed in our pending U.S. non-provisional applications. The patent landscape surrounding TOUR006 is crowded, and there can be no assurance that we will be able to secure patent protection that would adequately cover the use of such product candidate, that we will obtain sufficiently broad claims to be able to prevent others from selling competing products for the same or similar uses, or that we will be able to protect and maintain any patent protection that we initially secure.

Any changes we make to TOUR006 to cause it to have what we view as more advantageous properties may not be covered by its existing patent applications, and we may be required to file new patent applications and/or seek other forms of protection for any such altered product candidate.

We are dependent on patents, know-how and technology, both our own and licensed from others. In particular, we are dependent on our license agreements with Pfizer and Lonza. Any termination, or reduction or narrowing, of these licenses could result in the loss of significant rights and could harm our ability to commercialize TOUR006 and any potential future product candidates.

Disputes may also arise between us and our current licensor and future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our product candidates and technologies infringe intellectual property rights of the licensor that are not subject to the licensing agreement;
- our right to sublicense patent rights and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of TOUR006 and any potential future product candidates, and the activities that are deemed to satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- our payment obligations with respect to licensed intellectual property.

Additionally, with regard to the Pfizer License Agreement, if we fail to cure a material breach Pfizer has customary rights to terminate the Pfizer License Agreement. With regard to the Lonza License Agreement, Lonza has the right to terminate the Lonza License Agreement in the event of a change of control or if we contest the secret or substantial nature of the licensed know-how.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current or future licensing arrangements on acceptable terms, or if Pfizer or Lonza terminates their respective license agreement, we may be unable to successfully develop and commercialize the affected product candidates and technologies.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as it is for intellectual property that we own, which are described herein. If we, Pfizer, Lonza or any other current or future licensors fail to adequately protect any licensed intellectual property, our ability to commercialize products could suffer.

We may be unable to obtain intellectual property rights or technologies necessary to develop and commercialize TOUR006 or any potential future product candidates.

Several third parties are actively researching and seeking and obtaining patent protection in the fields of TED and Cardiovascular Disease, and there are issued third-party patents and published third-party patent applications in these fields. The patent landscape around our product candidate is complex, and we are aware of several third-party patents and patent applications containing claims directed to compositions-of-matter, methods of use and related subject matter, some of which pertain, at least in part, to subject matter that might be relevant to our product candidate. However, we may not be aware of all third-party intellectual property rights potentially relating to our product candidate and technologies, since patent applications are not published until eighteen months after their initial filing date. Therefore, we cannot know whether certain unpublished patent applications, if ultimately issued, may recover relevant uses of TOUR006 or other products of ours.

Depending on what patent claims ultimately issue and how courts construe the issued patent claims, as well as the ultimate formulation and methods of use of our product candidate, we may need to obtain a license to practice the technology claimed in such patents. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing rights to third-party intellectual property rights we have, we might be unable to develop and commercialize TOUR006 or any potential future product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We could lose the ability to continue the development, manufacture and commercialization of TOUR006 or any potential future product candidates if we breach any license agreement with service providers and vendors related to those product candidates.

Our commercial success depends upon our ability, and the ability of our current and future licensors, licensees, partners and collaborators, to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. A third-party may hold intellectual property rights, including patent rights, that are important or necessary to the development of our product candidates and products. As a result, we are a party to a number of technology and patent licenses that are important to our business, and we expect to enter into additional licenses in the future. If we fail to comply with the obligations under these agreements, including payment and diligence obligations, our licensors may have the right to terminate these agreements. In the event of a termination of these agreements, we may not be able to develop, manufacture, market or sell any product that is covered by the intellectual property rights that are the subject of these agreements or to engage in any other activities necessary to our business that require the freedom-to-operate afforded by the agreements, or we may face other penalties under the agreements. For example, in addition to the license agreements with Pfizer and Lonza described above we are party to license agreements with multiple vendors, under which we license technology used to produce TOUR006. We are required to obtain prior consent from some of these vendors to grant sub-licenses under these agreements. Therefore, these vendors may prevent us from granting sub-licenses to third parties, which could affect our ability to use certain desired manufacturers in order to manufacture our current and future product candidates. In the event of a termination of any of our license agreements, our ability to manufacture or develop any product candidates covered by these agreements may be limited or halted unless we can develop or obtain the rights to technology necessary to produce these product candidates.

Any of the foregoing could materially adversely affect the value of the product or product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in having to negotiate new or amended agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

We may become involved in lawsuits or other proceedings to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe patents or misappropriate or otherwise violate intellectual property rights owned or controlled by us or our current or future licensors, licensees, partners or collaborators. In the future, it may be necessary to initiate legal proceedings to enforce or defend these intellectual property rights, to protect trade secrets or to determine the validity or scope of intellectual property rights that are owned or controlled by us or our current or future licensors, licensees, partners or collaborators. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results.

If we or our current or future licensors, licensees, partners or collaborators initiate legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us or our current or future licensors, licensees, partners or collaborators is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent does not cover the technology in question. An adverse result in any litigation proceeding could put one or more of the patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

Third parties may initiate legal proceedings against us or our current or future licensors, licensees, partners or collaborators to challenge the validity or scope of intellectual property rights we own or control. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of patents owned or controlled by us or our current or future licensors, licensees, partners or collaborators. These proceedings can be expensive and time-consuming, and many of our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than us. Accordingly, despite our efforts, we or our current or future licensors, licensees, partners or collaborators may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or have rights to, particularly in countries where the laws may not protect those rights as fully as in the U.S.

There is a risk that some of our confidential information could be compromised by disclosure during litigation because of the substantial amount of discovery required. Additionally, many foreign jurisdictions have rules of discovery that are different than those in the U.S. and that may make defending or enforcing our patents extremely difficult. There also could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

Third-party pre-issuance submission of prior art to the USPTO, opposition, derivation, revocation, reexamination, inter partes review or interference proceedings, or other pre-issuance or post-grant proceedings, as well as other patent office proceedings or litigation in the U.S. or other jurisdictions brought by third parties against patents or patent applications owned or controlled by us or our current or future licensors, licensees, partners or collaborators, may affect the inventorship, priority, patentability or validity of these patents or patent applications. An unfavorable outcome could leave our technology or current and future product candidates without patent protection and allow third parties to commercialize its technology or product candidates without payment to us. Additionally, potential licensees, partners or collaborators could be dissuaded from collaborating with us to license, develop or commercialize current or future product candidates if the breadth or strength of protection provided by our patents and patent applications is threatened. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and we may distract our management and other employees.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of the third-party intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Third parties may initiate legal proceedings against us or our current or future licensors, licensees, partners or collaborators alleging that we infringe their intellectual property rights. Alternatively, we may initiate legal proceedings to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, revocations, reexaminations, inter partes review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. In this regard, we are aware of several third-party patents and patent applications containing claims directed to compositions-of-matter, methods of use and related subject matter, some of which pertain, at least in part, to subject matter that might be relevant to TOUR006. These proceedings can be expensive and time-consuming, and many of our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than us.

In addition, we may be subject to claims that we or our employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. Likewise, we and our current and future licensors, licensees, partners and collaborators may be subject to claims that former employees, partners, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor or an owner of rights via assignment from such an inventor or co-inventor. Litigation may be necessary to defend against these claims.

Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity in favor of the granted third-party patent. This is a high burden, requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim.

An unfavorable outcome in any such proceeding could require us and our current or future licensors, licensees, partners or collaborators to cease using the related intellectual property or developing or commercializing the product or product candidate, or to attempt to license rights to us from the prevailing party, which may not be available on commercially reasonable terms, or at all. Additionally, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing TOUR006 or any potential future product candidates or force us to cease some of our business operations, which could materially harm our business.

Reliance on third parties requires us to share our proprietary information, which increases the possibility that such information will be misappropriated or disclosed.

Because we rely on third parties for aspects of development, manufacture, or commercialization of TOUR006 and our technologies, or if we collaborate with third parties for the development or commercialization of our future product candidates and technologies, we must, at times, share proprietary information with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share confidential information increases the risk that such information become known by our competitors, is inadvertently incorporated into the technology of others, or is disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how, a competitor's discovery of our know-how or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our know-how. Despite our efforts to protect our know-how, we may not be able to prevent the unauthorized disclosure or use of our technical know-how by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third-party illegally obtained and is using our proprietary information, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect proprietary information.

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

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S., even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing its or its licensors' inventions in all countries outside the U.S., even in jurisdictions where we or our licensors pursue patent protection. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop its own competing products and, further, may export otherwise infringing products to territories where it has patent protection, but enforcement is not as strong as that in the U.S.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

In Europe, expected by the end of 2023, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (the "UPC"). This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. It is our initial belief that the UPC, while offering a cheaper streamlined process, has potential disadvantages to patent holders, such as making a single European patent vulnerable in all jurisdictions when challenged in a single jurisdiction.

We, our CROs, our CDMOs, service providers, our current and potential future partners or other third parties upon which we rely, could experience a security incident, system disruption or failure, data loss, cyberattack, or similar event that could compromise the confidentiality, integrity and availability of systems and data, result in material disruptions to our business operations, lead to regulatory investigations or actions, litigation, fines and penalties, affect our reputation, revenue or profits, or otherwise harm our business.

We collect, store and transmit proprietary, confidential and sensitive information, including personal information (such as health-related data of clinical trial participants and employee information), in the course of our business. Similarly, our third-party providers possess or process certain of that information on our behalf. The secure maintenance of this information is critical to our operations and business strategy. Our technology systems and the information and data processed and stored by us or by third parties with whom we work (*e.g.*, research collaborators, partners, CROs, CDMOs, contractors, consultants and other third parties), may be vulnerable to a variety of evolving online and offline threats that could result in security incidents, including unauthorized, unlawful, or accidental loss, damage, corruption, access, use or disclosure or misappropriation of such systems or data. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to operate our business and may have other adverse effects.

We and third parties on which we rely face threats that are constantly evolving and growing in frequency, sophistication, and intensity. For example, these threats may include (without limitation) malware, viruses, software vulnerabilities and bugs, software or hardware failure, hacking, denial of service attacks, social engineering (including phishing), ransomware, inside threats, credential stuffing or other cyberattacks, telecommunications failures, loss or theft of devices, data or other information technology assets, earthquakes, fires, floods and similar threats. Threats such as ransomware attacks, for example, are becoming increasingly prevalent and severe, and attackers are increasingly leveraging multiple attack methods to extort payment from victims, such as data theft and disabling systems. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Security incidents may result from the actions of a wide variety of actors with a wide range of motives and expertise, including traditional hackers, our personnel or the personnel of the third parties we work with, sophisticated nation-states and nation-state-supported actors. During times of war and other major conflicts, we, the third party upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We may be required to, or we may choose to, expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents, particularly where required by applicable data privacy and security laws or regulations or industry standards. While we have developed systems and processes designed to protect the integrity, confidentiality and security of the confidential and personal information under our control, we cannot assure you that any security measures that we or our third-party service providers implement will be effective in preventing security incidents, disruptions, cyberattacks, or other similar events. There are many different cyber-crime and hacking techniques, and as such techniques continue to evolve, we and our third-party providers may be unable to anticipate or detect attempted security incidents, identify them before our information is exploited or react in a timely manner.

Certain functional areas of our workforce work remotely on a full- or part-time basis outside of our corporate network security protection boundaries or otherwise utilize network connections, computers and devices outside of our premises or network, which imposes additional risks to our business, including increased risk of industrial espionage, phishing and other cybersecurity attacks, and unauthorized dissemination of proprietary or confidential information, including personal information, any of which could have a material adverse effect on our business. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, and other threats to our business operations. For example, we rely on third parties to operate critical business systems and process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, personnel email, and other functions. We also rely on third parties, including CROs, clinical trial sites and clinical trial vendors, to collect, store, and transmit sensitive data as part of our research activities. Our ability to monitor these third parties is limited, and these third parties may not have adequate information security measures in place and may expose us to cyberattacks and other security incidents. Supply-chain attacks have also increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

If our information systems or data, or that of the third parties on which we rely, are compromised, it could interrupt our operations, disrupt our development programs and have a material adverse effect on our business, financial condition and results of operations. For example, the loss or corruption of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of TOUR006, to analyze clinical trial samples and to conduct clinical trials, and security incidents experienced by these third parties could have a material adverse effect on our business. Security incidents affecting us or the third parties we rely on or partner with could also result in substantial remediation costs and expose us to litigation (including class claims), regulatory enforcement action (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and/or oversight, fines, penalties, indemnification obligations, negative publicity, reputational harm, monetary fund

diversions, interruptions in our operations (including availability of data), financial loss and other liabilities and harms. Additionally, such incidents may trigger data privacy and security obligations requiring us to notify relevant stockholders or take other remedial or corrective actions, and may subject us to liability under laws and regulations that protect the privacy and security of personal information. Such disclosures and remediation efforts may be costly, and related requirements or the failure to comply with them could lead to adverse consequences. Even a perceived security incident or failure in compliance by us or a third-party partner may result in negative publicity, harm to our reputation, or other adverse effects.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from claims related to our data privacy and security obligations. Additionally, we cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically and commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could adversely affect our reputation, business, financial condition and results of operations.

We are subject to rapidly changing and increasingly stringent foreign and domestic laws and regulations relating to privacy, data protection and information security. The restrictions imposed by these requirements or our actual or perceived failure to comply with them could harm our business.

We may collect, use, transfer or otherwise process proprietary, confidential and sensitive information, including personal information (including health-related data), which subjects us to numerous evolving and complex data privacy and security obligations, including various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts and other obligations that govern the processing of such information in connection with our business.

Outside the U.S., an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation, ("EU GDPR") and the United Kingdom's GDPR, or UK GDPR and the Swiss Federal Data Protection Act, or Swiss FADP, (collectively, "European Data Protection Laws") impose strict requirements for processing personal information, including relating to transfer of personal information to countries like the U.S. European Data Protection Laws and other relevant laws govern patient confidentiality and storage of personal health data, and may apply to us processing of personal information from clinical trial participants and other individuals located in the EEA, the UK, or Switzerland and, if TOUR006 or any potential future product candidates are approved, our possible commercialization of those products in the EEA, the UK, or Switzerland (as applicable). Companies that violate the EU GDPR can face private litigation, regulatory investigations and enforcement actions, prohibitions on data processing, other administrative measures, reputational damage and fines of up to the greater of 20 million Euros or 4% of their worldwide annual revenue. The EU GDPR requires us to, among other things: give detailed disclosures about how we collect, use and share personal information; contractually commit to data protection measures in our contracts with vendors; maintain adequate data security measures; notify regulators and affected individuals of certain personal data breaches; meet extensive privacy governance and documentation requirements; and honor individuals' data protection rights, including their rights to access, correct and delete their personal information. The UK has incorporated an amended version of the EU GDPR into UK law, commonly referred to as the UK GDPR, which is independent from, but at present materially aligned with, the EU GDPR, which together with the UK Data Protection Act of 2018, or UK DPA, covers the processing of personal information of UK residents. Non-compliance with UK GDPR may result in substantially similar adverse consequences to those in relation to the EU GDPR, including monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Enforcement uncertainty and the costs associated with ensuring compliance may be onerous and adversely affect our business, operating results, prospects and financial condition.

Certain jurisdictions have enacted data localization restrictions or laws and regulations restricting cross-border transfers of personal information, except in limited circumstances where adequate safeguards are in place. In particular, regulators and courts in the EEA, the UK, and Switzerland have significantly restricted the transfer of personal information to the U.S. and other countries that have not been declared "adequate" for data protection purposes by a relevant governmental authority. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may

be used to transfer personal information from the EEA, the UK, or Switzerland to the U.S. in compliance with European Data Protection Laws, currently the standard contractual clauses issued by the European Commission in June 2021 and the modifications mandated by UK and Swiss regulators are the most viable mechanism for us and similar companies in the U.S. to implement. However, these mechanisms (including the standard contractual clauses) are subject to legal challenges, and have recently come under significant scrutiny by EU regulators. For example, on May 22, 2023, the Irish Data Protection Commission announced that it had issued a €1.2 billion administrative fine against a U.S. technology and social media company for failing to ensure adequate protections for EU personal data transferred to the U.S. under the standard contractual clauses, as well as requiring the company to suspend future transfers of such EU personal data to the U.S. Although we and other clinical trial sponsors are not typically subject to some of the U.S. national security laws and requirements that raise concerns for data protection authorities under European Data Protection Laws, there is no assurance that we can satisfy or rely on measures like the standard contractual clauses to lawfully transfer personal information to the U.S.

Further, the free flow of personal data between the EU to the UK may eventually require additional safeguards. On June 28, 2021, the European Commission adopted an adequacy decision permitting flows of personal data between the EU and the UK to continue without additional safeguards (such as standard contractual clauses). The UK Government also adopted a reciprocal adequacy decision in respect of EEA member states permitting flows of personal data from the UK to the EEA. However, the European Commission's UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision and remains under review by the European Commission during this period. The entry into force of the US-UK Data Access Agreement on October 3, 2022 may put at risk the European Commission's adequacy decision granted to the UK. If such adequacy decision were to be withdrawn, personal data could not flow freely between the UK and the EU and additional safeguards would need to be adopted, which could result in additional compliance costs for us (e.g., engaging in new contract negotiations with third parties that aid in such data flows).

The relationship between the UK and the EU in relation to certain aspects of data protection laws remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. The UK's Data Protection and Digital Information Bill (No.2) (the "Bill"), was laid before the UK Parliament on March 8, 2023, introducing reforms intended to update and simplify the UK's data protection framework, deviating from the EU GDPR. However, the Bill's progress through Parliament is currently on pause following changes to the UK Government's leadership. The Bill is expected to re-enter the legislative process in due course. Development of a secondary framework, particularly if it hinders cross-border data flows between the EU and UK, may result in increased compliance costs.

We continue to monitor changes in data protection laws related to the cross-border transfer of personal information; however, uncertainty remains regarding any future regulations, interpretations of existing law or guidance that may be issued, particularly by the EU authorities. If we are unable to implement a valid compliance solution for cross-border transfers of personal information, or if the requirements for a legally-compliant transfer are too onerous, we will face increased exposure to significant adverse consequences, including substantial fines, regulatory actions, as well as injunctions against the export and processing of personal information from the EEA, UK, Switzerland, or other countries that implement cross-border data transfer restrictions. Our inability to import personal information from the EEA, UK or Switzerland or other countries may also restrict or prohibit our clinical trial activities in those countries; limit our ability to collaborate with CROs, service providers, contractors and other companies subject to laws restricting cross-border data transfers; require us to increase our data processing capabilities in other countries at significant expense and may otherwise negatively impact our business operations. We may also become subject to new laws in the EEA and other jurisdictions that regulate cybersecurity and non-personal data, such as data collected through the internet of things. Depending on how these laws are interpreted, we may have to make changes to our business practices and products to comply with such obligations.

Additionally, other countries have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

Privacy and data security laws in the U.S. at the federal, state and local level are increasingly complex and changing rapidly. For example, at the federal level, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, at the state level, the privacy and data protection landscape is changing rapidly. Many states have enacted comprehensive privacy laws. For example, the CCPA, first took effect on January 1, 2020. The CCPA gives California residents certain rights similar to the individual rights given under the EU GDPR, including the right to access and delete their personal information, opt-out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, including statutory fines for noncompliance and a limited private right of action in connection with certain data breaches. In addition, the CCPA was amended by the California Privacy Rights Act of 2020 which became operative January 1, 2023. The CCPA as amended has expanded requirements, including in that it applies to personal information of business representatives and employees, and establishes a new regulatory agency to implement and enforce the law. While the CCPA contains an exemption for certain personal information processed in connection with clinical trials, we may process other personal information that is subject to the CCPA. Other states, such as Virginia, Colorado, Connecticut, and Utah, have also passed comprehensive privacy laws that become effective in 2023, and similar laws have been passed or are being considered in several other states, as well as at the federal and local levels. The evolving patchwork of differing state and federal privacy and data security laws increases the cost and complexity of operating our business and increases our exposure to liability, including from third-party litigation and regulatory investigations, enforcement, fines, and penalties. We may also be bound by contractual obligations and our public statements related to data privacy and security, and our efforts to comply with such obligations may not be successful. We may publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Monitoring, preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems and practices and to those of any third parties that process personal information on its behalf. In addition, these obligations may require us to change aspects of our business model. Although we endeavor to comply with applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could impact whether or not we are in compliance.

If we (or third parties upon which we rely) fail, or are perceived to have failed, to address or comply with data privacy, protection and security obligations, we could face significant consequences, including (without limitation): government enforcement actions (*e.g.*, investigations, fines, penalties, audits, inspections and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and/or imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

Risks Related to Our Common Stock

The market price of our common stock is expected to be volatile, and the market price of the common stock may drop.

The market price of our common stock could be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of clinical trials and preclinical studies of our current and future potential product candidates, or those of our competitors or our existing or future collaborators;
- failure to meet or exceed financial and development projections we may provide to the public;

- failure to meet or exceed the financial and development projections of the investment community;
- failure of us to achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our current and future potential product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if we issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations and continued development of our current and future potential product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to IL-6 inhibitor and IL-6R inhibitor product candidates, including with respect to other such products on the market;
- the introduction of technological innovations or new therapies that compete with the products and services of ours; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event resulting from rising interest rates, inflation, global geopolitical conflict, or other macroeconomic conditions could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company’s securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

Provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may discourage any takeover attempts stockholders may consider favorable, and may lead to entrenchment of management.

Provisions of our amended and restated certificate of incorporation, as amended, and amended and restated bylaws could delay or prevent changes in control or changes in management without the consent of the board of directors. These provisions will include the following:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board;
- a requirement that no member of our board may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our charter; and

- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

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

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

Our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to any provisions of the DGCL, our certificate of incorporation or bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The exclusive forum provision does not apply to actions arising under the Exchange Act. The amended and restated bylaws will also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act. The provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in the certificate of incorporation and bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

An active trading market for our common stock may not develop and our stockholders may not be able to resell their shares of common stock for a profit, if at all.

Prior to the Merger, there was no public market for shares of our capital stock. An active trading market for shares of our common stock may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES, USE OF PROCEEDS, AND ISSUER PURCHASES OF EQUITY SECURITIES

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Effective November 10, 2023, we entered into a side letter (the "Side Letter") with Ryan Robinson, our Interim Chief Financial Officer, Vice President, Finance and Controller. Pursuant to the Side Letter, we agree to pay Mr. Robinson an additional $3,750 per semi-monthly pay period, less applicable withholdings, during the period Mr. Robinson serves as our Interim Chief Financial Officer, with such payments effective as of October 19, 2023 (such payments, the "Additional Compensation"). The Additional Compensation is in addition to, and not in lieu of the base salary, benefits and other terms as described in Mr. Robinson's existing offer letter dated June 7, 2023 (the "Offer Letter").

Effective November 10, 2023, we entered into a participation agreement with Mr. Robinson under our Executive Severance and Change in Control Plan (the "Severance Plan"). Pursuant to the Severance Plan and the participation agreement thereunder, if, within the 3 month period prior to or the 12 month period following a "change in control" (as defined in the Severance Plan), we terminate the employment of Mr. Robinson without "cause" (excluding death or disability) or Mr. Robinson resigns for "good reason" (each, as defined in the Severance Plan) and within no more than 60 days of such termination the Mr. Robinson executes and does not revoke a separation agreement and release of claims, Mr. Robinson will be entitled to receive (i) a lump sum payment equal to the sum of (a) six months of then current annual base salary and (b) a multiple of then current annual target bonus in an amount equal to the then current annual target bonus, multiplied by the quotient of the Severance Period (as defined in the participation agreement) divided by 12, less applicable withholdings, (ii) payment of premiums to maintain group health insurance continuation benefits pursuant to COBRA for up to six months for Mr. Robinson and Mr. Robinson's respective eligible dependents, and (iii) vesting acceleration as to 100% of the then-unvested shares subject to then outstanding equity awards (and in the case of awards subject to performance-based vesting conditions, such performance-based awards shall vest as specified in the applicable award agreement governing such award).

Pursuant to the Severance Plan and the participation agreements thereunder, if, outside of the 3 month period prior to or the 12 month period following a "change in control", we terminate the employment of Mr. Robinson without "cause" (excluding death or disability) or Mr. Robinson resigns for "good reason" and within 60 days of such termination Mr. Robinson executes and does not revoke a separation agreement and release of claims, Mr. Robinson will be entitled to receive (i) continuing payments of his or her then current annual base salary for a period of three months, and (ii) payment of premiums to maintain group health insurance continuation benefits pursuant to COBRA for Mr. Robinson and Mr. Robinson's respective eligible dependents for up to three months.

Pursuant to the Severance Plan, in the event any payment to Mr. Robinson would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, as amended (the "Code"), as a result of a payment being classified as a parachute payment under Section 280G of the Code, Mr. Robinson will receive such payment as would entitle Mr. Robinson to receive the greatest after-tax benefit, even if it means that we pay Mr. Robinson a lower aggregate payment so as to minimize or eliminate the potential excise tax imposed by Section 4999 of the Code.

The foregoing descriptions of the Side Letter, Offer Letter and Severance Plan and related participation agreement do not purport to be complete and is qualified in its entirety by reference to the full text of the Side Letter, Offer Letter and Severance Plan and related participation agreement, copies of which are filed as Exhibits 10.14, 10.7 and 10.1 to this Quarterly Report on Form 10-Q, respectively, and are incorporated by reference herein.

ITEM 6. EXHIBITS

Exhibit No.	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1*	Third Amended and Restated Certificate of Incorporation of the Registrant, as amended through October 19, 2023.				
3.2	Second Amended and Restated Bylaws of the Registrant.	8-K	001-40384	3.2	May 11, 2021
10.1#	Tourmaline Bio, Inc. Executive Severance and Change in Control Plan and Form of Participation Agreement.	8-K	001-40384	10.1	October 27, 2023
10.2#	Non-Employee Director Compensation Policy.	8-K	001-40384	10.2	October 27, 2023
10.3#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-4	333-273335	10.6	July 20, 2023
10.4#	Offer Letter, dated as of October 18, 2023, by and between the Registrant and Sandeep Kulkarni, M.D.	8-K	001-40384	10.2	October 20, 2023
10.5#	Offer Letter, dated as of October 18, 2023, by and between the Registrant and Brad Middlekauff, J.D.	8-K	001-40384	10.3	October 20, 2023
10.6#	Offer Letter, dated as of October 18, 2023, by and between the Registrant and Susan Dana Jones, Ph.D.	8-K	001-40384	10.4	October 20, 2023
10.7#	Offer Letter, dated as of June 7, 2023, by and between the Registrant and Ryan Robinson.	8-K	001-40384	10.5	October 20, 2023

10.8#	Tourmaline Bio, Inc. 2022 Equity Incentive Plan and forms of award agreements thereunder.	S-4/A	333-273335	10.1	September 13, 2023

10.9#	Tourmaline Bio, Inc. 2023 Equity Incentive Plan.	8-K	001-40384	10.7	October 20, 2023
10.10#	Forms of Option Grant Notice, Option Agreement and Notice of Exercise under Tourmaline Bio, Inc. 2023 Equity Incentive Plan.	8-K	001-40384	10.8	October 20, 2023
10.11#	Forms of Restricted Stock Unit Grant Notice and Award Agreement under Tourmaline Bio, Inc. 2023 Equity Incentive Plan.	8-K	001-40384	10.9	October 20, 2023
10.12#	Tourmaline Bio, Inc. 2023 Employee Stock Purchase Plan.	8-K	001-40384	10.10	October 20, 2023
10.13	Amendment No. 1 to Strategic Advisor Agreement, by and between the Registrant and Scott Requadt, dated August 25, 2023.	S-4/A	333-273335	10.22	August 25, 2023
10.14#*	Side Letter, dated as of November 10, 2023, by and between the Registrant and Ryan Robinson.				
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*+	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.ins*	Instance Document				
101.sch*	Inline XBRL Taxonomy Extension Schema Document				
101.cal*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.def*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.lab*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.pre*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)				

* Filed herewith.

\+ Furnished herewith and not deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

\# Indicates a management contract or any compensatory plan, contract or arrangement.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TOURMALINE BIO, INC.

Date: November 14, 2023

By: /s/ Sandeep Kulkarni
Name: Sandeep Kulkarni
Title: Chief Executive Officer
(*Principal Executive Officer*)

Date: November 14, 2023

By: /s/ Ryan Robinson
Name: Ryan Robinson
Title: Interim Chief Financial Officer, Vice President, Finance and Controller
(*Principal Financial and Accounting Officer*)

THIRD AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
TALARIS THERAPEUTICS, INC.

Talaris Therapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), hereby certifies as follows:

1. The name of the Corporation is Talaris Therapeutics, Inc. The date of the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was October 30, 2018 (the "Original Certificate"). The name under which the Corporation filed the Original Certificate was Regenerex LLC. The Corporation filed a Certificate of Conversion along with a Certificate of Incorporation converting from a limited liability company to a corporation under the name of Regenerex, Inc. on October 30, 2018. The Corporation filed an Amended and Restated Certificate of Incorporation under the name Regenerex, Inc. on November 1, 2018. The name of the Corporation was further changed to Talaris Therapeutics, Inc. on March 6, 2019.

2. This Third Amended and Restated Certificate of Incorporation (the "Certificate") amends, restates and integrates the provisions of the Second Amended and Restated Certificate of Incorporation that was filed with the Secretary of State of the State of Delaware on September 22, 2020 (the "Amended and Restated Certificate"), and was duly adopted in accordance with the provisions of Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware (the "DGCL").

3. The text of the Amended and Restated Certificate is hereby amended and restated in its entirety to provide as herein set forth in full.

4. That upon effectiveness of this Certificate, all outstanding and issued Class A Common Stock (as defined in the Original Certificate) and Class B Common Stock (as defined in the Original Certificate) shall be automatically designated and reclassified as Voting Common Stock (as defined herein) and Non-Voting Common Stock (as defined herein), respectively.

ARTICLE I

The name of the Corporation is Talaris Therapeutics, Inc.

ARTICLE II

The address of the Corporation's registered office in the State of Delaware is c/o Corporation Service Company, 251 Little Falls Drive, in the City of Wilmington, County of New Castle, 19808. The name of its registered agent at such address is Corporation Service Company.

ARTICLE III

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

ARTICLE IV

CAPITAL STOCK

The total number of shares of capital stock which the Corporation shall have authority to issue is One Hundred Sixty Million (160,000,000), of which (i) one hundred and forty million (140,000,000) shares shall be a class designated as common stock, par value $0.0001 per share (the "Voting Common Stock"), (ii) ten million (10,000,000) shares shall be a class designated as non-voting common stock, par value $0.0001 per share (the "Non-

Voting Common Stock") and (iii) Ten Million (10,000,000) shares shall be a class designated as undesignated preferred stock, par value $0.0001 per share (the "Undesignated Preferred Stock"). Any reference to "Common Stock" in this Certificate shall refer to Voting Common Stock and Non-Voting Common Stock, collectively. Any reference to "Common Stock" issued by the Corporation pursuant to any contract, agreement or otherwise to which the Corporation is a party, whether before or after the date of filing of this Certificate, shall refer to Voting Common Stock, unless specific reference is made to Non-Voting Common Stock; provided, however, that this sentence shall not alter or affect the rights of the Non-Voting Common Stock hereunder.

Except as otherwise provided in any certificate of designations of any series of Undesignated Preferred Stock, the number of authorized shares of the class of Voting Common Stock, Non-Voting Common Stock or Undesignated Preferred Stock may from time to time be increased or decreased (but not below the number of shares of such class outstanding) by the affirmative vote of the holders of a majority in voting power of the outstanding shares of capital stock of the Corporation entitled to vote thereon without a separate class vote irrespective of the provisions of Section 242(b)(2) of the DGCL.

The powers, preferences and rights of, and the qualifications, limitations and restrictions upon, each class or series of stock shall be determined in accordance with, or as set forth below in, this Article IV.

A. COMMON STOCK

Subject to all the rights, powers and preferences of the Undesignated Preferred Stock and except as provided by law or in this Certificate (or in any certificate of designations of any series of Undesignated Preferred Stock):

(a) the holders of the Voting Common Stock shall have the exclusive right to vote for the election of directors of the Corporation (the "Directors") and on all other matters requiring, or that are submitted by the Corporation for, stockholder action, each outstanding share entitling the holder thereof to one vote on each matter properly submitted to the stockholders of the Corporation for their vote; provided, however, that, except as otherwise required by law, holders of Voting Common Stock, as such, shall not be entitled to vote on any amendment to this Certificate (or on any amendment to a certificate of designations of any series of Undesignated Preferred Stock) that alters or changes the powers, preferences, rights or other terms of one or more outstanding series of Undesignated Preferred Stock if the holders of such affected series of Undesignated Preferred Stock are entitled to vote, either separately or together with the holders of one or more other such series, on such amendment pursuant to this Certificate (or pursuant to a certificate of designations of any series of Undesignated Preferred Stock) or pursuant to the DGCL; provided, further, that the holders of the Non-Voting Common Stock (i) shall not be entitled to vote on any matter except as may be required by law (or as provided in Article IX below) and (ii) shall not be entitled to vote on the election of directors at any time;

(b) dividends may be declared and paid or set apart for payment upon the Common Stock out of any assets or funds of the Corporation legally available for the payment of dividends, but only when and as declared by the Board of Directors or any authorized committee thereof;

(c) there shall be no cumulative voting;

(d) if the Corporation in any manner subdivides or combines the shares of Voting Common Stock, then the shares of Non-Voting Common Stock shall be subdivided or combined in the same proportion and manner, and if the Corporation in any manner subdivides or combines the shares of Non-Voting Common Stock, then the shares of Voting Common Stock shall be subdivided or combined in the same proportion and manner;

(e) all Common Stock shall rank equally, and share ratably, in any distributions of assets upon liquidation, dissolution or winding up of the Company, whether voluntary or involuntary; and

(f) for the avoidance of doubt, except as expressly set forth in this Article IV.A (with respect to voting power only), in Article IV.B, and in Article IX (with respect to amendment, modification or waiver of certain provisions), the Non-Voting Common Stock shall have the same rights of, and be identical in all respects and as to all matters to, the Voting Common Stock, including in connection with any merger or consolidation of the Corporation.

B. NON-VOTING COMMON STOCK

(a) Each holder of shares of Non-Voting Common Stock shall have the right to convert each share of Non-Voting Common Stock held by such holder into one (1) share of Voting Common Stock at such holder's election by providing written notice to the Corporation; provided, however, that such shares of Non-Voting Common Stock may only be converted into shares of Voting Common Stock to the extent that, as a result of such conversion, such conversion would not result in the holder(s) thereof beneficially owning (for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended and the rules and regulations promulgated thereunder (collectively, the "Exchange Act")), when aggregated with affiliates with whom such holder is required to aggregate beneficial ownership for purposes of Section 13(d) of the Exchange Act (collectively, the "Related Holders"), in excess of the Beneficial Ownership Limitation. For avoidance of doubt, in the event that the Related Holders beneficially own in the aggregate, directly or indirectly, shares of Voting Common Stock in excess of the Beneficial Ownership Limitation without taking account the conversion of Non-Voting Common Stock, then none of the Non-Voting Common Stock held by such Related Holders shall be convertible into Voting Common Stock until such time as such Related Holders no longer beneficially own in the aggregate, directly or indirectly, shares of Voting Common Stock in excess of the Beneficial Ownership Limitation. The "Beneficial Ownership Limitation" means initially 9.9 % of the Voting Common Stock. Any holder of Non-Voting Common Stock may elect to increase the Beneficial Ownership Limitation applicable to such holder (and only such holder and its Related Holders) upon 61 days' prior written notice of such election to the Corporation and may decrease the Beneficial Ownership Limitation applicable to such holder (and only such holder and its Related Holders) at any time upon providing written notice of such election to the Corporation; provided, however, that no holder may make such an election to change the Beneficial Ownership Limitation applicable to such holder unless all holders managed by the same investment advisor as such electing holder make the same election.

(b) A converting holder's acquisition of the shares of Voting Common Stock pursuant to the election provided for in such holder's conversion notice under this Article IV, Section B shall not result in Related Holders becoming in the aggregate, directly or indirectly, the beneficial owner of shares of Voting Common Stock that exceed the Beneficial Ownership Limitation, and any Voting Common Stock to which the converting holder would be otherwise entitled but for the Beneficial Ownership Limitation will remain Non-Voting Common Stock. Any purported delivery of shares of Voting Common Stock upon conversion of Non-Voting Common Stock shall be void ab initio and shall have no effect to the extent (but only to the extent) that such delivery would result in the Related Holders becoming in the aggregate, directly or indirectly, the beneficial owner of shares of Voting Common Stock that exceed the Beneficial Ownership Limitation. Any conversion of Non-Voting Common Stock into Voting Common Stock shall be deemed to have been made immediately prior to the close of business on the date of the written conversion notice, and the person or persons entitled to receive the shares of Voting Common Stock issuable upon such conversion shall be treated for all purposes as the record holder or holders of such shares of Voting Common Stock as of such date and time. Each share of Non-Voting Common Stock that is converted pursuant to this Article IV, Section B shall be retired by the Corporation and shall not be reissued. Within two (2) business days of any written request by a holder of Non-Voting Common Stock, the Corporation shall inform such holder in writing of the then current number of outstanding shares of Voting Common Stock and Non-Voting Common Stock.

(c) Any shares of Non-Voting Common Stock shall be converted into a corresponding number of fully paid and nonassessable shares of Voting Common Stock immediately upon request following a Non-Affiliate Transfer. A "Non-Affiliate Transfer" shall mean a transfer of shares of Non-Voting Common Stock to any person that is not an affiliate of a holder of the Non-Voting Common Stock immediately following the issuance thereof. The Corporation shall, upon the request of each such holder and a certification from such transferee holder of such holder's non-affiliation with the original holder of such Non-Voting Common Stock, issue and deliver to such holder new certificates (unless shares of Voting Common Stock are then maintained in book-entry form) representing such non-affiliate holder's shares of Voting Common Stock. Such conversion shall be deemed to have been made immediately prior to the close of business on the date of such request and certification, and the person or persons entitled to receive the shares of Voting Common Stock issuable upon such conversion shall be treated for all purposes as the record holder or holders of such shares of Voting Common Stock as of such date and time. Each share of Non-Voting Common Stock that is converted pursuant to this section shall be retired by the Corporation and shall not be reissued.

C. UNDESIGNATED PREFERRED STOCK

The Board of Directors or any authorized committee thereof is expressly authorized, to the fullest extent permitted by law, to provide by resolution or resolutions for, out of the unissued shares of Undesignated Preferred Stock, the issuance of the shares of Undesignated Preferred Stock in one or more series of such stock, and by filing a certificate of designations pursuant to applicable law of the State of Delaware, to establish or change from time to time the number of shares of each such series, and to fix the designations, powers, including voting powers, full or limited, or no voting powers, preferences and the relative, participating, optional or other special rights of the shares of each series and any qualifications, limitations and restrictions thereof, all to the fullest extent now or hereafter permitted by the DGCL. The powers, preferences and relative, participating, optional and other special rights of each such series of Undesignated Preferred Stock, and the qualifications, limitations or restrictions thereof, if any, may differ from those of any and all other series at any time outstanding. Without limiting the generality of the foregoing, the resolution or resolutions providing for the issuance of any series of Undesignated Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Undesignated Preferred Stock to the extent permitted by law.

ARTICLE V

STOCKHOLDER ACTION

1. Action without Meeting. Any action required or permitted to be taken by the stockholders of the Corporation at any annual or special meeting of stockholders of the Corporation must be effected at a duly called annual or special meeting of stockholders and may not be taken or effected by a written consent of stockholders in lieu thereof.

2. Special Meetings. Except as otherwise required by statute and subject to the rights, if any, of the holders of any series of Undesignated Preferred Stock, special meetings of the stockholders of the Corporation may be called only by the Board of Directors acting pursuant to a resolution approved by the affirmative vote of a majority of the Directors then in office, and special meetings of stockholders may not be called by any other person or persons. Only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders of the Corporation.

ARTICLE VI

DIRECTORS

1. General. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors except as otherwise provided herein or required by law.

2. Election of Directors. Election of Directors need not be by written ballot unless the Second Amended and Restated Bylaws of the Corporation (as the same may hereafter be amended and/or restated, the "Bylaws") shall so provide.

3. Number of Directors; Term of Office. The number of Directors of the Corporation shall be fixed solely and exclusively by resolution duly adopted from time to time by the Board of Directors. The Directors, other than those who may be elected by the holders of any series of Undesignated Preferred Stock, shall be classified, with respect to the term for which they severally hold office, into three classes The initial Class I Directors of the Corporation shall be Francois Nader, Scott Requadt, and Mark McDade; the initial Class II Directors of the Corporation shall be Nicholas Galakatos, Suzanne Ildstad, and Sandip Agarwala; and the initial Class III Directors of the Corporation shall be Sapna Srivastava, Gaurav Shah and Geoff MacKay. The initial Class I Directors shall serve for a term expiring at the annual meeting of stockholders to be held in 2022, the initial Class II Directors shall serve for a term expiring at the annual meeting of stockholders to be held in 2023, and the initial Class III Directors shall serve for a term expiring at the annual meeting of stockholders to be held in 2024. At each annual meeting of stockholders, Directors elected to succeed those Directors whose terms expire shall be elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election. Notwithstanding the foregoing, the Directors elected to each class shall hold office until their successors are duly elected and qualified or until their earlier resignation, death or removal.

Notwithstanding the foregoing, whenever, pursuant to the provisions of Article IV of this Certificate, the holders of any one or more series of Undesignated Preferred Stock shall have the right, voting separately as a series or together with holders of other such series, to elect Directors at an annual or special meeting of stockholders, the election, term of office, filling of vacancies and other features of such directorships shall be governed by the terms of this Certificate and any certificate of designations applicable to such series.

4. Vacancies. Subject to the rights, if any, of the holders of any series of Undesignated Preferred Stock to elect Directors and to fill vacancies in the Board of Directors relating thereto, any and all vacancies in the Board of Directors, however occurring, including, without limitation, by reason of an increase in the size of the Board of Directors, or the death, resignation, disqualification or removal of a Director, shall be filled solely and exclusively by the affirmative vote of a majority of the remaining Directors then in office, even if less than a quorum of the Board of Directors, and not by the stockholders. Any Director appointed in accordance with the preceding sentence shall hold office for the remainder of the full term of the class of Directors in which the new directorship was created or the vacancy occurred and until such Director's successor shall have been duly elected and qualified or until his or her earlier resignation, death or removal. Subject to the rights, if any, of the holders of any series of Undesignated Preferred Stock to elect Directors, when the number of Directors is increased or decreased, the Board of Directors shall, subject to Article VI, Section 3 hereof, determine the class or classes to which the increased or decreased number of Directors shall be apportioned; provided, however, that no decrease in the number of Directors shall shorten the term of any incumbent Director. In the event of a vacancy in the Board of Directors, the remaining Directors, except as otherwise provided by law, shall exercise the powers of the full Board of Directors until the vacancy is filled.

5. Removal. Subject to the rights, if any, of any series of Undesignated Preferred Stock to elect Directors and to remove any Director whom the holders of any such series have the right to elect, any Director (including persons elected by Directors to fill vacancies in the Board of Directors) may be removed from office (i) only for cause and (ii) only by the affirmative vote of the holders of not less than two-thirds (2/3) of the outstanding shares of capital stock then entitled to vote at an election of Directors. At least forty-five (45) days prior to any annual or special meeting of stockholders at which it is proposed that any Director be removed from office, written notice of such proposed removal and the alleged grounds thereof shall be sent to the Director whose removal will be considered at the meeting.

ARTICLE VII

LIMITATION OF LIABILITY

To the fullest extent permitted by the DGCL, as it presently exists or may hereafter be amended from time to time, a Director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of his or her fiduciary duty as a Director, except for liability (a) for any breach of the Director's duty of loyalty to the Corporation or its stockholders, (b) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (c) under Section 174 of the DGCL or (d) for any transaction from which the Director derived an improper personal benefit. If the DGCL is amended after the effective date of this Certificate to authorize corporate action further eliminating or limiting the personal liability of Directors, then the liability of a Director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

Any amendment, repeal or modification of this Article VII by either of (i) the stockholders of the Corporation or (ii) an amendment to the DGCL, shall not adversely affect any right or protection existing at the time of such amendment, repeal or modification with respect to any acts or omissions occurring before such amendment, repeal or modification of a person serving as a Director at the time of such amendment, repeal or modification.

ARTICLE VIII

AMENDMENT OF BYLAWS

1. Amendment by Directors. Except as otherwise provided by law, the Bylaws of the Corporation may be amended or repealed by the Board of Directors by the affirmative vote of a majority of the Directors then in office.

2. Amendment by Stockholders. Except as otherwise provided therein, the Bylaws of the Corporation may be amended or repealed at any annual meeting of stockholders, or special meeting of stockholders called for such purpose, by the affirmative vote of not less than two-thirds (2/3) of the outstanding shares of capital stock entitled to vote on such amendment or repeal, voting together as a single class; provided, however, that if the Board of Directors recommends that stockholders approve such amendment or repeal at such meeting of stockholders, such amendment or repeal shall only require the affirmative vote of the majority of outstanding shares of capital stock entitled to vote on such amendment or repeal, voting together as a single class.

ARTICLE IX

AMENDMENT OF CERTIFICATE OF INCORPORATION

If any provision of this Certificate becomes or is declared on any ground by a court of competent jurisdiction to be illegal, unenforceable or void, portions of such provision, or such provision in its entirety, to the extent necessary, shall be severed from this Certificate, and the court will replace such illegal, void or unenforceable provision of this Certificate with a valid and enforceable provision that most accurately reflects the Corporation's intent, in order to achieve, to the maximum extent possible, the same economic, business and other purposes of the illegal, void or unenforceable provision. The balance of this Certificate shall be enforceable in accordance with its terms.

The Corporation reserves the right to amend or repeal this Certificate in the manner now or hereafter prescribed by statute and this Certificate, and all rights conferred upon stockholders herein are granted subject to this reservation. Except as otherwise required by this Certificate or by law, whenever any vote of the holders of capital stock of the Corporation is required to amend or repeal any provision of this Certificate, such amendment or repeal shall require the affirmative vote of the majority of the outstanding shares of capital stock entitled to vote on such amendment or repeal, and the affirmative vote of the majority of the outstanding shares of each class entitled to vote thereon as a class (for clarification, the holders of Non-Voting Common Stock are not entitled to vote in the election of directors and should not be included in the calculation of such voting power), at a duly constituted meeting of stockholders called expressly for such purpose; provided, however, that (a) the affirmative vote of not less than two thirds (2/3) of the outstanding shares of capital stock entitled to vote thereon and the affirmative vote of not less than two thirds (2/3) of the outstanding shares of each class entitled to vote thereon as a class (for clarification, the holders of Non-Voting Common Stock are not entitled to vote in the election of directors and should not be included in the calculation of such voting power), shall be required to amend or repeal any provision of (i) Article V, Section 1, (ii) Article VI, Section 3, (iii) Article VII or (iv) this proviso (a) of Article IX; and (b) neither (i) subparagraphs (a) (final proviso only), (d) or (f) of Article IV.A., nor (ii) Article IV.B. nor (iii) this proviso of Article IX shall be amended, modified or waived without the unanimous vote or, in the case of a waiver, approval of the holders of the outstanding shares Non-Voting Common Stock.

[End of Text]

THIS THIRD AMENDED AND RESTATED CERTIFICATE OF INCORPORATION is executed this 11th day of May, 2021.

TALARIS THERAPEUTICS, INC.

By: /s/ Scott Requadt
Name: Scott Requadt
Title: Chief Executive Officer

CERTIFICATE OF AMENDMENT
TO THE
THIRD AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
TALARIS THERAPEUTICS, INC.

(Pursuant to Section 242 of the
General Corporation Law of the State of Delaware)

Talaris Therapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), hereby certifies as follows:

1. The name of the Corporation is Talaris Therapeutics, Inc. The date of the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was October 30, 2018 (the "Original Certificate"). The name under which the Corporation filed the Original Certificate was Regenerex, Inc. The Corporation filed a Certificate of Conversion along with a Certificate of Incorporation converting from a limited liability company to a corporation under the name of Regenerex, Inc. on October 30, 2018. The Corporation filed an Amended and Restated Certificate of Incorporation under the name Regenerex, Inc. on November 1, 2018. The name of the Corporation was further changed to Talaris Therapeutics, Inc. on March 6, 2019. A Second Amended and Restated Certificate of Incorporation was filed with the Secretary of State of Delaware on September 22, 2020. A Third Amended and Restated Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on May 11, 2021 (the "Charter"). Pursuant to Section 242 of the General Corporation Law of the State of Delaware ("DGCL"), this Certificate of Amendment (this "Amendment") amends certain provisions of the Charter.

2. The Board of Directors of the Corporation duly adopted resolutions approving the Amendment, declaring the Amendment to be advisable and recommending for its approval by the stockholders of the Corporation at the Corporation's special meeting of the stockholders in lieu of an annual meeting.

3. On October 17, 2023, the Corporation's special meeting of the stockholders in lieu of an annual meeting was duly called and held, upon notice in accordance with Section 222 of the DGCL, at which meeting the required number of shares were voted in favor of the Amendment.

4. Article IV of the Charter is hereby amended to add thereto the following:

"Effective upon filing this Certificate of Amendment to the Amended and Restated Certificate of Incorporation (the "Effective Time") pursuant to Section 242 of the DGCL, each ten (10) shares of the Corporation's Common Stock issued and outstanding immediately prior to the Effective Time shall automatically without further action on the part of the Corporation or any holder of such Common Stock, be reclassified, combined, converted and changed into one (1) fully paid and nonassessable share of Common Stock, subject to the treatment of fractional share interests as described below (the "Reverse Stock Split"). Any fractional shares resulting from the Reverse Stock Split and held by a single record stockholder shall be aggregated. No fractional shares shall be issued as a result of the Reverse Stock Split. Instead, any stockholder who would otherwise be entitled to a fractional share of Common Stock as a result of the Reverse Stock Split shall be entitled to receive a cash payment equal to the product of such resulting fractional interest in one share of Common Stock multiplied by the closing trading price on The Nasdaq Stock Market LLC of a share of Common Stock on the last trading day immediately prior to the date on which the Effective Time occurs. Each certificate or book entry share that immediately prior to the Effective Time represented shares of Common Stock ("Old Certificates"), shall thereafter represent that number of shares of Common Stock into which the shares of Common Stock represented by the Old Certificate shall have been combined, subject to the elimination of fractional share interests as described above."

5. This Amendment shall become effective at 4:00 p.m. Eastern Time on October 19, 2023.

IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of the Corporation as of October 19, 2023.

By: /s/ Mary Kay Fenton
Name: Mary Kay Fenton
Title: Chief Financial Officer and
Interim Chief Executive Officer and
President

CERTIFICATE OF AMENDMENT
TO THE
THIRD AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
TALARIS THERAPEUTICS, INC.

(Pursuant to Section 242 of the
General Corporation Law of the State of Delaware)

Talaris Therapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), hereby certifies as follows:

1. The name of the Corporation is Talaris Therapeutics, Inc. The date of the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was October 30, 2018 (the "Original Certificate"). The name under which the Corporation filed the Original Certificate was Regenerex, Inc. The Corporation filed a Certificate of Conversion along with a Certificate of Incorporation converting from a limited liability company to a corporation under the name of Regenerex, Inc. on October 30, 2018. The Corporation filed an Amended and Restated Certificate of Incorporation under the name Regenerex, Inc. on November 1, 2018. The name of the Corporation was further changed to Talaris Therapeutics, Inc. on March 6, 2019. A Second Amended and Restated Certificate of Incorporation was filed with the Secretary of State of Delaware on September 22, 2020. A Third Amended and Restated Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on May 11, 2021 (the "Charter"). Pursuant to Section 242 of the General Corporation Law of the State of Delaware (the "DGCL"), this Certificate of Amendment (this "Amendment") amends certain provisions of the Charter.

2. The Board of Directors of the Corporation duly adopted resolutions approving the Amendment, declaring the Amendment to be advisable and recommending for its approval by the stockholders of the Corporation at the Corporation's special meeting of the stockholders in lieu of an annual meeting.

3. On October 17, 2023, the Corporation's special meeting of the stockholders in lieu of an annual meeting was duly called and held, upon notice in accordance with Section 222 of the DGCL, at which meeting the required number of shares were voted in favor of the Amendment.

4. The Charter is hereby amended by adding a new Article X to read in its entirety as follows:

"ARTICLE X.

To the fullest extent permitted by the DGCL, as it presently exists or may hereafter be amended from time to time, an Officer (as defined below) of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of his or her fiduciary duty as an officer of the Corporation, except for liability (a) for any breach of the Officer's duty of loyalty to the Corporation or its stockholders, (b) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (c) for any transaction from which the Officer derived an improper personal benefit, or (d) arising from any action brought by or in the right of the Corporation. If the DGCL is amended after the effective date of this Certificate to authorize corporate action further eliminating or limiting the personal liability of Officers, then the liability of an Officer of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended. For purposes of this Article X, "Officer" shall mean an individual who has been duly appointed as an officer of the Corporation.

1. Amendment or Modification. Any amendment, repeal or modification of this ARTICLE X by either of (i) the stockholders of the Corporation or (ii) an amendment to the DGCL, shall not adversely affect any right or protection existing at the time of such amendment, repeal or modification with respect to any acts or omissions occurring before such amendment, repeal or modification of a person serving as an Officer at the time of such amendment, repeal or modification."

5. This Amendment shall become effective at 4:01 p.m. Eastern Time on October 19, 2023.

IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of the Corporation as of October 19, 2023.

By: /s/ Mary Kay Fenton
Name: Mary Kay Fenton
Title: Chief Financial Officer and
Interim Chief Executive Officer and President

CERTIFICATE OF AMENDMENT
TO THE
THIRD AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
TALARIS THERAPEUTICS, INC.

(Pursuant to Section 242 of the
General Corporation Law of the State of Delaware)

Talaris Therapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Corporation"), hereby certifies as follows:

1. The name of the Corporation is Talaris Therapeutics, Inc. The date of the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was October 30, 2018 (the "Original Certificate"). The name under which the Corporation filed the Original Certificate was Regenerex, Inc. The Corporation filed a Certificate of Conversion along with a Certificate of Incorporation converting from a limited liability company to a corporation under the name of Regenerex, Inc. on October 30, 2018. The Corporation filed an Amended and Restated Certificate of Incorporation under the name Regenerex, Inc. on November 1, 2018. The name of the Corporation was further changed to Talaris Therapeutics, Inc. on March 6, 2019. A Second Amended and Restated Certificate of Incorporation was filed with the Secretary of State of Delaware on September 22, 2020. A Third Amended and Restated Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on May 11, 2021 (as amended, the "Charter"). Pursuant to Section 242 of the General Corporation Law of the State of Delaware (the "DGCL"), this Certificate of Amendment (this "Amendment") amends certain provisions of the Charter.

2. The Board of Directors of the Corporation duly adopted resolutions approving the Amendment and declaring the Amendment to be advisable.

3. Article I of the Charter is hereby amended and restated in its entirety to read as follows:

"The name of the corporation is Tourmaline Bio, Inc. (the "Corporation")."

4. All other references to "Talaris Therapeutics, Inc." in the Charter shall be replaced with "Tourmaline Bio, Inc."

5. This Amendment shall become effective at 4:03 p.m. Eastern Time on October 19, 2023.

IN WITNESS WHEREOF, this Certificate of Amendment has been executed by a duly authorized officer of the Corporation as of October 19, 2023.

By: /s/ Mary Kay Fenton

Name: Mary Kay Fenton
Title: Chief Financial Officer and
Interim Chief Executive Officer
and President

Exhibit 10.14

November 9, 2023

Ryan Robinson
28 Winship Drive
Stoneham, MA 02180

Re: Interim CFO – Additional Compensation

Dear Ryan:

As you know, effective October 18, 2023, the Board of Directors of Tourmaline Sub, Inc., formerly known as Tourmaline Bio, Inc ("Tourmaline Sub"), a wholly owned subsidiary of Tourmaline Bio, Inc. ("Tourmaline"), formerly known as Talaris Therapeutics, Inc., appointed you as Interim Chief Financial Officer ("Interim CFO") of Tourmaline Sub and effective November 7, 2023 the Board of Directors of Tourmaline ratified your appointment as Interim CFO of Tourmaline.

In recognition of this appointment, during the period that you serve as Interim CFO, Tourmaline Sub will pay you an additional $3,750 per pay period (the "Additional Compensation"). The Additional Compensation will be subject to deductions and withholdings and will be paid on Tourmaline's regular payroll dates, with such payments effective as of October 19, 2023. The Additional Compensation is in addition to, and not in lieu of the base salary, benefits and other terms as described in your Offer Letter with Tourmaline dated June 7, 2023 (the "Offer Letter"). The Offer Letter remains in full force and effect.

In connection with this Additional Compensation, you agree to execute and comply with the Company's updated Employee Confidential Information and Inventions Assignment Agreement enclosed (the "CIIA").

This letter, together with Offer Letter and CIIA, forms the complete and exclusive statement regarding the subject matter hereof and it supersedes any other representations, promises, or agreements, whether written or oral, regarding this subject matter. No term or provision of this letter may be amended waived, released, discharged or modified except in writing, signed by you and the Company's Chief Executive Officer.

Please sign below to confirm your agreement and return with the signed CIIA.

Sincerely,

/s/ Sandeep Kulkarni
Name: Sandeep Kulkarni
Title: Chief Executive Officer

Accepted:

/s/ Ryan Robinson
Ryan Robinson

11/10/2023
Date

Exhibit 31.1

CERTIFICATIONS

I, Sandeep Kulkarni, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Tourmaline Bio, 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(s) 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;

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2023

/s/ Sandeep Kulkarni
Sandeep Kulkarni
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Ryan Robinson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Tourmaline Bio, 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(s) 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;

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2023

/s/ Ryan Robinson

Ryan Robinson
Interim Chief Financial Officer, Vice President, Finance and Controller
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Sandeep Kulkarni, Chief Executive Officer of Tourmaline Bio, Inc. (the "Company"), and Ryan Robinson, Interim Chief Financial Officer, Vice President, Finance and Controller of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2023, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 14th day of November, 2023.

/s/ Sandeep Kulkarni
Sandeep Kulkarni
Chief Executive Officer
(Principal Executive Officer)

/s/ Ryan Robinson
Ryan Robinson
Interim Chief Financial Officer, Vice President, Finance and Controller
(Principal Financial Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Tourmaline Bio, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.