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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 June 30, 2025

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 each exchange on which registered
Common Stock, $0.0001 par value per share	TRML	The Nasdaq Global Select Market

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

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 Exchange Act). Yes ☐ No ☒

The registrant had outstanding 25,692,268 shares of common stock, $0.0001 par value per share, as of August 1, 2025.

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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 pacibekitug 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 (the “U.S.”) 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 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 international trade relations and tariffs, the war in Ukraine and hostilities in the Middle East, potential bank failures and global health crises.

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.
Condensed Consolidated Balance Sheets (unaudited)
(amounts in thousands, except share and par value amounts)

	June 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 31,423	$ 30,506
Short-term investments	207,811	227,797
Prepaid expenses and other current assets	9,867	10,539
Total current assets	249,101	268,842
Property and equipment, net	47	55
Long-term investments	17,184	36,633
Restricted cash	227	227
Operating lease right-of-use asset	127	212
Other non-current assets	2,609	3,032
Total assets	$ 269,295	$ 309,001
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 3,170	$ 3,583
Accrued expenses and other current liabilities	6,780	5,099
Operating lease liability, current portion	145	227
Total current liabilities	10,095	8,909
Operating lease liability, net of current portion	—	17
Other liabilities	8	23
Total liabilities	10,103	8,949
Commitments and Contingencies		
Stockholders' equity		
Undesignated preferred stock, $0.0001 par value – 10,000,000 shares authorized as of June 30, 2025 and December 31, 2024, no shares issued or outstanding as of June 30, 2025 or December 31, 2024	—	—
Common stock, $0.0001 par value – 140,000,000 voting shares authorized as of June 30, 2025 and December 31, 2024, 25,692,268 and 25,617,805 voting shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively; 10,000,000 non-voting shares authorized as of June 30, 2025 and December 31, 2024, no non-voting shares issued or outstanding as of June 30, 2025 or December 31, 2024	3	3
Additional paid-in capital	440,391	435,014
Accumulated other comprehensive income	121	296
Accumulated deficit	(181,323)	(135,261)
Total stockholders' equity	259,192	300,052
Total liabilities and stockholders' equity	$ 269,295	$ 309,001

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

Tourmaline Bio, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)
(amounts in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 19,634	$ 15,734	$ 39,892	$ 27,110
General and administrative	6,340	6,237	12,313	12,378
Total operating expenses	25,974	21,971	52,205	39,488
Loss from operations	(25,974)	(21,971)	(52,205)	(39,488)
Other income, net	2,882	4,484	6,143	8,690
Net loss	$ (23,092)	$ (17,487)	$ (46,062)	$ (30,798)
Net loss per share, basic and diluted	$ (0.90)	$ (0.68)	$ (1.79)	$ (1.24)
Weighted-average common shares outstanding, basic and diluted	25,755	25,724	25,723	24,908
Comprehensive loss:				
Net loss	$ (23,092)	$ (17,487)	$ (46,062)	$ (30,798)
Other comprehensive loss:				
Unrealized loss on investments	(106)	(199)	(175)	(519)
Comprehensive loss	$ (23,198)	$ (17,686)	$ (46,237)	$ (31,317)

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

Tourmaline Bio, Inc.
Condensed Consolidated Statements of Stockholders' Equity (unaudited)
(amounts in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2023	20,337,571	$ 2	$ 267,024	$ 67	$ (62,051)	$ 205,042
Issuance of common stock from public offering, net of issuance costs	5,307,691	1	161,352	—	—	161,353
Stock-based compensation expense	—	—	1,388	—	—	1,388
Vesting of early exercised stock options	—	—	7	—	—	7
Issuance of common stock upon vesting of restricted stock units	1,247	—	—	—	—	—
Unrealized loss on investments	—	—	—	(320)	—	(320)
Net loss	—	—	—	—	(13,311)	(13,311)
Balance at March 31, 2024	25,646,509	3	429,771	(253)	(75,362)	354,159
Stock-based compensation expense	—	—	1,789	—	—	1,789
Vesting of early exercised stock options	—	—	20	—	—	20
Issuance of common stock upon vesting of restricted stock units	1,246	—	—	—	—	—
Unrealized loss on investments	—	—	—	(199)	—	(199)
Net loss	—	—	—	—	(17,487)	(17,487)
Balance at June 30, 2024	**25,647,755**	**$ 3**	**$ 431,580**	**$ (452)**	**$ (92,849)**	**$ 338,282**

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2024	25,617,805	$ 3	$ 435,014	$ 296	$ (135,261)	$ 300,052
Stock-based compensation expense	—	—	2,273	—	—	2,273
Vesting of early exercised stock options	—	—	8	—	—	8
Repurchase of common stock originally issued upon early exercise of stock options	(2,600)	—	—	—	—	—
Issuance of common stock upon exercise of options	68,027	—	569	—	—	569
Issuance of common stock upon vesting of restricted stock units	1,247	—	—	—	—	—
Unrealized loss on investments	—	—	—	(69)	—	(69)
Net loss	—	—	—	—	(22,970)	(22,970)
Balance at March 31, 2025	25,684,479	3	437,864	227	(158,231)	279,863
Stock-based compensation expense	—	—	2,466	—	—	2,466
Vesting of early exercised stock options	—	—	7	—	—	7
Issuance of common stock upon exercise of options	6,543	—	54	—	—	54
Issuance of common stock upon vesting of restricted stock units	1,246	—	—	—	—	—
Unrealized loss on investments	—	—	—	(106)	—	(106)
Net loss	—	—	—	—	(23,092)	(23,092)
Balance at June 30, 2025	**25,692,268**	**$ 3**	**$ 440,391**	**$ 121**	**$ (181,323)**	**$ 259,192**

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

Tourmaline Bio, Inc.
Condensed Consolidated Statements of Cash Flows (unaudited)
(amounts in thousands)

	Six Months Ended June 30,	
	2025	**2024**
Operating activities:		
Net loss	$ (46,062)	$ (30,798)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	4,739	3,177
Non-cash lease expense	86	72
Depreciation on property and equipment	24	20
Accretion of discount on investments	(2,997)	(3,471)
Realized gain on investments	—	(87)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	670	(2,669)
Other non-current assets	618	(457)
Accounts payable	(609)	1,316
Accrued expenses and other current liabilities	1,687	49
Operating lease liabilities	(99)	(82)
Net cash used in operating activities	(41,943)	(32,930)
Investing activities:		
Purchases of property and equipment	(16)	—
Purchases of investments	(125,618)	(258,400)
Maturities of investments	167,878	59,400
Net cash provided by (used in) investing activities	42,244	(199,000)
Financing activities:		
Proceeds from public offering of common stock, net of issuance costs	—	161,352
Proceeds from exercise of stock options	623	—
Repurchase of common stock originally issued upon early exercise of stock options	(7)	—
Net cash provided by financing activities	616	161,352
Net increase (decrease) in cash, cash equivalents and restricted cash	917	(70,578)
Cash, cash equivalents and restricted cash—Beginning of period	30,733	140,953
Cash, cash equivalents and restricted cash—End of period	$ 31,650	$ 70,375
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 31,423	$ 70,148
Restricted cash	227	227
Total cash, cash equivalents and restricted cash	$ 31,650	$ 70,375
Non-cash investing and financing activities:		
Unpaid public offering costs included in accounts payable	$ 195	$ —

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

Tourmaline Bio, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Nature of Business

Overview

Tourmaline Bio, Inc. (the "Company") is a late-stage clinical biotechnology company focused on developing transformative medicines that dramatically improve the lives of patients with life-altering immune and inflammatory diseases. The Company is developing pacibekitug, 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. The Company's corporate headquarters are in New York, New York.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive clinical testing and regulatory approval, prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

Reverse Merger and Pre-Merger Financing Transaction

On October 19, 2023, the Company completed its reverse merger with Tourmaline Sub, Inc. (formerly Tourmaline Bio, Inc.) ("Legacy Tourmaline") in accordance with the terms of the Agreement and Plan of Merger, dated as of June 22, 2023 (the "Merger Agreement"), by and among the Company, Terrain Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of the Company ("Merger Sub"), and Legacy Tourmaline, pursuant to which, among other matters, Merger Sub merged with and into Legacy Tourmaline, with Legacy Tourmaline surviving as a wholly owned subsidiary of the Company (the "Reverse Merger"). In connection with the completion of the Reverse Merger, the Company changed its name from "Talaris Therapeutics, Inc." to "Tourmaline Bio, Inc.," and the business conducted by the Company became primarily the business conducted by Legacy Tourmaline. References to "the Company" refer to Legacy Tourmaline for periods prior to the closing of the Reverse Merger, and to Tourmaline Bio, Inc. (formerly Talaris Therapeutics, Inc., or "Talaris") for all other periods, as the context requires.

Immediately prior to the effective time of the Reverse Merger, Talaris effected a 1-for-10 reverse stock split of its common stock.

At the effective time of the Reverse Merger, the Company issued an aggregate of 15,877,090 shares of Company common stock to the Legacy Tourmaline stockholders, based on the exchange ratio of approximately 0.07977 shares of Company common stock for each share of Legacy Tourmaline common stock, including those shares of Legacy Tourmaline common stock issued upon the conversion of Legacy Tourmaline Series A convertible preferred stock and those shares of the Legacy Tourmaline common stock issued in the Pre-Merger Financing Transaction (as defined below), resulting in 20,336,741 shares of Company common stock being issued and outstanding following the effective time of the Reverse Merger.

At the effective time of the Reverse Merger, Legacy Tourmaline's 2022 Equity Incentive Plan was assumed by the Company, and each outstanding and unexercised option to purchase shares of Legacy Tourmaline common stock immediately prior to the effective time of the Reverse Merger was assumed by the Company and converted into an option to purchase shares of Company common stock, with necessary adjustments to the number of shares and exercise price to reflect the exchange ratio.

The Reverse Merger was accounted for as a reverse recapitalization in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP"). Under this method of accounting, Legacy Tourmaline was deemed to be the accounting acquirer for financial reporting purposes. This determination was primarily based on the expectation that, immediately following the Reverse Merger: (i) Legacy Tourmaline's stockholders own a substantial majority of the voting rights in the combined company; (ii) Legacy Tourmaline's largest stockholders retain the largest interest in the combined company; (iii) Legacy Tourmaline designated a majority (five of seven) of the initial members of

the board of directors of the combined company; and (iv) Legacy Tourmaline's executive management team became the management team of the combined company. Accordingly, for accounting purposes: (i) the Reverse Merger was treated as the equivalent of Legacy Tourmaline issuing stock to acquire the net assets of Talaris; (ii) the net assets of Talaris are recorded at their acquisition-date fair value in the consolidated financial statements of Legacy Tourmaline and (iii) the reported historical operating results of the combined company prior to the Reverse Merger are those of Legacy Tourmaline. Historical common share figures of Legacy Tourmaline have been retroactively restated based on the exchange ratio of 0.07977.

Concurrently with the execution and delivery of the Merger Agreement, and in order to provide Legacy Tourmaline with additional capital for its development programs, Legacy Tourmaline entered into a Securities Purchase Agreement (the "Private Placement Agreement"), with certain investors named therein (the "Private Placement Investors"), pursuant to which, subject to the terms and conditions of the Private Placement Agreement, immediately prior to the effective time of the Reverse Merger, Legacy Tourmaline issued and sold, and the Private Placement Investors purchased 4,092,035 shares (as effected by the exchange ratio described above) of Legacy Tourmaline common stock for gross proceeds of approximately $75.0 million (the "Pre-Merger Financing Transaction").

Following the completion of the Reverse Merger, on June 30, 2024, Tourmaline Sub, Inc. merged with and into Tourmaline Bio, Inc., with Tourmaline Bio, Inc. as the surviving entity (the "Roll-Up Merger").

Liquidity

As of June 30, 2025, the Company had cash, cash equivalents, and investments of $256.4 million. The Company expects that its existing cash, cash equivalents and investments will enable it to fund its expected operating expenses and capital expenditure requirements for at least 12 months from August 13, 2025, the filing date of this Quarterly Report on Form 10-Q. The Company expects to finance its future cash needs through a combination of equity or debt financings, collaborations, licensing arrangements and strategic alliances.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying condensed consolidated financial statements as of June 30, 2025 and December 31, 2024, and for the three and six months ended June 30, 2025 and 2024, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the "SEC") and generally accepted accounting principles in the United States of America ("GAAP") as found in the Accounting Standards Codification ("ASC") of the Financial Accounting Standards Board ("FASB") for condensed consolidated financial information. In the opinion of management, these condensed consolidated financial statements reflect all normal recurring adjustments which are necessary for a fair presentation of the Company's financial position and results of its operations, as of and for the periods presented. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 13, 2025 (the "2024 Form 10-K").

The information presented in the condensed consolidated financial statements and related notes as of June 30, 2025, and for the three and six months ended June 30, 2025 and 2024, is unaudited. The condensed consolidated balance sheet as of December 31, 2024 included herein was derived from the audited financial statements included in the 2024 Form 10-K.

Interim results for the three and six months ended June 30, 2025 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2025, or any future period.

The condensed consolidated financial statements include the accounts of Tourmaline Bio, Inc. and its former wholly owned subsidiary, Tourmaline Sub, Inc. As outlined within Note 1, "Nature of Business", Tourmaline Sub, Inc. was merged with and into Tourmaline Bio, Inc., with Tourmaline Bio, Inc. as the surviving entity, upon the consummation of the Roll-Up Merger on June 30, 2024. All historical intercompany transactions and balances have been eliminated in consolidation.

Summary of Significant Accounting Policies

The significant accounting policies and estimates used in the preparation of the condensed consolidated financial statements are described in the Company's audited financial statements as of and for the year ended December 31, 2024

and the notes thereto, which are included in the 2024 Form 10-K. There have been no material changes in the Company's significant accounting policies during the six months ended June 30, 2025.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company's management evaluates its estimates, which include, but are not limited to, accrued expenses and stock-based compensation expense. The Company bases its estimates on historical experience and other market specific or other relevant assumptions it believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. This guidance is intended to improve reportable segment disclosure requirements through enhanced disclosures as well as clarify that entities with a single reportable segment are subject to new and existing segment reporting requirements. This guidance is effective for annual periods in fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. Entities must apply this guidance on a retrospective basis. Accordingly, the Company adopted this new standard for the fiscal year ended December 31, 2024. The adoption of ASU 2023-07 resulted in the inclusion of additional interim disclosures within Note 10, "Segment Information".

Recent Accounting Pronouncements - Yet to be Adopted

In March 2024, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the United States and in foreign jurisdictions. This guidance is effective for fiscal years beginning after December 15, 2024 on a prospective basis, with the option to apply the standard retrospectively, and early adoption is permitted. The Company is currently evaluating this guidance to determine the impact it may have on its condensed consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. The amendments in ASU 2024-03 address investor requests for more detailed expense information and require additional disaggregated disclosures in the notes to financial statements for certain categories of expenses that are included on the face of the income statement. This guidance is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating this guidance to determine the impact it may have on its condensed consolidated financial statements.

3. Pfizer License Agreement

On May 3, 2022 (the "Effective Date"), the Company entered into a License Agreement (the "Pfizer License Agreement") with Pfizer Inc. ("Pfizer"), pursuant to which the Company obtained an exclusive, sublicensable, royalty-bearing, worldwide right to use and license under certain know-how for the development, commercialization and manufacture of PF-04236921 (the "Compound", now known as pacibekitug) and any pharmaceutical or biopharmaceutical product incorporating the Compound (the "Product"), for the treatment, diagnosis, or prevention of any and all diseases, disorders, illnesses and conditions in humans and animals. In consideration for the license and other rights the Company received under the Pfizer License Agreement, the Company paid Pfizer an upfront payment of $5.0 million and issued to Pfizer 7,125,000 Series A preferred units of Tourmaline Bio, LLC (the predecessor of Legacy Tourmaline), which subsequently converted to 7,125,000 shares of Series A convertible preferred stock of Legacy Tourmaline, representing a 15% interest in the Company on a fully-diluted basis at the time of issuance. The units were issued for $1.00 per unit, representing a total value of $7.1 million. In accordance with ASC Topic 805, *Business Combinations*, the Pfizer License Agreement was accounted for as an asset acquisition as the licensed compound represented substantially all of the fair value of the gross assets acquired. On the Effective Date, the licensed compound had not yet received regulatory approval and did not have an alternative use.

As additional consideration for the license, the Company is obligated to pay Pfizer up to $128.0 million upon the achievement of specific development and regulatory milestones. The Company is also obligated to pay Pfizer up to $525.0

million upon the first achievement of specific sales milestones. The Company is also obligated to pay Pfizer a marginal royalty rate in the low double digits (less than 15%), subject to specified royalty reductions. The royalty term, on a Product-by-Product and country-by-country basis, begins on the first commercial sale of such Product and expires upon the later of twelve years following the date of the first commercial sale or the expiration of regulatory exclusivity protecting such Product. In the event the Company completes a Significant Transaction (as defined in the Pfizer License Agreement), the Company will be obligated to pay Pfizer a one-time payment in the low-eight digits (up to $20.0 million); the amount of such payment is based on the timing of the transaction.

As of June 30, 2025, the Company does not owe any milestone or royalties under the Pfizer License Agreement and no such milestones or royalties have been paid to date.

4. Fair Value Measurements

The Company measures the fair value of money market funds based on quoted prices in active markets for identical securities. Investments also include commercial paper, government securities, and corporate debt securities which are valued either based on recent trades of securities in inactive markets or based on quoted market prices of similar instruments and other significant inputs derived from or corroborated by observable market data. The carrying amounts reflected in the condensed consolidated balance sheets for cash, prepaid expenses and other current assets, accounts payable, and accrued expenses and other current liabilities approximate their fair values, due to their short-term nature.

Assets measured at fair value on a recurring basis as of June 30, 2025 were as follows (in thousands):

	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents and short-term investments:				
Money market funds, included in cash equivalents	$ 23,889	$ 23,889	$ —	$ —
Commercial paper	48,037	—	48,037	—
Government securities	62,646	53,172	9,474	—
Corporate debt securities	97,128	—	97,128	—
Total cash equivalents and short-term investments	231,700	77,061	154,639	—
Long-term investments:				
Government securities	2,510	2,510	—	—
Corporate debt securities	14,674	—	14,674	—
Total long-term investments	17,184	2,510	14,674	—
Total cash equivalents and investments	$ 248,884	$ 79,571	$ 169,313	$ —

Assets measured at fair value on a recurring basis as of December 31, 2024 were as follows (in thousands):

	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents and short-term investments:				
Money market funds, included in cash equivalents	$ 23,324	$ 23,324	$ —	$ —
Commercial paper	46,773	—	46,773	—
Government securities	59,170	46,813	12,357	—
Corporate debt securities	121,854	—	121,854	—
Total cash equivalents and short-term investments	251,121	70,137	180,984	—
Long-term investments:				
Government securities	10,888	10,888	—	—
Corporate debt securities	25,745	—	25,745	—
Total long-term investments	36,633	10,888	25,745	—
Total cash equivalents and investments	$ 287,754	$ 81,025	$ 206,729	$ —

There were no liabilities measured at fair value on a recurring basis as of June 30, 2025 or December 31, 2024. There were no changes in valuation techniques, nor were there any transfers among the fair value hierarchy levels during the six months ended June 30, 2025 or during the year ended December 31, 2024.

5. Investments

Cash equivalents, short-term and long-term investments as of June 30, 2025 were comprised as follows (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents and short-term investments:				
Money market funds, included in cash equivalents	$ 23,889	$ —	$ —	$ 23,889
Commercial paper	48,045	1	(9)	48,037
Government securities	62,632	26	(12)	62,646
Corporate debt securities	97,060	90	(22)	97,128
Total cash equivalents and short-term investments	231,626	117	(43)	231,700
Long-term investments:				
Government securities	2,507	3	—	2,510
Corporate debt securities	14,630	44	—	14,674
Total long-term investments	17,137	47	—	17,184
Total cash equivalents and investments	$ 248,763	$ 164	$ (43)	$ 248,884

Cash equivalents, short-term investments and long-term investments as of December 31, 2024 were comprised as follows (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents and short-term investments:				
Money market funds, included in cash equivalents	$ 23,324	$ —	$ —	$ 23,324
Commercial paper	46,738	50	(15)	46,773
Government securities	59,130	48	(8)	59,170
Corporate debt securities	121,713	162	(21)	121,854
Total cash equivalents and short-term investments	250,905	260	(44)	251,121
Long-term investments:				
Government securities	10,878	10	—	10,888
Corporate debt securities	25,675	84	(14)	25,745
Total long-term investments	36,553	94	(14)	36,633
Total cash equivalents and investments	$ 287,458	$ 354	$ (58)	$ 287,754

As of June 30, 2025, the aggregate fair value of securities that were in an unrealized loss position for less than twelve months was $101.9 million. As of December 31, 2024, the aggregate fair value of securities that were in an unrealized loss position for less than twelve months was $30.6 million. As of June 30, 2025 and December 31, 2024, the Company did not hold any securities that were in an unrealized loss position for greater than twelve months. Based upon its assessment of securities in an unrealized loss position, the Company did not record any allowances for credit losses during the six months ended June 30, 2025 or during the year ended December 31, 2024.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of June 30, 2025 and December 31, 2024 were comprised as follows (in thousands):

	June 30, 2025	December 31, 2024
Accrued bonus	$ 2,346	$ 3,830
Accrued clinical and manufacturing costs	3,133	696
Accrued consulting fees	893	153
Accrued external audit and tax fees	223	73
Accrued legal fees	67	—
Other accrued expenses and other current liabilities	118	347
Total accrued expenses and other current liabilities	$ 6,780	$ 5,099

7. Common Stock and Preferred Stock

Common Stock

On January 25, 2024, the Company entered into an underwriting agreement with Jefferies LLC, Piper Sandler & Co., Guggenheim Securities, LLC and Truist Securities, Inc. (collectively, the "Underwriters") in connection with the offering, issuance and sale by the Company of 4,615,384 shares of the Company's common stock at a public offering price of $32.50 per share, less underwriting discounts and commissions, pursuant to an effective shelf registration statement on Form S-3 (the "January 2024 Offering"). Under the January 2024 Offering, the Company also granted the Underwriters a 30-day option to purchase up to 692,307 shares of common stock at the public offering price, less the underwriting

discounts and commissions, which was exercised by the Underwriters in full on January 25, 2024. The January 2024 Offering closed on January 29, 2024.

Total gross proceeds from the January 2024 Offering were approximately $172.5 million, including the full exercise by the Underwriters of their option to purchase additional shares. Net proceeds were approximately $161.4 million after deducting underwriting discounts and commissions and offering expenses payable by the Company.

As of June 30, 2025, the Company is authorized to issue 140,000,000 shares of voting common stock and 10,000,000 shares of non-voting common stock. Holders of voting common stock are entitled to one vote per share. In addition, holders of voting common stock are entitled to receive dividends, if and when declared by the Company's Board of Directors. As of June 30, 2025, no dividends had been declared.

Preferred Stock

The Company was authorized to issue 10,000,000 shares of undesignated preferred stock. However, no such shares were issued or outstanding as of June 30, 2025 or December 31, 2024.

Shares Reserved for Future Issuance

As of June 30, 2025 and December 31, 2024, the Company had reserved for future issuance the following number of shares of common stock:

	June 30, 2025	December 31, 2024
Exercises of outstanding stock options under 2022 Equity Incentive Plan	1,183,925	1,244,691
Exercises of outstanding stock options under 2023 Equity Incentive Plan	2,675,991	1,479,091
Vesting of restricted stock units under 2023 Equity Incentive Plan	11,634	14,127
Common stock subject to repurchase related to early exercised stock options	91,929	170,210
Future issuances under 2023 Equity Incentive Plan	1,614,045	1,551,522
Future issuances under 2023 Employee Stock Purchase Plan	662,920	406,742
Total shares reserved for future issuance	6,240,444	4,866,383

8. Stock-Based Compensation

2022 Equity Incentive Plan

On September 2, 2022, the Board of Directors and the stockholders of the Company adopted the 2022 Equity Incentive Plan (the "2022 Plan"), which provided for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other stock awards to employees, consultants, and non-employee directors of the Company.

2023 Equity Incentive Plan

On October 17, 2023, the Company adopted the 2023 Equity Incentive Plan (the "2023 Plan") which became effective upon completion of the Reverse Merger. The 2023 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to employees, consultants, and non-employee directors of the Company. The terms of stock award agreements, including vesting requirements, are determined by the Company's Board of Directors and are subject to the provisions of the 2023 Plan. The term of each stock option shall be no more than ten years from the date of grant. Following the effectiveness of the 2023 Plan, no further grants will be made under the 2022 Plan; however, any outstanding equity awards granted under the 2022 Plan will continue to be governed by the terms of the 2022 Plan.

The 2023 Plan initially provided for the issuance of up to 2,033,677 shares of common stock (the "Initial 2023 Plan Share Reserve"). Subject to any other adjustments as defined in the 2023 Plan, such aggregate number of shares of common stock will automatically increase on January 1st of each year for a period of ten years commencing on January 1, 2024 and ending on (and including) January 1, 2033, in an amount equal to 5% of the total number of shares of common stock issued

and outstanding determined as of the day prior to such increase (such increase, the "2023 Plan Evergreen Refresh"); provided, however, that the Board of Directors may act prior to January 1st of a given year to provide that the increase for such year will be a lesser number of shares of common stock. The aggregate maximum number of shares of common stock that may be issued pursuant to the exercise of incentive stock options is three multiplied by the Initial 2023 Plan Share Reserve.

Under the aforementioned 2023 Plan Evergreen Refresh, 1,280,890 and 1,016,878 shares were added to the Initial 2023 Plan Share Reserve effective January 1, 2025 and January 1, 2024, respectively. As of June 30, 2025, there were 1,614,045 shares available for issuance under the 2023 Plan.

2023 Employee Stock Purchase Plan

On October 17, 2023, the Company adopted the 2023 Employee Stock Purchase Plan (the "2023 ESPP"), which became effective upon completion of the Reverse Merger. The maximum number of shares of common stock that may be issued under the 2023 ESPP will not exceed 203,367 shares (the "Initial ESPP Share Reserve"), plus the number of shares of common stock that are automatically added on January 1st of each year for a period of up to ten years commencing on January 1, 2024 and ending on (and including) January 1, 2033, in an amount equal to the lesser of (x) 1% of the total number of shares of common stock issued and outstanding determined as of the day prior to such increase and (y) a number of shares equal to three times the Initial ESPP Share Reserve (such increase, the "ESPP Evergreen Refresh"). Notwithstanding the foregoing, the Board of Directors may act prior to the first day of any calendar year to provide that there will be no January 1st increase in the share reserve for such calendar year or that the increase in the share reserve for such calendar year will be a lesser number of shares of common stock than would otherwise occur pursuant to the preceding sentence.

Under the aforementioned ESPP Evergreen Refresh, 256,178 and 203,375 shares were added to the Initial ESPP Share Reserve effective January 1, 2025 and January 1, 2024, respectively, such that 662,920 shares of common stock may be issued under the 2023 ESPP as of June 30, 2025.

No offering periods under the 2023 ESPP had been initiated as of June 30, 2025.

Stock-based Compensation Expense

Total stock-based compensation expense recognized in the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2025 and 2024 was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development	$ 1,113	$ 698	$ 2,156	$ 1,254
General and administrative	1,353	1,091	2,583	1,923
Total stock-based compensation expense	$ 2,466	$ 1,789	$ 4,739	$ 3,177

Stock Option Activity

The fair value of stock options granted during the three and six months ended June 30, 2025 and 2024 was calculated on the date of grant using the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Risk-free interest rate	3.9% – 4.4%	4.2% – 4.7%	3.9% – 4.4%	3.9% – 4.7%
Dividend yield	—%	—%	—%	—%
Volatility	80.4% – 82.6%	82.4% – 84.6%	80.4% – 82.6%	82.4% – 85.7%
Expected term (in years)	5.5 – 10.0	5.5 – 6.1	5.5 – 10.0	5.5 – 6.1

The weighted-average fair value of the Company's common stock utilized in the valuation of stock options granted during the three months ended June 30, 2025 and 2024 was $17.77 and $15.86 per share, respectively. The weighted-average fair value of the Company's common stock utilized in the valuation of stock options granted during the six months ended June 30, 2025 and 2024 was $16.78 and $18.81, respectively. Using the Black-Scholes option pricing model, the weighted-average grant date fair value of stock options granted during the three months ended June 30, 2025 and 2024 was $12.56 and $11.59 per share, respectively. The weighted-average grant date fair value of stock options granted during the six months ended June 30, 2025 and 2024 was $12.08 and $13.81, respectively.

The following table summarizes changes in stock option activity during the six months ended June 30, 2025:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	2,723,782	$ 11.08	8.6	$ 25,998
Granted	1,270,602	$ 16.78		
Exercised	(74,570)	$ 8.35		
Cancelled	(59,898)	$ 17.18		
Outstanding as of June 30, 2025	3,859,916	$ 12.91	8.7	$ 14,848
Exercisable as of June 30, 2025	1,189,375	$ 10.30	8.1	$ 7,329

The aggregate intrinsic value of stock options exercised during the three and six months ended June 30, 2025 was $0.1 million and $0.6 million, respectively. No stock options were exercised during the three and six months ended June 30, 2024.

As of June 30, 2025, the total unrecognized stock-based compensation expense related to unvested stock options was $25.6 million, which the Company expects to recognize over a weighted-average period of approximately 2.7 years.

Early Exercise of Stock Options

The 2022 Plan and certain stock options issued under the 2022 Plan were amended in February 2023 to permit the stock option holder to early exercise at any time between the grant date and the vesting date. The amendment did not result in any incremental stock-based compensation expense. During the year ended December 31, 2023, certain employees, advisors and non-employee directors early exercised 647,386 stock options. In the event of the termination of an employee, advisor or non-employee director's Continued Service (as defined in the 2022 Plan), the Company can repurchase common stock issued pursuant to early exercised and unvested stock options for a period of six months following the later of (i) the termination date of the employee or non-employee director or (ii) the exercise date. The Company received $0.1 million in cash proceeds related to the early exercise of stock options during the year ended December 31, 2023.

As a result of this repurchase right, the Company initially recorded the proceeds received from the early exercise of stock options as a liability in the condensed consolidated balance sheets. Amounts are reclassified to additional paid-in capital when the underlying stock options vest and the Company's right of repurchase lapses. The aggregate liability associated with the early exercise of stock options was less than $0.1 million as of June 30, 2025. As of June 30, 2025, 91,929 early exercised stock options remain unvested. The shares of common stock subject to repurchase related to early exercised stock options are legally outstanding, as each holder is deemed to be a common stockholder that has dividend and voting rights during the vesting term. During the six months ended June 30, 2025, upon the termination of service of an employee, the Company repurchased 2,600 shares of common stock subject to a repurchase right arising from unvested early exercised stock options. These shares were repurchased at the original exercise price.

Restricted Stock Unit Activity

The following table summarizes changes in restricted stock unit activity during the six months ended June 30, 2025:

	Shares	Weighted-Average Grant Date Fair Value per Share
Unvested as of December 31, 2024	14,127	$ 11.89
Granted	—	$ —
Vested	(2,493)	$ 11.89
Cancelled	—	$ —
Unvested as of June 30, 2025	11,634	$ 11.89

The total grant date fair value of restricted stock units vested was less than $0.1 million for each of the three and six months ended June 30, 2025 and 2024. As of June 30, 2025, the total unrecognized stock-based compensation expense related to unvested restricted stock units was $0.1 million, which the Company expects to recognize over a weighted-average period of approximately 2.2 years.

9. Net Loss per Share

The following common stock equivalents have been excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive:

	Three and Six Months Ended June 30,	
	2025	2024
Outstanding stock options under 2022 Equity Incentive Plan	1,183,925	1,403,409
Outstanding stock options under 2023 Equity Incentive Plan	2,675,991	1,429,811
Unvested restricted stock units under 2023 Equity Incentive Plan	11,218	16,204
Common stock subject to repurchase related to early exercised stock options	91,929	293,466
Total	3,963,063	3,142,890

10. Segment Information

In accordance with ASC Topic 280, *Segment Reporting*, the Company has determined that it operates as a single operating and reportable segment, the pacibekitug segment, which is engaged in the business of drug discovery and development.

The Company's chief operating decision maker ("CODM"), the Company's Chief Executive Officer, assesses performance and allocates resources on a consolidated basis. The CODM, assesses the performance of the pacibekitug segment and decides how to allocate resources based on net loss, which is also reported on the consolidated statements of operations and comprehensive loss as net loss**.** Segment asset information is not used by the CODM to assess performance or allocate resources. The accounting policies of the pacibekitug segment are the same as those described in Note 2, "Basis of Presentation and Summary of Significant Accounting Policies".

As the Company is pre-commercial and does not yet generate revenue, net loss is used by the CODM to evaluate the performance of the pacibekitug segment based on costs incurred and determine where changes in expenditures are needed to achieve the pacibekitug program's goals. The CODM also uses the components of net loss to monitor budget versus actual results.

There are no differences from the Company's 2024 Form 10-K in the factors used to identify the reportable segments or measurement basis for segment loss. Significant segment expenses, as provided to the CODM, are presented below (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Research and development payroll-related costs	$ 5,089	$ 4,253	$ 10,321	$ 7,281
General and administrative payroll-related costs	2,003	1,750	4,156	3,299
Clinical trial expenses	6,023	3,043	12,032	5,238
Chemistry, manufacturing, and controls costs	3,124	5,842	7,470	10,235
Medical affairs expenses	977	657	1,532	944
Research and development consulting expenses	1,537	948	2,910	1,779
General and administrative consulting expenses	1,302	1,605	2,338	3,595
Other segment items[1]	3,037	(611)	5,303	(1,573)
Segment and consolidated net loss	$ 23,092	$ 17,487	$ 46,062	$ 30,798

[1]Other segment items include legal expenses, accounting expenses, IT and facilities expenses, insurance expenses, other operating expenses, interest income, investment income, stock-based compensation expense, depreciation expense, and other income, net.

Interest income was $1.5 million and $1.2 million for the three months ended June 30, 2025 and 2024, respectively, and $3.2 million and $2.6 million for the six months ended June 30, 2025 and 2024, respectively.

All of the Company's long-lived assets are located in the United States. Depreciation expense related to long-lived assets was less than $0.1 million for each of the three and six months ended June 30, 2025 and 2024.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with (i) our unaudited condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and (ii) the audited consolidated financial statements and related notes thereto as of and for the year ended December 31, 2024 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on March 13, 2025 (our "Annual Report").

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."

Overview

We are a late-stage clinical biotechnology company focused on developing transformative medicines that dramatically improve the lives of patients with life-altering immune and inflammatory diseases. In doing so, we seek to identify and develop medicines that have the potential to establish new standards-of-care in areas of high unmet medical need.

Our initial product candidate is pacibekitug, a fully human monoclonal antibody that selectively binds to interleukin-6 ("IL-6"), a key proinflammatory cytokine involved in the pathogenesis of many autoimmune and inflammatory disorders. The anti-IL-6 and anti-IL-6 receptor ("IL-6R") antibody class ("IL-6 class") has over two decades of clinical and commercial experience treating over a million patients with a variety of autoimmune and inflammatory diseases. To date, four anti-IL-6 or anti-IL-6R antibodies have been approved in the United States ("U.S."). These four anti-IL-6 or anti-IL-6R antibodies together generated more than $3.5 billion in global sales in 2024.

Pacibekitug is a long-acting anti-IL-6 antibody which we believe has best-in-class properties including a high binding affinity to IL-6, long half-life, and low observed immunogenicity. These characteristics may allow pacibekitug to achieve substantial IL-6 pathway suppression with relatively low amounts of drug exposure, potentially enabling delivery in a convenient, low volume, infrequently administered, subcutaneous injection.

We are pursuing two strategic paths for pacibekitug, the first of which is cardiovascular inflammation. We believe pacibekitug has the potential to transform the standard of care for patients living with high risk of cardiovascular disease by targeting key inflammatory pathways driving cardiovascular disease. Atherosclerotic cardiovascular disease ("ASCVD") is a leading cause of death globally. Preventing major adverse cardiovascular events ("MACE"), such as death, nonfatal myocardial infarction or nonfatal stroke, has the potential to significantly reduce global cardiovascular disease burden. IL-6 has been identified as a promising drug target for addressing the risk of MACE in ASCVD, and multiple external Phase 3 cardiovascular outcome trials investigating IL-6 blockade are ongoing. We believe that pacibekitug potentially offers a meaningfully enhanced product profile to these competitor programs with a potential for subcutaneous dosing once every three months.

As previously announced in January 2024, we have reached alignment with the U.S. Food and Drug Administration (the "FDA") on our ASCVD clinical development program, including our Phase 2 TRANQUILITY trial evaluating the reduction of high sensitivity C-reactive protein ("hs-CRP"), a validated biomarker for inflammation, with quarterly and monthly dosing of pacibekitug in patients with elevated hs-CRP and chronic kidney disease. In March 2024, the FDA cleared our Investigational New Drug application ("IND") related to our ASCVD clinical development program. The Phase 2 TRANQUILITY trial commenced in April 2024 and completed over-enrollment in December 2024.

In May 2025, we reported positive topline data from the ongoing Phase 2 TRANQUILITY trial. Rapid, deep, and durable reductions in hs-CRP through Day 90 were achieved across all pacibekitug arms with high statistical significance as compared to placebo ($p<0.0001$ for all arms). Based upon these results, pacibekitug became the first and only IL-6 inhibitor known to demonstrate deep hs-CRP reductions with quarterly dosing in a clinical trial, achieving >85% hs-CRP reductions from baseline in the 50 mg quarterly arm. The overall incidence rates of adverse events and serious adverse events in the

pacibekitug groups were comparable to placebo through the data extract date of April 23, 2025. Tourmaline continues to make progress in the planning for a potential Phase 3 cardiovascular outcomes trial in ASCVD.

Additionally, we have nominated abdominal aortic aneurysm ("AAA") as an additional indication within our cardiovascular inflammation disease focus. We completed a successful pre-IND interaction with the FDA in the second quarter of 2025 and have reached alignment with the agency on our plans to conduct a Phase 2 proof-of-concept trial in AAA, including the design of the study and the use of multi-modality imaging. We plan to initiate this Phase 2 proof-of-concept trial in AAA in the second half of 2025.

Our second strategic path is thyroid eye disease ("TED"). TED is an autoimmune disease characterized by autoantibody-mediated activation of the tissues surrounding the eye, causing inflammation and disfigurement which can be sight-threatening in severe cases. We have identified a substantial body of published clinical observations characterizing the beneficial off-label use of currently marketed IL-6 pathway inhibitors, namely Actemra® (tocilizumab), an anti-IL-6R monoclonal antibody, in reducing inflammation, eye-bulging, and levels of autoantibodies in patients with TED. However, no formal, industry-sponsored development effort studying the IL-6 class for the treatment of TED has been completed to date. We are currently evaluating pacibekitug in a pivotal Phase 2b trial in first-line TED, which we refer to as the spiriTED trial. We initiated the spiriTED trial in September 2023 and expect to report topline data in early 2026.

We continue to identify additional indication opportunities for pacibekitug and evaluate new in-licensing and acquisition opportunities for assets that we believe have standard-of-care changing potential for patients with immune and inflammatory diseases.

Since our inception, we have funded our operations primarily through the sale of convertible preferred stock, the Reverse Merger and Pre-Merger Financing Transaction, each as defined and outlined further below, and the January 2024 Offering, as defined and described in Note 7, "Common Stock and Preferred Stock", to our unaudited condensed financial statements included elsewhere in this Quarterly Report on Form 10-Q. As of June 30, 2025, we had total cash, cash equivalents and investments of $256.4 million.

Due to our significant research and development expenditures, we have accumulated substantial losses since our inception, including net losses of $46.1 million and $30.8 million for the six months ended June 30, 2025 and 2024, respectively. In addition, we had an accumulated deficit of $181.3 million as of June 30, 2025. We expect to incur additional losses in the future as we expand our research and development activities.

Reverse Merger with Talaris and Pre-Merger Financing Transaction

On June 22, 2023, privately-held Tourmaline Sub, Inc. (formerly Tourmaline Bio, Inc., "Legacy Tourmaline") entered into an Agreement and Plan of Merger (the "Merger Agreement") with Talaris Therapeutics, Inc. ("Talaris"), a publicly traded company, and Terrain Merger Sub, Inc., a direct, wholly owned subsidiary of Talaris ("Merger Sub"). On October 19, 2023, Legacy Tourmaline completed the merger with Talaris in accordance with the terms of the Merger Agreement, pursuant to which, among other matters, Merger Sub merged with and into Legacy Tourmaline, with Legacy Tourmaline surviving as a wholly owned subsidiary of Talaris (such transaction, the "Reverse Merger"). The Reverse Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Immediately prior to the effective time of the Reverse Merger, Talaris effected a 1-for-10 reverse stock split of its common stock.

Pursuant to the terms of the Merger Agreement, immediately prior to the effective time of the Reverse Merger, each share of Legacy Tourmaline's Series A convertible preferred stock was converted into a share of Legacy Tourmaline common stock. At the effective time of the Reverse Merger, Talaris issued an aggregate of approximately 15,877,090 shares of common stock to Legacy Tourmaline's stockholders, based on an exchange ratio of 0.07977 shares of common stock for each share of Legacy Tourmaline's capital stock, including those shares of Legacy Tourmaline's common stock issued upon the conversion of the Series A convertible preferred stock and those shares of Legacy Tourmaline's common stock issued in the Pre-Merger Financing Transaction (as described below), resulting in approximately 20,336,741 shares of common stock of the combined company being issued and outstanding immediately following the effective time of the Reverse Merger. In connection with the Reverse Merger, the Amended and Restated Investor Rights Agreement, dated May 2, 2023, between Tourmaline and certain of its stockholders and the Amended and Restated Investors' Rights Agreement, dated September 22, 2020, between Talaris and certain of its stockholders, were terminated.

Immediately prior to the completion of the Reverse Merger, pursuant to a securities purchase agreement, Legacy Tourmaline issued 4,092,035 shares (as effected by the exchange ratio described above) of Legacy Tourmaline's common stock in a private placement for gross proceeds of $75.0 million (the "Pre-Merger Financing Transaction").

In connection with the completion of the Reverse Merger, Talaris changed its name from "Talaris Therapeutics, Inc." to "Tourmaline Bio, Inc.," Legacy Tourmaline changed its name to "Tourmaline Sub, Inc.," and we began conducting the business conducted by Legacy Tourmaline. On June 30, 2024, Tourmaline Sub, Inc. was merged with and into Tourmaline Bio, Inc., with Tourmaline Bio, Inc. as the surviving entity.

License Agreements

Pfizer License Agreement

On May 3, 2022, we entered into a License Agreement (the "Pfizer License Agreement") with Pfizer Inc. ("Pfizer"), pursuant to which we obtained an exclusive, sublicensable, royalty-bearing, worldwide right to use and license under certain know-how for the development, commercialization and manufacture of PF-04236921 (now known as pacibekitug) and any pharmaceutical or biopharmaceutical product incorporating such compound for the treatment, diagnosis, or prevention of any and all diseases, disorders, illnesses and conditions in humans and animals. In consideration for the license and other rights we received under the Pfizer License Agreement, we paid Pfizer an upfront payment of $5.0 million and granted Pfizer 7,125,000 Series A preferred units of Tourmaline Bio, LLC, the predecessor of Legacy Tourmaline (which subsequently converted to 7,125,000 shares of our Series A preferred stock) at $1.00 per share for aggregate consideration of approximately $7.1 million, with such shares representing 15% of all of our capital stock on a fully-diluted basis at the time of issuance.

As additional consideration for the license, we are obligated to pay Pfizer up to $128.0 million upon the achievement of specific development and regulatory milestones. We are also obligated to pay Pfizer up to $525.0 million upon the first achievement of specific sales milestones. We are obligated to pay Pfizer a marginal royalty rate in the low double digits (less than 15%), subject to specified royalty reductions. The royalty term, on a Product-by-Product and country-by-country basis, begins on the first commercial sale of such Product and expires upon the later of twelve years following the date of the first commercial sale or the expiration of regulatory exclusivity protecting such Product. In the event we complete a Significant Transaction (as defined in the Pfizer License Agreement), we will be obligated to pay Pfizer a one-time payment in the low-eight digits (up to $20.0 million); the amount of such payment is based on the timing of the transaction.

The Pfizer License Agreement expires, unless earlier terminated, upon the last to expire royalty term, and at such time our license will become fully paid-up, irrevocable and perpetual. Each party has the right to terminate the Pfizer License Agreement in its entirety in the event of a material breach if the breaching party fails to cure such breach within a specified cure period after written notice. Pfizer may terminate the Pfizer License Agreement on a Product-by-Product and country-by-country basis if we have materially breached our diligence obligations. Each party has the right to terminate the Pfizer License Agreement in the event of a bankruptcy event. We have the right to terminate the Pfizer License Agreement at our convenience in its entirety or on a country-by-country basis (except with respect to the major market countries identified therein) upon a specified notice period based on the time of the termination.

As of June 30, 2025, we do not owe any amounts under the Pfizer License Agreement, and no royalties or milestone payments have been paid to date under the Pfizer License Agreement.

Lonza License Agreement

In May 2022, we entered into the Lonza License Agreement with Lonza Sales AG ("Lonza"), pursuant to which we obtained a worldwide, non-exclusive, sublicensable (subject to certain conditions) license under certain know-how to market, sell, offer for sale, distribute, import and export products containing pacibekitug ("Product"). We also obtained a non-exclusive, sublicensable (subject to certain conditions) license under certain licensed know-how to use, develop, and manufacture (including have manufactured in accordance with the terms of the Lonza License Agreement) the Product at premises approved by Lonza.

In consideration for the licenses and other rights we received under the Lonza License Agreement, we are obligated to pay Lonza a royalty in the low-single digits on the Net Sales (as defined in the Lonza License Agreement) of Product, and the royalty rate shall be based on the entity manufacturing the drug substance contained in the Product. Royalties are payable on a Product-by-Product basis and a country-by-country basis for ten years following the first commercial sale of a Product

in a certain country. In addition, we may owe Lonza a low six figure annual fee following the occurrence of a specified event depending on which entity manufactures the drug substance, all as specified in the Lonza License Agreement.

The Lonza License Agreement shall continue in full force and effect unless terminated in accordance with the terms of the Lonza License Agreement. Each party shall have the right to terminate the Lonza License Agreement in its entirety in the event of a breach by the other party if the breach is irremediable or the breaching party fails to cure such breach within a specified cure period after written notice. Each party shall have the right to terminate the Lonza License Agreement in the event of a bankruptcy event of the other party. We shall have the right to terminate the Lonza License Agreement at its convenience upon a specified notice period. Lonza shall have the right to terminate the Lonza License Agreement in the event of a change of control of our company or we contest the secret or substantial nature of the licensed know-how.

As of June 30, 2025, we do not owe any amounts under the Lonza License Agreement, and no royalty payments or other fees have been paid to date under the Lonza License Agreement.

Macroeconomic Considerations

Worldwide economic conditions remain uncertain and we continue to monitor the impact of macroeconomic conditions, including those related to inflation and fluctuations in interest rates, financial and credit market fluctuations, international trade relations and tariffs, global health crises, and global geopolitical conflicts such as the war in Ukraine and hostilities in the Middle East. The effect of macroeconomic conditions may not be fully reflected in our results of operations until future periods. If, however, economic uncertainty increases or the global economy worsens, our business, financial condition and results of operations may be harmed.

Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience increases in the near future on our operating costs, including our labor costs and research and development costs, due to supply chain constraints, consequences associated with global geopolitical conflicts, and employee availability and wage increases, which may result in additional stress on our working capital resources.

Financial Operations Overview

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts are successful and result in commercialization of pacibekitug or any future product candidates or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales, payments from such collaboration or license agreements or a combination thereof.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs related to our clinical trials, costs related to manufacturing material for clinical and preclinical studies, and other costs incurred for the development of our product candidate, pacibekitug. Research and development expenses include:

- personnel-related costs, including salaries, bonuses, benefits and stock-based compensation expenses for employees engaged in research and development functions;
- payments to third parties in connection with the research and development of pacibekitug and any future product candidates, including agreements with third parties such as contract research organizations (“CROs”), clinical trial sites and consultants;
- the cost of manufacturing products for use in our clinical and preclinical studies, including payments to contract development and manufacturing organizations (“CDMOs”) and consultants; and
- payments to third parties in connection with the preclinical development of pacibekitug and any future product candidates, including for outsourced professional scientific development services, consulting research and collaborative research.

Research and development expenses also include the cost of in-process research and development ("IPR&D") assets purchased in asset acquisition transactions. IPR&D assets are expensed as incurred if the asset has not yet received regulatory approval and does not have an alternative future use. Acquired IPR&D payments are immediately expensed in the period in which they are incurred and have historically included upfront payments as well as shares of our capital stock. Research and development costs incurred after the acquisition of IPR&D assets are expensed as incurred.

We recognize research and development expenses in the periods in which they are incurred. Our internal resources, employees and infrastructure are not directly tied to any one research or drug discovery program and are typically deployed across multiple programs. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We utilize CROs for research and development activities and CDMOs for manufacturing activities and we do not have our own laboratory or manufacturing facilities. Therefore, we have no material facilities expenses attributed to research and development.

Product candidates in later stages of development generally have higher development costs than those in earlier stages. As a result, management expects that our research and development expenses will increase substantially over the next several years as we advance our product candidate, pacibekitug, and any future product candidates into larger and later-stage clinical trials, work to discover and develop additional product candidates, seek to expand, maintain, protect and enforce our intellectual property portfolio, and hire additional research and development personnel.

The successful development of pacibekitug and any future product candidates is highly uncertain, and management does not believe it is possible at this time to accurately project the nature, timing and estimated costs of the efforts necessary to complete the development of, and obtain regulatory approval for, pacibekitug and any future product candidates. To the extent pacibekitug and any future product candidates continue to advance into larger and later-stage clinical trials, our expenses will increase substantially and may become more variable. The duration, costs and timing of development of pacibekitug and any future product candidates are subject to numerous uncertainties and will depend on a variety of factors, including:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to activate clinical sites and recruit, screen, and enroll eligible patients;
- the number of patients that participate in the trials;
- the length of hospitalization of patients in clinical trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing pacibekitug and any future product candidates;
- the phase of development of pacibekitug and any future product candidates;
- the efficacy and safety profile of pacibekitug and any future product candidates;
- the timing and progress of nonclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;

- raising necessary additional funds;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current development program and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of drug substance and drug product for use in production of pacibekitug and any future product candidates;
- the development of commercial scale manufacturing and distribution processes for pacibekitug and any future product candidates;
- establishing and maintaining agreements with third-party manufacturers for commercial manufacturing, if we pursue a third-party manufacturing strategy outside of the U.S, and if pacibekitug and any future product candidates are approved;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the U.S. and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- our ability to successfully recruit and retain employees;
- the commercialization of pacibekitug and any future product candidates, if and when approved;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of pacibekitug and any future product candidates, if approved, by patients, the medical community and third-party payors;
- evolving standards of care in target indications;
- competition with other marketed or development-stage products; and
- a continued acceptable safety profile of our therapies following approval, if and when approved.

A change in the outcome of any of these variables with respect to the development of pacibekitug or any future product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for our product candidate or any future product candidates.

General and Administrative Expenses

General and administrative expenses primarily consist of salaries, bonuses, benefits, and stock-based compensation expense for personnel in operational, finance, and administrative functions; professional fees for legal, consulting, accounting, and audit services; recruiting costs; travel expenses; technology costs; and insurance premiums. General and administrative expenses also include corporate facility costs, including rent, utilities, depreciation, and maintenance. We recognize general and administrative expenses in the periods in which they are incurred.

We expect that our general and administrative expenses will increase in the future to support our continued research and development activities, pre-commercial preparation activities for our product candidate and any future product candidates and, if any product candidate receives marketing approval, commercialization activities. Going forward, we expect to

continue to incur expenses associated with being a public company, including expenses related to accounting, audit, legal, public company reporting and compliance, director and officer insurance, investor and public relations, and other administrative and professional services.

Other Income, Net

Other income, net is primarily comprised of interest and investment income on our cash equivalents and investments.

Results of Operations

Comparison of the Three Months Ended June 30, 2025 and 2024

The following table summarizes our results of operations for the three months ended June 30, 2025 and 2024:

	Three Months Ended June 30,		
(in thousands)	**2025**	**2024**	**$ Change**
Operating expenses:			
Research and development	$ 19,634	$ 15,734	$ 3,900
General and administrative	6,340	6,237	103
Total operating expenses	25,974	21,971	4,003
Loss from operations	(25,974)	(21,971)	(4,003)
Other income, net	2,882	4,484	(1,602)
Net loss	$ (23,092)	$ (17,487)	$ (5,605)

Research and Development Expenses

Research and development expenses increased by $3.9 million from $15.7 million for the three months ended June 30, 2024 to $19.6 million for the three months ended June 30, 2025. The increase in research and development expenses was primarily attributable to the following:

- $3.0 million of increased clinical trial expenses related to our TRANQUILITY and spiriTED trials;
- $1.5 million of increased routine toxicology study expenses;
- $1.3 million of increased payroll-related costs, including $0.4 million of increased stock-based compensation expense, attributable to an increase in headcount;
- $0.6 million of increased research and development consulting expenses; and
- $0.3 million of increased medical affairs expenses.

These increases were partially offset by $2.7 million of decreased chemistry, manufacturing, and controls costs due to timing of the production of drug substance and drug product for use in our clinical trials.

General and Administrative Expenses

General and administrative expenses increased by $0.1 million from $6.2 million for the three months ended June 30, 2024 to $6.3 million for the three months ended June 30, 2025. The increase in general and administrative expenses was primarily attributable to $0.5 million of increased payroll-related costs, including $0.3 million of increased stock-based

compensation expense, partially offset by $0.3 million of decreased consulting expenses and $0.1 million of decreased legal, audit, and tax expenses.

Other Income, Net

Other income, net decreased by $1.6 million from $4.5 million for the three months ended June 30, 2024 to $2.9 million for the three months ended June 30, 2025. The decrease in other income, net was primarily attributable to a $1.8 million decrease in investment income, partially offset by a $0.3 million increase in interest income.

Comparison of the Six Months Ended June 30, 2025 and 2024

The following table summarizes our results of operations for the six months ended June 30, 2025 and 2024:

	Six Months Ended June 30,		
(in thousands)	**2025**	**2024**	**$ Change**
Operating expenses:			
Research and development	$ 39,892	$ 27,110	$ 12,782
General and administrative	12,313	12,378	(65)
Total operating expenses	52,205	39,488	12,717
Loss from operations	(52,205)	(39,488)	(12,717)
Other income, net	6,143	8,690	(2,547)
Net loss	$ (46,062)	$ (30,798)	$ (15,264)

Research and Development Expenses

Research and development expenses increased by $12.8 million from $27.1 million for the six months ended June 30, 2024 to $39.9 million for the six months ended June 30, 2025. The increase in research and development expenses was primarily attributable to the following:

- $6.8 million of increased clinical trial expenses related to our TRANQUILITY and spiriTED trials;
- $3.9 million of increased payroll-related costs, including $0.9 million of increased stock-based compensation expense, attributable to an increase in headcount;
- $3.0 million of increased routine toxicology study expenses;
- $1.1 million of increased research and development consulting expenses; and
- $0.6 million of increased medical affairs expenses.

These increases were partially offset by $2.8 million of decreased chemistry, manufacturing, and controls costs due to timing of the production of drug substance and drug product for use in our clinical trials.

General and Administrative Expenses

General and administrative expenses decreased by $0.1 million from $12.4 million for the six months ended June 30, 2024 to $12.3 million for the six months ended June 30, 2025. The decrease in general and administrative expenses was primarily attributable to $1.3 million of decreased consulting expenses and $0.3 million of decreased legal expenses. These decreases were partially offset by $1.5 million of increased payroll-related costs, including $0.7 million of increased stock-based compensation expense.

Other Income, Net

Other income, net decreased by $2.5 million from $8.7 million for the six months ended June 30, 2024 to $6.1 million for the six months ended June 30, 2025. The decrease in other income, net was primarily attributable to a $3.1 million decrease in investment income, partially offset by a $0.6 million increase in interest income.

Liquidity and Capital Resources

Sources of Liquidity

Since inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our product candidate and any future product candidates. We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and potentially manufacturing for our product candidate and any future product candidates to support commercialization and providing general and administrative support for our operations, including the cost associated with operating as a public company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

Since our inception, we have funded our operations primarily with outside capital, including proceeds from the sale of Series A convertible preferred stock, the Pre-Merger Financing Transaction and the January 2024 Offering, having raised aggregate gross proceeds of approximately $359.7 million as of the date hereof. However, we have incurred significant recurring losses, including net losses of $46.1 million and $30.8 million for the six months ended June 30, 2025 and 2024, respectively. In addition, we have an accumulated deficit of $181.3 million as of June 30, 2025.

As of June 30, 2025, we had $256.4 million in cash, cash equivalents and investments. Based upon our current operating plan, we believe that our working capital will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2027. We have based this estimate on assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect.

November 2024 ATM Sales Agreement

In November 2024, we entered into a Sales Agreement (the "ATM Sales Agreement") with Leerink Partners LLC ("Leerink"), as sales agent, under which we may offer and sell, from time to time, shares of our common stock (the "ATM Shares"), through Leerink (the "ATM Offering"). In November 2024, we filed a registration statement on Form S-3 (the "Shelf Registration Statement"), including a base prospectus and sales agreement prospectus, with the SEC, for the issuance and sale of up to $100.0 million of shares of our common stock under the ATM Sales Agreement. Under the ATM Sales Agreement, Leerink may sell the ATM Shares by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Exchange Act of 1934, as amended. We may sell the ATM Shares in amounts and at times to be determined by us from time to time subject to the terms and conditions of the ATM Sales Agreement, but we have no obligation to sell any of the ATM Shares in the ATM Offering.

As of June 30, 2025, we have not sold any shares of our common stock pursuant to the ATM Offering. We may offer and sell ATM shares at an aggregate offering price of up to the remaining $100.0 million available under the ATM Offering.

Future Capital Requirements

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

In order to complete the development of pacibekitug 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, we will require substantial additional capital. Accordingly, until such time that we 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 we raise additional capital through equity financings or convertible debt

securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our own common stock, make certain investments or engage in merger, consolidation, licensing, or asset sale transactions. If we raise capital through collaborations, partnerships, and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market themselves. We may be unable to raise additional capital from these sources on favorable terms, or at all. Our 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 U.S. 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 our business, results of operations or financial condition, including requiring us to delay, reduce or curtail our research, product development or future commercialization efforts. We may also be required to license rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. Management cannot provide assurance that we 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, we are unable to estimate the exact amount and timing of our capital requirements. Our future funding requirements will depend on many factors, including:

- the scope, timing, progress, results, and costs of researching and developing pacibekitug, and conducting larger and later-stage clinical trials;
- the scope, timing, progress, results, and costs of researching and developing other product candidates that we may pursue;
- the costs, timing, and outcome of regulatory review of pacibekitug and any future product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, and distribution, for pacibekitug and any future product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sales of our products, should any of our product candidates and any future product candidates receive marketing approval;
- the cost and timing of attracting, hiring, and retaining skilled personnel to support our operations and continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our 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 our products;
- the extent to which we acquire 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 pacibekitug and any of our future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional capital to meet the capital requirements associated with such operating plans.

As described above, if we progress pacibekitug through clinical development and, if approved, commercialize it, we may be required to pay Pfizer up to $128.0 million upon the achievement of specific development and regulatory milestones and up to $525.0 million upon the first achievement of specific sales milestones. Upon commercialization, we would also be obligated to pay Pfizer and Lonza royalties on product sales, as outlined in more detail above.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2025 and 2024:

	Six Months Ended June 30,	
(in thousands)	**2025**	**2024**
Net cash (used in) provided by:		
Operating activities	$ (41,943)	$ (32,930)
Investing activities	42,244	(199,000)
Financing activities	616	161,352
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 917	$ (70,578)

Cash Used in Operating Activities

Net cash used in operating activities for the six months ended June 30, 2025 was $41.9 million, compared to net cash used in operating activities of $32.9 million for the six months ended June 30, 2024. Net cash used in operating activities increased by $9.0 million primarily due to the overall growth in our operations, including increased headcount and clinical trial activities.

Cash Provided by Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2025 was $42.2 million, compared to net cash used in investing activities of $199.0 million for the six months ended June 30, 2024. This change from net cash used in investing activities to net cash provided by investing activities was primarily due to maturities of investments during the six months ended June 30, 2025.

Cash Provided by Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2025 was $0.6 million, compared to net cash provided by financing activities of $161.4 million for the six months ended June 30, 2024. Net cash provided by financing activities during the six months ended June 30, 2025 was primarily comprised of net proceeds from the exercise of stock options whereas net cash provided by financing activities during the six months ended June 30, 2024 was primarily comprised of net proceeds received from the January 2024 Offering.

Contractual Obligations and Commitments

Research and Development and Manufacturing Agreements

We enter into agreements with certain vendors for the provision of goods and services, which includes manufacturing services with CDMOs and development and clinical trial services with CROs. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement. These obligations and commitments are not separately presented.

Pfizer License Agreement

In May 2022, we entered into the Pfizer License Agreement. We have not included milestone or royalty payments or other contractual payment obligations under the Pfizer License Agreement as the timing and amount of such obligations are unknown or uncertain and are contingent upon the initiation and successful completion of future activities. See "*License Agreements—Pfizer License Agreement*" included above for further details on the Pfizer License Agreement.

Critical Accounting Policies and Critical Accounting Estimates

Our financial statements are prepared in accordance with U.S. generally accepted accounting principles. The preparation of the financial statements and related disclosures requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that management 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. Management evaluates estimates and assumptions on a periodic basis. Our actual results may differ from these estimates.

For a description of critical accounting policies that require significant judgments and estimates during the preparation of our financial statements, refer to "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Critical Accounting Estimates*" and Note 2, "Basis of Presentation and Summary of Significant Accounting Policies", to our consolidated financial statements contained in our Annual Report. There have been no significant changes to our critical accounting policies from those disclosed in our Annual Report.

Recently Issued and Adopted Accounting Pronouncements

See Note 2, "Basis of Presentation and Summary of Significant Accounting Policies", to our condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for a discussion of recently adopted and recently issued accounting pronouncements.

Emerging Growth Company and Smaller Reporting Company 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. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early to the extent allowed by the standard.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (iii) the date on which we have 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 our initial public offering.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue was less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue was less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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 Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2025, 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 Chief Financial Officer have concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of June 30, 2025.

Changes in Internal Control over Financial Reporting

During the period covered by this Quarterly Report on Form 10-Q, 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.

Inherent Limitations on Effectiveness of Internal Controls

A control system, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of these inherent limitations, misstatements due to error or fraud may occur and not be detected.

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. 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 of 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 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 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 pacibekitug 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, pacibekitug 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 the development and commercialization of pacibekitug 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 will incur additional costs and increased demands upon management as a result of complying with the laws and regulations applicable 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 pacibekitug and any potential future product candidates.
- We rely completely on contract development and manufacturing organizations ("CDMOs") for the manufacture and testing of pacibekitug 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. Additionally, any difficulties in the transfer of drug substance or drug product to or from clinical sites or manufacturing facilities could materially adversely affect our business, financial condition, and results of operations.
- Our manufacturing and testing of bulk drug substance for pacibekitug currently takes place in the U.S. through a global CDMO with facilities around the world. Our manufacturing and testing of drug product for pacibekitug occurs

in facilities in Austria and the U.S. A significant disruption in the operation of these manufacturing facilities, 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.

- Pacibekitug 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 pacibekitug or any potential future product candidates fail to timely initiate, enroll, complete, or produce positive results, or to demonstrate safety and efficacy to the satisfaction of the U.S. Food and Drug Administration (the "FDA") or comparable health authorities or sufficiently 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 pacibekitug, 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 pacibekitug 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.

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

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

- Our current and future relationships with investigators, healthcare professionals, 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 ability to use our U.S. net operating loss carryforwards and certain other U.S. tax attributes may be limited.

- 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.

- We have previously identified material weaknesses in our internal control over financial reporting. 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.

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

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

- Global trade issues and changes in and uncertainties with respect to trade policies and regulations, including import and export license requirements, trade sanctions, tariffs and international trade disputes, could materially and adversely impact our business and operations and reduce the competitiveness of our products relative to local and global competitors.

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, pacibekitug, 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 pacibekitug 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, pacibekitug and any potential future product candidates. We also expect to continue to incur significant operating losses 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 pacibekitug, or any potential future product candidate, 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 pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug 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, pacibekitug 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 pacibekitug 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. If pacibekitug encounters undesirable safety signals, insufficient efficacy results, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

We have identified atherosclerotic cardiovascular disease ("ASCVD") as the lead indication for pacibekitug. As previously announced in January 2024, we reached alignment with the FDA on the ASCVD clinical development program, including a Phase 2 trial evaluating the reduction of high-sensitivity C-reactive protein ("hs-CRP"), a validated biomarker for inflammation, with quarterly and monthly dosing of pacibekitug in patients with elevated cardiovascular risk. The related Investigational New Drug application ("IND") was cleared by the FDA in March 2024, and we initiated a Phase 2 trial of pacibekitug in patients with chronic kidney disease and elevated hs-CRP in April 2024, which we refer to as the TRANQUILITY trial. In May 2025, we announced positive topline results from the ongoing Phase 2 TRANQUILITY trial. Development of pacibekitug for ASCVD will require substantial additional investment for clinical development prior to potentially being submitted for regulatory review and approval in one or more jurisdictions.

Our second indication for pacibekitug is thyroid eye disease ("TED"). We submitted an IND in the U.S. to support initiation of a Phase 2b trial of pacibekitug in first-line TED. This IND was cleared by the FDA in August 2023, and we initiated the aforementioned Phase 2b trial in September 2023, which we refer to as the spiriTED trial. Topline data from the spiriTED trial are expected in early 2026, and initiation of a pivotal Phase 3 trial of pacibekitug in first-line TED will be dependent on those results.

If in either our TRANQUILITY trial or our spiriTED trial, pacibekitug encounters undesirable safety signals, insufficient efficacy results, development delays, regulatory issues or other problems, our development plans and business would be significantly harmed.

We will need significant additional capital to proceed with the development and commercialization of pacibekitug 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 pacibekitug and our other potential future product candidates;
- the initiation, progress, timing, delays, costs, and results of preclinical studies and clinical trials for pacibekitug 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 pacibekitug 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 pacibekitug 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 at least twelve months from the date of issuance of this Quarterly Report on Form 10-Q. More specifically, based on our current development plans and related assumptions, we believe our cash, cash equivalents and investments are sufficient to fund our operations into the second half of 2027. 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 pacibekitug 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, fluctuating 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, international trade relations and tariffs, fluctuating 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 pacibekitug 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 pacibekitug 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 applicable 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 Reverse 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 on board 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 common 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 pacibekitug 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 pacibekitug 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 pacibekitug 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, pacibekitug 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 pacibekitug 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 pacibekitug 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. Additionally, any difficulties in the transfer of drug substance or drug product to or from clinical sites or manufacturing facilities could materially adversely affect our business, financial condition, and results of operations.

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 pacibekitug 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 pacibekitug 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.

Pacibekitug 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, pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug currently takes place in the U.S. through a global CDMO with facilities around the world. Our manufacturing and testing of drug product for pacibekitug occurs in facilities in Austria and the U.S. A significant disruption in the operation of these manufacturing facilities, 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. Pacibekitug bulk drug substance for clinical studies is manufactured and tested within third-party facilities in the U.S. Pacibekitug drug product is manufactured in Austria and the U.S. 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. 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 plan to conduct manufacturing and testing of pacibekitug drug product at a facility in Europe that is licensed for commercial production, through a global CDMO. Pacibekitug drug product produced at the commercial facility may not be comparable to the current pacibekitug drug product that is being used in our clinical studies.

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 pacibekitug or any of our future product candidates will require substantial additional cash to fund expenses. For pacibekitug 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, business combinations of pharmaceutical and biotechnology companies 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 pacibekitug or any potential future product candidates.

We currently have no sales, marketing or distribution capabilities. To commercialize pacibekitug 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.

We, our CROs, our CDMOs, our service providers, our current and potential future partners or other third parties with whom we work, could experience a security incident, system disruption or failure, data loss, cyberattack, or similar event that could compromise our systems and data (or those of the third parties with whom we work), 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, receive, transmit, generate, use, transfer, disclose, make accessible, protect, secure, dispose, share and otherwise process (collectively, process) proprietary, confidential and otherwise sensitive information, including personal information (such as health-related data of clinical trial participants and employee information), in the course of our business. 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), are

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, encryption, acquisition, disclosure, misappropriation, or other compromise of such systems or data. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business (including to conduct our clinical trials) and may have other adverse effects.

We and third parties with whom we work face threats that are constantly evolving and growing in frequency, sophistication, and intensity. These threats include (without limitation) malware (including as a result of advanced persistent threat intrusions), viruses, worms, software vulnerabilities and bugs, software or hardware failures, hacking, denial of service attacks, social engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing), credential harvesting, ransomware, personnel misconduct or errors, credential stuffing, telecommunications failures, loss or theft of devices, data or other information technology assets, attacks enhanced or facilitated by AI, earthquakes, fires, floods and other 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. If a security incident were to materially impact us, our CROs, our CDMOs, our service providers, our current or potential future parties or other third parties with whom we work, there could be material disruptions to our business operations or other significant harm to our business.

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

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. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, 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 process 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 the supply chains of the third parties with whom we work have not been compromised. If the third parties with whom we work experience a security incident or other interruption, we could experience materially adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

We may be required to, or we may choose to, expend significant resources (including financial) or modify our business activities (including our clinical trial activities) in an effort to protect our information systems and data (including against security incidents) or to detect, investigate, mitigate, contain and remediate a security incident, particularly where required by applicable data privacy and security laws or regulations or industry standards. While we have implemented security measures and processes designed to protect against, mitigate and remediate security incidents, we cannot assure you that these security measures that we or our service providers implement will be effective in preventing security incidents, disruptions, cyberattacks, or other similar events. For example, we have been the target of unsuccessful phishing attempts in the past and expect such attempts will continue in the future. We take steps designed to detect, mitigate, and remediate

vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect and remediate, all such vulnerabilities including on a timely and effective basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats could cause a security incident. A security incident could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to data. If our information systems or data, or that of the third parties with whom we work, are compromised or were perceived to be 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 pacibekitug, 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. Actual or perceived security incidents affecting us or the third parties with whom we work or partner with could 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, diversion of management attention, interruptions in our operations (including availability of data or processing of sensitive information), financial loss and other liabilities, and harms. Additionally, such incidents may trigger data privacy and security obligations requiring us to notify relevant stakeholders, such as individuals, regulators, and others, or take other required remedial or corrective actions and may subject us to liability. Such disclosures and remediation efforts may be costly, and related requirements or the failure to comply with them could lead to adverse consequences.

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.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our personnel's, or vendors' use of generative AI technologies.

We (and the third parties with whom we work) are subject to rapidly changing and increasingly stringent foreign and domestic laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations relating to privacy, data protection and information security. The restrictions imposed by these requirements or our actual or perceived failure to comply with such obligations (or such failure by the third parties with whom we work) could lead to regulatory investigations or actions, litigation (including class claims) and mass arbitration demands, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, loss of customers or sales, and other adverse business consequences.

We 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 govern data privacy and security. For example, the European Union's General Data Protection Regulation, ("EU GDPR") and the United Kingdom's GDPR, ("UK GDPR") and the Swiss Federal Data Protection Act, ("Swiss FADP") impose strict requirements for processing personal information, and may apply to our processing of personal information from clinical trial participants and other individuals located in the European Economic Area ("EEA"), the UK, or Switzerland and, if pacibekitug 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 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 under the EU GDPR/17.5 million pounds sterling under the UK GDPR, or 4% of their worldwide annual revenue, in either case, whichever is greater.

In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the U.S. or other countries. Certain jurisdictions have enacted data localization restrictions or laws and regulations restricting cross-border transfers of personal information. 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 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, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement/Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the EU-U.S. Data Privacy Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to transfer personal data to the U.S.

If we are unable to implement a valid compliance mechanism 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. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the U.S, are subject to increased scrutiny from regulators, individual litigants, and activist groups. 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. Regulators in the U.S. are also increasingly scrutinizing certain personal data transfers and may impose personal data localization requirements.

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 that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. Certain state laws also impose stricter requirements for processing sensitive personal information such as obligating covered businesses to conduct data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act ("CCPA"), applies to personal data of consumers, business representatives, and employees who are California residents, and requires certain businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines for noncompliance and a limited private right of action in connection with certain data breaches. While the CCPA and other comprehensive state privacy laws contain exemptions for certain personal information processed in connection with clinical trials, 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 are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We publish privacy policies and provide notices regarding data privacy and security. Regulators are increasingly scrutinizing these statements, and if these policies or notices are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or not representative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our personnel and others with whom we work use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

Our obligations related to data privacy and security (and individuals' data privacy expectations) are quickly changing in an increasingly stringent fashion and creating uncertainty. 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 our behalf. In addition, these obligations may require us to change aspects of our business model (such as where we conduct clinical trials). 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 with whom we work may fail to comply with such obligations, which could negatively impact our business operations.

If we (or third parties with whom we work) 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) and mass arbitration demands; 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. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. 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 the Discovery, Development and Regulatory Approval of Our Product Candidates

Pacibekitug 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.

Pacibekitug 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 pacibekitug 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 and other 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 pacibekitug 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 pacibekitug or any potential future product candidates fail to timely initiate, enroll, complete, or produce positive results or to demonstrate safety and efficacy to the satisfaction of the FDA or comparable health authorities or sufficiently 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 pacibekitug 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 pacibekitug 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 pacibekitug, 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 pacibekitug 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 pacibekitug, 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;
- availability of approved therapies, other medicines, surgical procedures, or other therapies or interventions that would lead a patient to opt for that treatment or care approach instead of enrolling in our trial;
- 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 pacibekitug, 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 pacibekitug.

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, pacibekitug 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 pacibekitug failing to reproduce any positive efficacy, safety, or other findings from laboratory and preclinical studies and earlier-stage clinical trials for pacibekitug.

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 pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug, pacibekitug is not approved by the FDA or other regulatory authorities, pacibekitug is not reimbursed by payors or other similar bodies, or there is limited or no success achieved in the commercialization of pacibekitug.

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 pacibekitug, the approvability or commercialization of pacibekitug 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, pacibekitug may be harmed, which could significantly harm our business, financial condition, results of operations and prospects.

Pacibekitug 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 pacibekitug.

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 pacibekitug may be observed in any future or ongoing clinical trial of pacibekitug. For example, dosing in the 200 mg arm of the prior Pfizer Phase 2 trial of pacibekitug 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 pacibekitug, 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 pacibekitug clinical trial(s) may not be indicative of similar safety and tolerability results or profile for pacibekitug 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, pacibekitug 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 pacibekitug, we may need to delay, halt, or terminate our clinical trials and the affected product candidates. pacibekitug 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 pacibekitug 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 pacibekitug, 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 pacibekitug;
- abandonment of the development of pacibekitug 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 pacibekitug;
- requirement to develop a Risk Evaluation and Mitigation Strategy ("REMS") for pacibekitug in the U.S. or a similar strategy as required by a comparable foreign regulatory authority;
- a view by healthcare professionals that pacibekitug presents an unfavorable benefit-risk profile which in turn may significantly limit the prescribing and usage of pacibekitug;
- a meaningful rate of patients either choosing to not start pacibekitug treatment or to prematurely discontinue usage of pacibekitug;
- 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 pacibekitug that in turn may significantly limit the prescribing and usage of pacibekitug;
- a view by payors that pacibekitug presents an unfavorable benefit-risk profile which in turn may significantly limit the reimbursement of pacibekitug;
- 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.

Pacibekitug 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 pacibekitug, 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 pacibekitug.

Pacibekitug 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 pacibekitug or its perceived product profile and could terminate further development of pacibekitug, 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 pacibekitug.

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

The markets for immune and inflammatory 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 ASCVD and TED. We anticipate that, if we obtain regulatory approval of pacibekitug, 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, pacibekitug may also compete with unregulated, unapproved and off-label treatments. Pacibekitug may also face biosimilar competition following loss of regulatory exclusivity and/or patent expiry. Even if an approved biosimilar product is less effective than pacibekitug, a less effective biosimilar may be more quickly adopted by physicians and patients than our competing product candidate based upon cost. Pacibekitug 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, efficacy, and dosing profile 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 various mechanisms of action in both ASCVD and TED. For example, in 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. For TED, Amgen Inc.'s (formerly Horizon Therapeutics Public Limited Company) TEPEZZA (teprotumumab), an anti-IGF-1R antibody, is currently the only FDA-approved treatment. 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 AAA, while there is currently no FDA-approved, non-invasive pharmacotherapy available and we are not aware of any such programs in development from industry competitors, we may face competition in this indication in the future.

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 immune and inflammatory 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 pacibekitug 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 pacibekitug and any potential future product candidates;
- obtain required regulatory approvals, including approvals to market pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug 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 approvals of pacibekitug as therapies for patients with ASCVD, abdominal aortic aneurysm ("AAA") and TED. 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 pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug. 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 pacibekitug 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 development and 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, product 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 pacibekitug 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 pacibekitug would substantially harm our business.

Currently, we have no product candidate that has received regulatory approval and pacibekitug 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.

Pacibekitug 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. If we obtain approval, regulatory authorities may approve pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug or any potential future product candidates fail to comply with applicable regulatory requirements, or if pacibekitug 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 pacibekitug or any potential future product candidates. For example, the U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo ("Loper") overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and decisions issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Certain policies of any administration may impact our business and industry. 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 pacibekitug 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 pacibekitug 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 August 16, 2022, the Inflation Reduction Act of 2022 (the "IRA") was signed into law, which among other things, (1) directs the HHS, to negotiate the price of certain single-source biologics that have been on the market for at least 11 years covered under Medicare (the "Medicare Drug Price Negotiation Program") 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 began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement price of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. 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. 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 amendments to and 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, particularly given recent U.S. elections. 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 pacibekitug and any potential future product candidates, which would adversely affect our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, on July 4, 2025, the annual reconciliation bill, commonly referred to as the "One Big Beautiful Bill Act" (“OBBBA”) was signed into law which, is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. OBBBA also narrows access to ACA marketplace exchange enrollment and declines to extend the ACA enhanced advanced premium tax credits, set to expire in 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance.

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, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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, particularly given recent U.S. Presidential and Congressional elections. The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, propose policy changes that create additional uncertainty for our business. These actions and proposals include, for example, (1) reducing agency workforce; (2) rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation (“CMMI”) to consider new payment and healthcare models to limit drug spending; (3) eliminating the Biden administration’s executive order that directed HHS to establishing an AI task force and developing a strategic plan; (4) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (5) imposing tariffs on imported pharmaceutical products; and (6) directing certain federal agencies to enforce existing law regarding hospital and plan price transparency and by standardizing prices across hospitals and health plans. Additionally, in the June 2024 Loper decision, the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies’ reasonable interpretations of ambiguous federal statutes. The Loper

decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. We cannot predict which additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for pacibekitug. Such reforms could have an adverse effect on anticipated revenue from pacibekitug 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 became 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 current and future relationships with investigators, healthcare professionals, 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 professionals, including physicians and healthcare institutions, 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 existing and future arrangements with healthcare professionals and institutions, and any arrangements we enter into with 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 currently research, and in the future, market, sell and distribute products for which we or our partner obtain marketing approval. Restrictions under federal and state healthcare laws and regulations that are or may be applicable to us include, without limitation, the following:

- the federal Anti-Kickback Statute, which is a criminal law, prohibits, 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 the 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 or other federally financed healthcare programs. The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted by the federal government to include anything of value, for example, cash payments, gifts, discounts, coupons, and the furnishing of free or discounted services or supplies, and other items or services of value to the recipient. This statute has been broadly interpreted to apply to manufacturer arrangements with prescribers, purchasers, formulary managers and patients, among others. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for such exceptions or safe harbors. 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;

- the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;

- other federal healthcare fraud-related laws also impose criminal liability for violations. For example, the Criminal Healthcare Fraud Statute (18 U.S.C. §1347) prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. Federal criminal law also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;

- a number of states also have statutes or regulations similar to the federal Anti-Kickback Statute and FCA that apply to items and services reimbursed under Medicaid and other state programs. Some state anti-kickback statutes apply not just to government payors, but to all payors, including commercial payors and patients;

- the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act, imposes obligations on "covered entities," including health plans and healthcare providers, and their business associates with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, as well as their covered subcontractors. Although we are not directly subject to HIPAA as a covered entity or business associate, we could be subject to criminal or civil penalties if we knowingly obtain individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. We are also subject to state, federal and international privacy and security laws governing the processing and security of personal identifiable information. HIPAA also 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;

- the federal Physician Payments Sunshine Act requirements under the Affordable Care Act, as amended, and its implementing regulations, require 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 certain direct and indirect "payments or other transfers of value" made to covered recipients (defined to include physicians, 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 requirements 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. Failure to comply with these laws and requirements could result in significant civil penalties and other adverse consequences.

Efforts to ensure that our current and future 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, disgorgement, additional regulatory oversight, litigation, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Even the mere issuance of a subpoena, civil investigative demand or the fact of an investigation alone, regardless of the merit, may result in negative publicity, a drop in our share price and other harm to our business, financial condition and our results of operations. Other pharmaceutical companies have settled alleged or admitted violations of these fraud and abuse laws with state and federal authorities in recent years and in some cases these settlements have amounted to hundreds of millions, or even billions, of dollars in damages, fines, and penalties, as well as the imposition of compliance program obligations through Corporate Integrity Agreements and other means. Lawsuits, or enforcement actions brought under fraud and abuse laws, can be extremely costly to defend, even if a company has strong defenses and ultimately succeeds in getting the allegations or enforcement action dismissed. If any of the physicians or other healthcare professionals 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.

Changes in tax laws or regulations could adversely affect our business and financial condition.

New tax laws, statutes, rules, regulations, or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted differently, changed, repealed, or modified at any time. Any such enactment, interpretation, change, repeal, or modification could adversely affect us, possibly with retroactive effect. For instance, legislation commonly referred to as the One Big Beautiful Bill Act ("OBBBA") enacted on July 4, 2025, makes significant changes to the U.S. tax laws. For example, for tax years beginning after December 31, 2024, the OBBBA restores the tax deductibility of domestic research and development expenses in the year incurred, which expenses had been required under the 2017 Tax Cuts and Jobs Act to be capitalized and subsequently amortized over five years. The OBBBA did not change the tax treatment of expenses incurred in research and development activities conducted outside the United States, which expenses continue to be required to be capitalized and amortized over 15 years. We are currently evaluating the impact, if any, of the OBBBA on our business and financial condition and expect the results of such evaluation to be reflected on the Company's Form 10-K for the year ended December 31, 2025.

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, 2024, we had U.S. federal net operating loss carryforwards of approximately $50.6 million. Under current law, U.S. federal net operating loss carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such net operating loss carryforwards is limited to 80% of taxable income. In addition, our U.S. federal net operating loss carryforwards and tax credits may be subject to limitations under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, 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 loss carryforwards and tax credits may also be impaired or restricted under state law. If we earn taxable income, such limitations could result in increased future income tax liability and our future cash flows could be adversely affected. We have recorded a valuation allowance related to our net operating loss carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

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 previously identified material weaknesses in our internal control over financial reporting. 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 Reverse

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.

We determined the material weaknesses previously identified have been remediated as of December 31, 2024 through effective implementation of our remediation plan, which included 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 misstatements, and establishing controls to identify and account for certain non-routine, unusual or complex transactions in a timely fashion.

While we have remediated the previously identified material weaknesses in our internal control over financial reporting, we may in the future identify additional material weaknesses which may adversely affect our business and could result in a future 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 expect to expand our clinical development, manufacturing and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, including significant growth in the number of our employees, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of August 1, 2025, we had 76 full-time employees, including 56 who are engaged in research and development activities, and 1 part-time employee. 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 pacibekitug 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 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 pacibekitug 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 pacibekitug 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 or otherwise, 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 (i) severance and other benefits and (ii) 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 pacibekitug 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 tariffs, embargoes, sanctions or other limitations on trade, geopolitical conflicts such as the ongoing war in Ukraine and hostilities in the Middle East, terrorism and political unrest, disease outbreaks, epidemics and pandemics, curtailment of trade and other business restrictions and implementation of tariffs;
- export control and economic sanctions restrictions, which may restrict or prohibit altogether the sale or supply of certain of our product candidates to certain governments, persons, entities, countries and territories, including those that are the target of comprehensive sanctions, unless there are license exceptions that apply or specific licenses are obtained; 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.

Global trade issues and changes in and uncertainties with respect to trade policies and regulations, including import and export license requirements, trade sanctions, tariffs and international trade disputes, could materially and adversely impact our business and operations and reduce the competitiveness of our products relative to local and global competitors.

There is inherent risk, based on the complex relationships among the United States and the countries in which we conduct our business, that political, diplomatic and national security factors could lead to global trade restrictions and changes in trade policies and regulations that may adversely affect our business and operations. The United States and other countries have imposed, and may continue to impose, new trade restrictions and regulations, have levied tariffs and taxes on certain goods, and could significantly increase tariffs on a broad array of goods. While pharmaceutical products have customarily been granted exemptions from tariffs, recent proposals do not contemplate such exemptions. Trade restrictions and regulations, or increases in tariffs and additional taxes, including any retaliatory measures, can negatively impact demand, increase our supply chain complexity and our manufacturing costs, decrease margins, reduce the competitiveness of our products, or restrict our ability to sell products, provide services or purchase necessary equipment and supplies, any or all of which could have a material and adverse effect on our business, results of operations, or financial condition.

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 pacibekitug and any potential future product candidates, if at all. Disease outbreaks, epidemics and pandemics also could adversely impact clinical trial results for pacibekitug 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 pacibekitug, 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 pacibekitug.

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 pacibekitug 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 domestic or 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 domestic or global economy and in the domestic or 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 and the third parties with whom we contract use and generate materials that may expose us to material liability.

Our clinical development activities require the use of hazardous materials, chemicals, and radioactive and biological materials. We contract with CDMOs, laboratories and other vendors that are subject to foreign, federal, state and local environmental and health and safety laws and regulations related to such hazardous materials and byproducts. We cannot completely eliminate the risks associated with the use, manufacture, handling, storage and disposal of hazardous materials and waste products, which could cause personal injuries or illnesses, accidental contamination of our raw materials, drug substance, and/or drug product, interruption of our development or manufacturing efforts, environmental damage resulting in costly cleanup, or liabilities under domestic or foreign laws and regulations. Also, we may incur significant costs to ensure our CDMOs, laboratories and other vendors comply with these current or future environmental and health and safety laws and regulations. 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 applicable 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 litigation, including stockholder litigation, which could have an adverse effect on our business and operations.

We may be exposed to litigation from stockholders, suppliers and other third parties from time to time. 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 fifteen provisional patent applications (one of which has expired in favor of a new provisional patent application and nine of which have been converted to non-provisional or Patent Cooperation Treaty ("PCT") applications) and four non-provisional patent applications in the U.S., as well as seven PCT patent applications and four non-PCT applications related to the U.S. applications, 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 pacibekitug, although this product candidate is disclosed and its use claimed in our pending U.S. provisional applications, U.S. non-provisional applications, and PCT applications. The patent landscape surrounding pacibekitug 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 pacibekitug 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 pacibekitug and any potential future product candidates.

Disputes may also arise between us and our current licensors 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 pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug 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 pacibekitug. 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 pacibekitug. 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 pacibekitug 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 pacibekitug 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 our or our 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, starting from June 1, 2023, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the Unified Patent Court (the "UPC"). This is 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.

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;
- 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 fluctuating interest rates, inflation, tariffs, 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 U.S. 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.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Securities

None.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits

		Incorporated by Reference			
Exhibit Number	**Description of Exhibit**	**Form**	**File No.**	**Exhibit**	**Filing Date**
3.1	Third Amended and Restated Certificate of Incorporation of the Registrant, as amended through October 19, 2023.	10-Q	001-40384	3.1	November 14, 2023
3.2	Third Amended and Restated Bylaws of the Registrant.	8-K	001-40384	3.1	September 11, 2024
10.1*#	Amendment to offer letter, by and between the Registrant and Susan Dana Jones, dated May 15, 2025.				
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*	Inline XBRL Instance Document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Document.				
104*	Cover Page 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.

SIGNATURES

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: August 13, 2025

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

Date: August 13, 2025

By: /s/ Ryan Robinson
Ryan Robinson
Chief Financial Officer
(Principal Financial and Accounting Officer)

March 24, 2025

Susan Dana Jones
***
***

Subject: Your part-time employment arrangement

This letter serves to confirm the terms of your transition from full-time to part-time employment with Tourmaline Bio, Inc., effective April 1, 2025. We are pleased to continue our working relationship with you in this new capacity. Below are the details of your new employment arrangement:

- **Employment Status**: Your status will change from full-time to part-time, effective April 1, 2025. As a part-time employee, you will be working an average of 28 hours per week, anticipated to be worked Mondays – Thursdays with flexibility that is mutually agreeable between you and your manager, the Chief Executive Officer, based on personal and business needs.
- **Job Title and Duties**: Your job title will remain Chief Technology Officer, and your primary duties and responsibilities will remain the same.
- **Base Compensation**: Your base compensation will be $296,800.
- **Annual Discretionary Bonus Target**: 40% (no change)[1]
- **Benefits**: There will be no change to your benefits eligibility.
- **Equity**: There will be no change to the vesting schedule for equity granted to date.

Please sign below to acknowledge your understanding and acceptance of the terms outlined in this letter.

Employee Acknowledgement:
I, Susan Dana Jones, acknowledge and agree to the terms of the new part-time employment arrangement outlined above, effective April 1, 2025.

/s/ Susan Dana Jones March 24, 2025
Signature Date

Tourmaline Representative:

Brad Middlekauff Chief Business Officer
Name Title

/s/ Brad Middlekauff May 15, 2025
Signature Date

1 Bonus target calculation for January 1-March 31, 2025 will reflect base salary and bonus target % effective during this time period, i.e., $424,000 and 40%, respectively. Bonus target calculation for April 1-December 31, 2025 will reflect base salary and bonus target % effective during this time period, i.e., $296,800 and 40%, respectively. Final bonus amount, if eligible, will also reflect corporate and individual performances.

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; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in 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: August 13, 2025

By: /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; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in 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: August 13, 2025

By: /s/ Ryan Robinson

Ryan Robinson
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

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, Chief Financial Officer 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 June 30, 2025, to which this Certification is attached as Exhibit 32.1 (the "Quarterly 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 Quarterly 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 August 13, 2025.

/s/ Sandeep Kulkarni	/s/ Ryan Robinson
Sandeep Kulkarni	Ryan Robinson
Chief Executive Officer	Chief Financial Officer
(Principal Executive Officer)	*(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 the Company. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.