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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2026

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: 001-43501

TREX BIO, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**36-4902297**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
269 East Grand Avenue, Suite 300	
South San Francisco, CA	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 567-5582

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	TRXB	The Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

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

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

As of November 5, 2026, the registrant had 28,788,654 shares of common stock, $0.0001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors," contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial condition, business strategy and plans, expected market growth, our plans and objectives for future operations and commercialization, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, and future results of anticipated products and prospects, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that 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.

The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "could," "target," "predict," "seek," "consider," "contemplate," "plan," "potential," "project," "would," or the negative of these words or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- the commercial opportunities stemming from the development of our product candidates for multiple autoimmune and inflammatory diseases;
- our ability to develop and, if approved, ultimately commercialize our product candidates and other future programs;
- the initiation, timing, progress, results, and cost of our development programs, and our current and future preclinical and clinical studies, including statements regarding the timing of initiation and completion of our clinical trials, and the period during which the results of the trials will become available;
- the success, cost and timing of our clinical development of our product candidates;
- our ability to establish clinical differentiation of our product candidates;
- our ability to develop product candidates that have broad therapeutic potential;
- our ability to utilize our business development strategy and expertise to build a balanced portfolio;
- our ability to build our operational and commercial capabilities for supplying and marketing our products, if approved, in key markets;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- the trading volume of our common stock;
- our ability to obtain additional funding;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;
- our reliance on third parties to manufacture drug substance for use in our clinical trials;
- our ability to retain and recruit key personnel;
- our ability to obtain and maintain adequate intellectual property rights;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our estimates of our expenses, ongoing losses, capital requirements and our needs for or ability to obtain additional financing;
- our existing cash and the sufficiency of our existing cash and proceeds from future capital-raising efforts to fund our future operating expenses and capital expenditure requirements;
- our ability to identify collaborations and strategic partnerships to maximize the value of our portfolio;
- the potential benefits of strategic collaboration agreements;

- our ability to enter into strategic collaborations or arrangements, including potential business development opportunities and potential licensing partnerships, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to remediate a material weakness in our internal control over financial reporting;
- sales of our stock by us, our insiders or our stockholders, as well as the anticipation of lock-up releases or expiration of market stand-off or lock-up agreements;
- our expectations regarding the time during which we will be an emerging growth company and smaller reporting company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act");
- general economic, industry, geopolitical and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control;
- additions or departures of senior management, directors or key personnel;
- our financial performance;
- developments and projections relating to our competitors or our industry; and
- other risks and uncertainties, including those included in the section titled "Risk Factors."

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate, future events and financial trends that we believe may affect our business, financial condition, results of operations and prospects. These forward-looking statements are not guarantees of future performance or development. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors" and elsewhere in this Quarterly Report. Moreover, we operate in a very competitive and rapidly changing environment and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements included in this Quarterly Report are made only as of the date of this Quarterly Report. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report to conform these statements to actual results or to changes in our expectations.

In addition, statements that "we believe" and similar expressions 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 and, while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete.

You should read this Quarterly Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Risk Factors Summary

Our business is subject to a number of risks that are discussed more fully in the "Risk Factors" section of this Quarterly Report on Form 10-Q. These risks include the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale; we have incurred substantial losses since our inception, and we anticipate incurring substantial and increasing losses for the foreseeable future;
- We will require substantial additional financing to achieve our goals, and failure to obtain additional capital when needed, or on acceptable terms, would cause us to delay, limit, reduce or terminate our product development efforts;
- Raising additional capital may cause dilution to our stockholders, impose restrictions on our operations or require us to relinquish rights to our product candidates;
- Clinical development is lengthy and expensive, characterized by uncertain outcomes, with results of earlier studies and trials often failing to predict future trial results or results in other indications of a product candidate. We may incur additional costs or experience delays in completing, or fail to complete, the development and commercialization of our current product candidates or any future product candidates;
- Delays or difficulties in the enrollment and dosing of patients in clinical trials could delay or prevent receipt of necessary regulatory approvals;
- Any significant adverse events or undesirable side effects caused by our product candidates may delay or prevent regulatory approval or market acceptance of our product candidates, or result in significant negative consequences following marketing approval, if any;
- We face potential competition from different sources that have made substantial investments into the rapid development of novel treatments for autoimmune and inflammatory indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications;
- We have identified a material weakness in our internal control over financial reporting. If we are unable to implement and maintain the effectiveness of our internal control over financial reporting, our investors may lose confidence in the accuracy and completeness of our financial reports, which could adversely affect our stock price;
- We may not realize the benefits of our current or future collaborations or licensing arrangements and may be unsuccessful in consummating future partnerships;
- Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize any product candidate in the United States or any other jurisdiction, and any such approval may be for a more narrow indication than we seek;
- We are dependent on the services of our senior management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer;
- We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business;
- The manufacturing of our product candidates is complex, and our third-party manufacturers may encounter difficulties in production. If our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or provide commercial supply of our products, if approved, could be delayed or halted;
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates or any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely impacted;

- We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates;
- The operations of our suppliers, many of which are located outside of the United States, including our current sole contract manufacturing organization for drug substance and drug product, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects;
- An active and liquid trading market for our common stock may not be sustained; and
- The market price of our common stock may be volatile, which could result in substantial losses for investors.

If we are unable to adequately address these and other risks we face, our business, results of operations, financial condition and prospects may be harmed.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

TRex Bio, Inc.
Condensed Balance Sheets
(In thousands, except share data)
(Unaudited)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 16,810	$ 15,192
Marketable securities	61,340	52,533
Prepaid expenses and other current assets	1,699	3,707
Total current assets	79,849	71,432
Property and equipment, net	826	482
Operating lease right-of-use assets, net	2,727	681
Other assets	5,353	538
Total assets	$ 88,755	$ 73,133
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,715	$ 371
Accrued liabilities	8,097	3,906
Lease liabilities, current	717	717
Total current liabilities	10,529	4,994
Lease liabilities, noncurrent	2,096	—
Income taxes payable, noncurrent	1,299	1,171
Other noncurrent liabilities	103	72
Total liabilities	14,027	6,237
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock:		
Series A-1 redeemable convertible preferred stock, $0.0001 par value per share; 5,000,000 shares authorized, issued and outstanding as of September 30, 2026 and December 31, 2025; liquidation preference of $9,806 as of September 30, 2026 and December 31, 2025	6,530	6,530
Series A-2 redeemable convertible preferred stock, $0.0001 par value per share; 7,700,000 shares authorized, issued and outstanding as of September 30, 2026 and December 31, 2025; liquidation preference of $42,721 as of September 30, 2026 and December 31, 2025	25,181	25,181
Series A-3 redeemable convertible preferred stock, $0.0001 par value per share, 12,482,976 shares authorized, issued and outstanding as of September 30, 2026 and December 31, 2025; liquidation preference of $61,844 as of September 30, 2026 and December 31, 2025	43,730	43,730
Series B redeemable convertible preferred stock, $0.0001 par value per share; 43,388,910 and 27,510,762 shares authorized as of September 30, 2026 and December 31, 2025 respectively; 43,388,910 and 27,206,115 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively; liquidation preference of $134,059 and $84,059 as of September 30, 2026 and December 31, 2025, respectively	133,397	83,574
Stockholders' deficit:		
Common Stock, $0.0001 par value; 89,000,000 and 72,213,000 shares authorized as of September 30, 2026 and December 31, 2025, respectively; 1,501,984 and 1,285,835 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively; and 124,823 and 83,741 shares subject to repurchase as of September 30, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	2,847	2,123
Accumulated other comprehensive (loss) income	(151)	17
Accumulated deficit	(136,806)	(94,259)
Total stockholders' deficit	(134,110)	(92,119)
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	$ 88,755	$ 73,133

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

TRex Bio, Inc.
Condensed Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 11,429	$ 6,969	$ 37,459	$ 21,935
General and administrative	2,487	1,744	7,475	6,002
Total operating expenses	13,916	8,713	44,934	27,937
Loss from operations	(13,916)	(8,713)	(44,934)	(27,937)
Interest income	768	853	2,523	2,421
Other expense, net	(3)	—	(6)	(66)
Total other income, net	765	853	2,517	2,355
Loss before provision for income taxes	(13,151)	(7,860)	(42,417)	(25,582)
Provision for income taxes	88	—	130	—
Net loss	$ (13,239)	$ (7,860)	$ (42,547)	$ (25,582)
Net loss per share attributable to common stockholders, basic and diluted	$ (10.06)	$ (7.58)	$ (34.02)	$ (24.89)
Weighted-average shares outstanding, basic and diluted	1,315,428	1,037,449	1,250,617	1,027,901
Comprehensive loss:				
Net loss	(13,239)	(7,860)	(42,547)	(25,582)
Unrealized (loss) gain on marketable securities	(3)	30	(168)	19
Comprehensive loss	$ (13,242)	$ (7,830)	$ (42,715)	$ (25,563)

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

TRex Bio, Inc.
Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(In thousands, except share data)
(Unaudited)

	Redeemable Convertible Preferred Stock								Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Series A-1		Series A-2		Series A-3		Series B							
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances as of December 31, 2025	5,000,000	$ 6,530	7,700,000	$ 25,181	12,482,976	$ 43,730	27,206,115	$ 83,574	1,285,835	$ —	$ 2,123	$ 17	$ (94,259)	$ (92,119)
Issuance of common stock	—	—	—	—	—	—	—	—	5,065	—	6	—	—	6
Vesting of early exercised shares	—	—	—	—	—	—	—	—	—	—	8	—	—	8
Issuance of Series B preferred stock, net of issuance costs of $177	—	—	—	—	—	—	16,182,795	49,823	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	161	—	—	161
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	(95)	—	(95)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(16,223)	(16,223)
Balances as of March 31, 2026	5,000,000	$ 6,530	7,700,000	$ 25,181	12,482,976	$ 43,730	43,388,910	$ 133,397	1,290,900	$ —	$ 2,298	$ (78)	$ (110,482)	$ (108,262)
Issuance of common stock	—	—	—	—	—	—	—	—	79,231	—	14	—	—	14
Vesting of early exercised shares	—	—	—	—	—	—	—	—	—	—	10	—	—	10
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	183	—	—	183
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	(70)	—	(70)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(13,085)	(13,085)
Balances as of June 30, 2026	5,000,000	$ 6,530	7,700,000	$ 25,181	12,482,976	$ 43,730	43,388,910	$ 133,397	1,370,131	$ —	$ 2,505	$ (148)	$ (123,567)	$ (121,210)
Issuance of common stock	—	—	—	—	—	—	—	—	131,853	—	149	—	—	149
Vesting of early exercised shares	—	—	—	—	—	—	—	—	—	—	15	—	—	15
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	178	—	—	178
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(13,239)	(13,239)
Balances as of September 30, 2026	5,000,000	$ 6,530	7,700,000	$ 25,181	12,482,976	$ 43,730	43,388,910	$ 133,397	1,501,984	$ —	$ 2,847	$ (151)	$ (136,806)	$ (134,110)

	Redeemable Convertible Preferred Stock								Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Series A-1		Series A-2		Series A-3		Series B							
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances as of December 31, 2024	5,000,000	$ 6,530	7,700,000	$ 25,181	12,482,976	$ 43,730	13,683,972	$ 41,805	1,019,195	$ —	$ 1,473	$ 8	$ (59,453)	$ (57,972)
Issuance of common stock	—	—	—	—	—	—	—	—	3,255	—	4	—	—	4
Issuance of Series B preferred stock, net of issuance costs of $10	—	—	—	—	—	—	13,522,143	41,769	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	51	—	—	51
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	(7)	—	(7)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(9,394)	(9,394)
Balances as of March 31, 2025	5,000,000	$ 6,530	7,700,000	$ 25,181	12,482,976	$ 43,730	27,206,115	$ 83,574	1,022,450	$ —	$ 1,528	$ 1	$ (68,847)	$ (67,318)
Issuance of common stock	—	—	—	—	—	—	—	—	102,734	—	6	—	—	6
Vesting of early exercised shares	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	132	—	—	132
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(8,328)	(8,328)
Balances as of June 30, 2025	5,000,000	$ 6,530	7,700,000	$ 25,181	12,482,976	$ 43,730	27,206,115	$ 83,574	1,125,184	$ —	$ 1,666	$ (3)	$ (77,175)	$ (75,512)
Issuance of common stock	—	—	—	—	—	—	—	—	6,218	—	1	—	—	1
Vesting of early exercised shares	—	—	—	—	—	—	—	—	—	—	8	—	—	8
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	129	—	—	129
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—	—	—	30	—	30
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(7,860)	(7,860)
Balances as of September 30, 2025	5,000,000	$ 6,530	7,700,000	$ 25,181	12,482,976	$ 43,730	27,206,115	$ 83,574	1,131,402	$ —	$ 1,804	$ 27	$ (85,035)	$ (83,204)

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

TRex Bio, Inc.
Condensed Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities:		
Net loss	$ (42,547)	$ (25,582)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	176	162
Stock-based compensation	522	312
Amortization of operating lease right-of-use assets	1,049	986
Net amortization of premiums and discounts on marketable securities	(1,431)	(1,221)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	1,856	(523)
Other assets	(61)	(479)
Accounts payable	636	272
Accrued liabilities	2,785	(3,038)
Lease liabilities	(848)	(991)
Income taxes payable, noncurrent	128	—
Net cash used in operating activities	(37,735)	(30,102)
Cash flows from investing activities:		
Purchases of property and equipment	(93)	(38)
Purchases of investments in marketable securities	(81,544)	(100,438)
Proceeds from maturities of marketable securities	74,000	67,000
Net cash used in investing activities	(7,637)	(33,476)
Cash flows from financing activities:		
Proceeds from issuance of common stock	255	131
Proceeds from sales of Series B redeemable convertible preferred stock	50,000	41,779
Payment of Series B redeemable convertible preferred stock issuance costs	(177)	(10)
Payment of initial public offering costs	(2,928)	—
Net cash provided by financing activities	47,150	41,900
Net increase (decrease) in cash, cash equivalents and restricted cash	1,778	(21,678)
Cash, cash equivalents and restricted cash, beginning of period	15,192	47,469
Cash, cash equivalents and restricted cash, end of period	$ 16,970	$ 25,791
Supplemental disclosure:		
Cash paid for income taxes, net of refunds received	$ 100	$ 1,965
Supplemental disclosure of non-cash transactions:		
Right-of-use assets acquired in exchange for lease obligations	$ 2,944	$ 1,346
Property and equipment included in accounts payable and accrued liabilities	$ 426	$ —
Unpaid deferred initial public offering costs included in accounts payable and accrued liabilities	$ 1,666	$ —

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

TRex Bio, Inc.
Notes to Condensed Financial Statements

Note 1. Organization

Description of Business

TRex Bio, Inc. (the "Company") is a clinical-stage biotechnology company focused on studying the regulation of tissue inflammation to develop breakthrough medicines. The Company has created a multi-faceted discovery platform to gain insights into regulatory T cell biology through transcriptomic analyses. The Company has translated these findings into drug discovery campaigns, including a collaboration with Eli Lilly and Company ("Lilly"). In June 2025, the Company announced that it had initiated dosing in its first clinical trial for TRB-061, a novel TNFR2 agonist initially being developed for the treatment of atopic dermatitis.

Reverse Stock Split

On October 2, 2026, the Company effected a 1-for-3.8649 reverse stock split of its issued and outstanding shares of common stock. Upon the effectiveness of the reverse stock split: (i) the number of shares of outstanding common stock was adjusted; (ii) the conversion ratio of the convertible preferred stock was proportionately adjusted; (iii) the number of shares of common stock underlying each outstanding stock option was adjusted; and (iv) the exercise price of each outstanding stock option was proportionately adjusted. All outstanding common stock (including shares of common stock subject to outstanding options and the common shares issuable upon conversion of the outstanding convertible preferred stock), share prices, exercise prices, and per-share amounts contained in the condensed financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented. The reverse stock split did not impact the number of outstanding shares of convertible preferred stock, the authorized number of shares of common and preferred stock, or the par value per share.

Initial Public Offering

In October 2026, the Company completed its initial public offering ("IPO"), issuing and selling an aggregate of 9,539,237 shares of its common stock at the IPO price of $14.00 per share, including 1,205,903 shares sold pursuant to the underwriters' partial exercise of their option to purchase additional shares. The IPO resulted in net proceeds of approximately $119.0 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. Immediately prior to the closing of the IPO, the Company's outstanding redeemable convertible preferred stock automatically converted into 17,742,217 shares of common stock. Following the closing of the IPO, no shares of redeemable convertible preferred stock were authorized or outstanding.

In connection with the completion of the IPO, the Company's certificate of incorporation was amended and restated to (i) authorize 225.0 million shares of common stock, par value $0.0001 per share, (ii) eliminate all references to the previously existing series of redeemable convertible preferred stock and (iii) authorize 25.0 million shares of undesignated preferred stock, par value $0.0001 per share, that may be issued from time to time by the Company's board of directors in one or more series.

The Company's unaudited condensed financial statements as of September 30, 2026, including share and per-share amounts, do not give effect to the IPO and related actions, as the IPO closed subsequent to September 30, 2026.

Liquidity and Capital Resources

The accompanying unaudited condensed financial statements have been prepared on a going concern basis, which contemplates that the Company will realize its assets and satisfy its liabilities in the normal course of business. The Company is subject to risks inherent in operating a clinical-stage biotechnology business, including dependence on successful product development, the ability to attract and retain qualified personnel, rapid technological change and the evolving nature of the biotechnology industry.

As of September 30, 2026, the Company had cash, cash equivalents and marketable securities of $78.2 million and an accumulated deficit of $136.8 million. The Company has incurred net losses and negative cash flows from operations since inception, except for the year ended December 31, 2023, during which it commenced the Research Collaboration and License Agreement with Lilly (as amended, the "Lilly Collaboration Agreement"), received a one-time upfront payment of $55.0 million and recognized total collaboration revenue of $41.9 million across its collaboration agreements.

The Company believes its existing cash, cash equivalents and marketable securities as of September 30, 2026, together with the net proceeds received from the IPO, will be sufficient to fund its operations for at least twelve months from the date these unaudited condensed financial statements are issued. This estimate is based on assumptions that may prove incorrect, and the Company could use its available capital resources sooner than currently expected.

The Company expects to continue to incur substantial losses for the foreseeable future. Unless and until it generates sufficient revenue, it will need additional capital to fund research and development and maintain operations. If capital is unavailable when needed on acceptable terms, the Company could be required to delay, reduce or discontinue one or more development programs or other operations.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP") for interim financial information and the rules and regulations of the Securities and Exchange Commission ("SEC") applicable to interim reporting by smaller reporting companies. Accordingly, they do not include all information and disclosures required by GAAP for complete annual financial statements. The condensed balance sheet as of December 31, 2025 was derived from audited financial statements and notes included in the Company's final prospectus filed with the SEC pursuant to Rule 424(b)(4) on October 9, 2026 (the "IPO Prospectus"). These unaudited condensed financial statements should be read with the audited financial statements in the IPO Prospectus. The accompanying unaudited condensed financial statements and related notes give retroactive effect to the reverse stock split described in Note 1 for all periods presented.

In management's opinion, the unaudited condensed financial statements include all adjustments, consisting only of normal recurring adjustments, necessary to present fairly the Company's financial position, results of operations and cash flows for the interim periods. Results for the three and nine months ended September 30, 2026 are not necessarily indicative of results for the year ending December 31, 2026, or any future period.

Significant Accounting Policies

During the nine months ended September 30, 2026, there were no material changes to the Company's significant accounting policies from those described in Note 2 to the audited financial statements for the years ended December 31, 2025 and 2024 and notes thereto, included in the IPO Prospectus, except for the completed offering-cost accounting described below.

Cash, Cash Equivalents and Restricted Cash

The following table reconciles cash and cash equivalents and restricted cash reported in the condensed balance sheets to the amounts in the condensed statements of cash flows (in thousands):

	September 30, 2026	December 31, 2025
Cash and cash equivalents	$ 16,810	$ 15,192
Restricted cash included in other assets	160	—
Total cash, cash equivalents and restricted cash shown in the condensed statements of cash flows	$ 16,970	$ 15,192

Deferred Offering Costs

The Company capitalizes certain legal, accounting, printing and other third-party costs directly attributable to an in-process equity offering as deferred offering costs. As of September 30, 2026, the Company had deferred offering costs of $4.6 million, which were included in other assets on the condensed balance sheet.

Upon completion of the IPO in October 2026, approximately $5.2 million of offering costs, including estimated costs for services incurred but not yet invoiced, were reclassified as a reduction of the gross proceeds from the IPO within additional paid-in capital. See Note 1.

Recent Accounting Pronouncements

The Company adopted Accounting Standards Update ("ASU") 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, prospectively on January 1, 2026. Because the standard primarily requires enhanced annual disclosures, adoption did not have a material impact on the interim condensed financial statements. The required disclosures will be included in the annual financial statements for the year ending December 31, 2026.

Accounting Pronouncements Not Yet Adopted

In November 2024, the Financial Accounting Standards Board ("FASB") issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40). The amendments require public business entities to disclose, in the notes to the financial statements, additional information about certain costs and expenses included in each relevant expense caption presented on the face of the income statement. The standard is effective for the Company for fiscal years beginning after December 15, 2026 and interim periods beginning after December 15, 2027. Early adoption is permitted. The Company is evaluating the impact on its financial statements and disclosures.

Note 3. Fair Value Measurements

The Company measures cash equivalents and marketable securities at fair value on a recurring basis using a three-level fair value hierarchy. There were no changes to valuation methodologies during the nine months ended September 30, 2026.

The following tables present the amortized cost, gross unrealized gains and losses, and fair value of cash equivalents and marketable securities by major type and fair value hierarchy level (in thousands):

	September 30, 2026				
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents:					
Money market funds	Level 1	$ 16,602	$ —	$ —	$ 16,602
Marketable securities:					
U.S. Treasury securities	Level 1	61,491	—	(151)	61,340
Total		$ 78,093	$ —	$ (151)	$ 77,942

	December 31, 2025				
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash equivalents:					
Money market funds	Level 1	$ 14,925	$ —	$ —	$ 14,925
Marketable securities:					
U.S. Treasury securities	Level 1	52,516	17	—	52,533
Total		$ 67,441	$ 17	$ —	$ 67,458

Interest receivable was approximately $0.3 million and $0.1 million as of September 30, 2026 and December 31, 2025, respectively, and was included in prepaid expenses and other current assets.

Available-for-Sale Debt Securities in an Unrealized Loss Position

The following table presents the fair value and gross unrealized losses of the Company's available-for-sale debt securities in a continuous unrealized loss position as of September 30, 2026 (in thousands):

	September 30, 2026	
	Fair Value	Gross Unrealized Losses
U.S. Treasury securities in a continuous unrealized loss position for less than 12 months	$ 61,340	$ (151)

No available-for-sale debt securities were in an unrealized loss position as of December 31, 2025. The Company determined that the unrealized losses as of September 30, 2026 were attributable to changes in market interest rates and not to credit-related factors. The Company does not intend to sell these securities, and it is not more likely than not that it will be required to sell them before recovery of their amortized cost bases. Accordingly, no allowance for credit losses was recorded as of September 30, 2026.

Note 4. Balance Sheet Components

Accrued Liabilities

Accrued liabilities as of September 30, 2026 and December 31, 2025 consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued payroll related expenses	$ 2,513	$ 2,369
Accrued research and development expenses	3,862	1,109
Accrued initial public offering costs	974	—
Other current liabilities	748	428
Total accrued liabilities	$ 8,097	$ 3,906

Note 5. Leases

South San Francisco Laboratory and Office Lease

In April 2026, the Company entered into an operating lease agreement (the "ARE Lease") with ARE-San Francisco No. 46, LLC, an affiliate of Alexandria Real Estate Equities, Inc. ("Alexandria"), for approximately 33,780 rentable square feet of laboratory and office space in South San Francisco, California. The ARE Lease commenced in August 2026 and expires in November 2028. The ARE Lease provides for abatement of base rent for the first six months following commencement, after which base rent is payable and increases 3% annually. Fixed lease payments over the term total approximately $3.3 million. In addition to base rent, the Company is responsible for its share of operating expenses, including during the abatement period, which are recognized as variable lease cost as incurred. Lease cost is recognized on a straight-line basis over the lease term. The lessor is a related party (see Note 11).

The ARE Lease includes one option to extend the term by 36 months at market rent. The extension period is not included in the lease term because the Company was not reasonably certain at commencement that it would exercise the option.

As required by the ARE Lease, the Company provided the lessor a $0.2 million letter of credit as a security deposit. The letter of credit is collateralized by $0.2 million of restricted cash, which is included in other assets on the condensed balance sheet.

At commencement, the Company recognized an operating lease right-of-use ("ROU") asset of $2.9 million and an operating lease liability of $2.8 million. The ROU asset exceeds the lease liability due to rent paid in advance of lease commencement. The ARE Lease was measured using an incremental borrowing rate of 9.5%.

The Company also leased certain laboratory and office space from Lilly under a lease agreement that expired in August 2026. The operating lease ROU asset and operating lease liability as of December 31, 2025 related entirely to this lease (see Note 11).

Lease Cost and Supplemental Information

The components of lease cost are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating lease cost	$ 450	$ 344	$ 1,103	$ 1,022
Variable lease cost	130	—	130	—
Total lease cost	$ 580	$ 344	$ 1,233	$ 1,022

Cash paid for amounts included in the measurement of operating lease liabilities was $0.9 million and $1.0 million for the nine months ended September 30, 2026 and 2025, respectively. These payments related entirely to the Company's lease with Lilly, as the ARE Lease was still within its six-month base rent abatement period. As of September 30, 2026, the ARE Lease was the Company's only operating lease, with a remaining lease term of 2.2 years and a discount rate of 9.5%. As of

December 31, 2025, the Company's only operating lease was its lease with Lilly, with a remaining lease term of 0.5 years and a discount rate of 4.0%.

Future minimum fixed lease payments under the operating lease as of September 30, 2026 are as follows (in thousands):

Year Ending December 31,	Amount
Remainder of 2026	$ —
2027	1,437
2028	1,736
Total undiscounted lease payments	3,173
Less: imputed interest	(360)
Total lease liabilities	2,813
Lease liabilities, current	(717)
Lease liabilities, noncurrent	$ 2,096

Note 6. Significant Agreements

Lilly

In January 2023, the Company entered into the Lilly Collaboration Agreement with Lilly. Under the agreement, the Company granted Lilly exclusive worldwide rights to develop and commercialize certain program molecules and products. Under the terms of the agreement, the Company received a $55.0 million upfront payment and, in July 2024, received a $15.0 million development milestone payment. After giving effect to the $15.0 million milestone payment received, the Company is eligible to receive up to an additional $577.5 million in development, commercialization, and sales milestone payments, as well as royalties on net sales.

In June 2026, the Company and Lilly entered into the First Amendment to the Research Collaboration and License Agreement. The amendment modified the achievement criteria for certain development milestones related to specified product candidates under the collaboration and established related development reporting requirements. Under the amended terms, the applicable milestones are tied to specified clinical-development events. The amendment also modified certain rights and obligations of the parties in connection with Lilly's continuation or discontinuation of development of the applicable product candidates, including certain contingent rights of the Company following discontinuation. The amendment did not provide for any additional consideration, and no additional variable consideration was included in the transaction price upon execution of the amendment. The Company did not recognize any collaboration revenue under the Lilly Collaboration Agreement for the three and nine months ended September 30, 2026 and 2025 because the research term expired and the combined performance obligation was fully satisfied during the year ended December 31, 2024, and no development, commercialization, or sales milestones were achieved during those periods.

Note 7. Commitments and Contingencies

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of September 30, 2026 and December 31, 2025, the Company did not have any material indemnification claims that were probable or reasonably possible and, consequently, had not recorded related liabilities.

Legal Proceedings

From time to time, the Company may have contingent liabilities that arise in the ordinary course of business activities. The Company assesses, in conjunction with its legal counsel, the need to record a liability for litigation and contingencies. Reserve estimates are recorded when and if it is determined that a loss-related matter is both probable and reasonably estimable. As of September 30, 2026 and December 31, 2025, the Company did not have any material reserve estimates recorded.

Contractual Commitments

The Company enters into contracts in the normal course of business for contract research services, contract manufacturing services, professional services and other services and products used in its operations. These contracts generally provide for

termination after a notice period. As of September 30, 2026, the Company had no material non-cancelable contractual commitments. See Note 5 for information regarding the Company's lease commitments.

Note 8. Stockholders' Equity and Redeemable Convertible Preferred Stock

In January 2026, the Company filed an Amended and Restated Certificate of Incorporation with the Secretary of State of Delaware, which increased the number of authorized shares of Series B redeemable convertible preferred stock from 27,510,762 shares to 43,388,910 shares. Following the amendment, the total number of shares of all classes of stock that the Company was authorized to issue consisted of (i) 89,000,000 shares of common stock, $0.0001 par value per share, and (ii) 68,571,886 shares of preferred stock, $0.0001 par value per share. Immediately prior to the closing of the IPO in October 2026, all 68,571,886 outstanding shares of redeemable convertible preferred stock automatically converted into 17,742,217 shares of common stock (see Note 1).

Common Stock

The Company had 1,501,984 and 1,285,835 shares of common stock outstanding as of September 30, 2026 and December 31, 2025, respectively. The Company had the following shares reserved for issuance as of September 30, 2026 and December 31, 2025:

	September 30, 2026	December 31, 2025
Options issued and outstanding under the 2024 Equity Incentive Plan, as amended (the "2024 Plan")	2,848,293	2,173,642
Shares reserved for future grants under 2024 Plan	768,560	701,119
Total	3,616,853	2,874,761

Upon the effectiveness of the 2026 Equity Incentive Plan (the "2026 Plan") in connection with the IPO in October 2026, the shares reserved for future grants under the 2024 Plan ceased to be available for issuance. Awards previously granted under the 2024 Plan were not affected (see Note 14).

Redeemable Convertible Preferred Stock

In March 2025, the Company issued an aggregate of 13,522,143 shares of Series B redeemable convertible preferred stock at an issuance price of $3.0897 per share for net proceeds of $41.8 million related to the second tranche.

In January 2026, the Company issued an aggregate of 16,182,795 shares of Series B redeemable convertible preferred stock to multiple investors at an issuance price of $3.0897 per share for net proceeds of $49.8 million (the "Series B Extension").

No dividends have been declared or paid during the three and nine months ended September 30, 2026 and 2025.

Note 9. Equity Incentive Plans

Stock Option Activity

	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2025	2,173,642	$ 1.20		
Granted	890,790	1.28		
Exercised	(216,139)	1.19		
Cancelled	—	—		
Outstanding as of September 30, 2026	2,848,293	1.23	8.27	36,386
Exercisable as of September 30, 2026	1,091,013	1.18	7.18	13,991
Vested and expected to vest as of September 30, 2026	2,848,293	$ 1.23	8.27	$ 36,386

Stock-Based Compensation Expense

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
General and administrative	$ 120	$ 88	$ 359	$ 234
Research and development	58	41	163	78
Total	$ 178	$ 129	$ 522	$ 312

As of September 30, 2026, unrecognized stock-based compensation related to unvested awards was $2.0 million, expected to be recognized over a weighted-average period of 2.9 years.

Note 10. Income Taxes

Provision for income taxes was $0.1 million for each of the three and nine months ended September 30, 2026, primarily attributable to interest and penalties accrued on the Company's liability for uncertain tax positions. The Company did not record a provision for income taxes for the three and nine months ended September 30, 2025.

The effective tax rate for all periods presented differed from the 21% U.S. federal statutory rate primarily due to a full valuation allowance against the Company's deferred tax assets.

Note 11. Related Parties

Lilly

Lilly held more than 10% of the Company's outstanding capital stock as of December 31, 2025 and September 30, 2026. In addition, Julie Gilmore, a member of the Company's Board of Directors, is an employee of Lilly.

In March 2025, Lilly purchased 2,930,404 shares of Series B redeemable convertible preferred stock at an issuance price of $3.0897 per share, for an aggregate purchase price of approximately $9.1 million, in connection with the second tranche of the Series B financing. In January 2026, Lilly purchased 2,237,940 shares of Series B redeemable convertible preferred stock at an issuance price of $3.0897 per share, for an aggregate purchase price of approximately $6.9 million, in connection with the Series B Extension.

As of December 31, 2025, Lilly held 7,700,000 shares of Series A-2 redeemable convertible preferred stock, 2,002,487 shares of Series A-3 redeemable convertible preferred stock and 5,860,808 shares of Series B redeemable convertible preferred stock. As of September 30, 2026, Lilly held 7,700,000 shares of Series A-2 redeemable convertible preferred stock, 2,002,487 shares of Series A-3 redeemable convertible preferred stock and 8,098,748 shares of Series B redeemable convertible preferred stock, including 2,237,940 shares purchased in January 2026.

In July 2025, the Company entered into a Master Management Services Agreement with Lilly (the "Lilly Services Agreement"), pursuant to which Lilly provides preclinical research and development services in support of the Company's research projects. The Company incurred expense of approximately $0.2 million under the Lilly Services Agreement for each of the three and nine months ended September 30, 2026, and did not incur any expense under the Lilly Services Agreement for the three and nine months ended September 30, 2025.

Additionally, the Company and Lilly entered into the Lilly Collaboration Agreement in January 2023, which was amended in June 2026 (see Note 6). The Company also leased certain laboratory and office space from Lilly under a lease agreement that expired in August 2026 (see Note 5).

Johnson & Johnson Innovation

Johnson & Johnson Innovation – JJDC, Inc. ("Johnson & Johnson Innovation") held more than 5% of the Company's outstanding capital stock as of December 31, 2025 and September 30, 2026. In addition, an affiliate of Johnson & Johnson Innovation was party to a collaboration agreement with the Company until October 2025, as described below.

In March 2025, Johnson & Johnson Innovation purchased 802,299 shares of Series B redeemable convertible preferred stock at a price of $3.0897 per share for an aggregate purchase price of approximately $2.5 million in connection with the second tranche of the Series B financing. In January 2026, Johnson & Johnson Innovation purchased 612,713 shares of Series B redeemable convertible preferred stock at a price of $3.0897 per share for an aggregate purchase price of approximately $1.9 million in connection with the Series B Extension.

As of December 31, 2025, Johnson & Johnson Innovation held 2,656,391 shares of Series A-3 redeemable convertible preferred stock and 1,604,598 shares of Series B redeemable convertible preferred stock. As of September 30, 2026, Johnson & Johnson Innovation held 2,656,391 shares of Series A-3 redeemable convertible preferred stock and 2,217,311 shares of Series B redeemable convertible preferred stock, including the 612,713 shares purchased in January 2026.

The Company was also a party to a Collaboration and License Agreement, dated as of December 28, 2021 (the "Janssen Agreement"), with Janssen Pharmaceutica NV ("Janssen"), one of the Janssen Pharmaceutical Companies of Johnson & Johnson and an affiliate of Johnson & Johnson Innovation. The Janssen Agreement was terminated in October 2025, and the Company did not recognize any revenue under it during the three and nine months ended September 30, 2026 and 2025.

Alexandria Real Estate Equities, Inc.

Joel S. Marcus, a member of the Company's Board of Directors, serves as Executive Chairman of Alexandria. In addition, Alexandria Venture Investments, LLC ("Alexandria Venture Investments"), an affiliate of Alexandria, held more than 5% of the Company's outstanding capital stock as of September 30, 2026.

In March 2025, Alexandria Venture Investments purchased 1,456,452 shares of Series B redeemable convertible preferred stock at a price of $3.0897 per share for aggregate proceeds of approximately $4.5 million in connection with the second tranche of the Series B financing. In January 2026, Alexandria Venture Investments purchased 567,483 shares of Series B redeemable convertible preferred stock at a price of $3.0897 per share for aggregate proceeds of approximately $1.8 million in connection with the Series B Extension.

As of December 31, 2025, Alexandria Venture Investments held 1,033,541 shares of Series A-3 redeemable convertible preferred stock and 2,912,904 shares of Series B redeemable convertible preferred stock. As of September 30, 2026, Alexandria Venture Investments held 1,033,541 shares of Series A-3 redeemable convertible preferred stock and 3,480,387 shares of Series B redeemable convertible preferred stock, including the 567,483 shares purchased in January 2026.

In April 2026, the Company entered into the ARE Lease with ARE-San Francisco No. 46, LLC, an affiliate of Alexandria, for laboratory and office space in South San Francisco, California. The ARE Lease commenced in August 2026, has an initial term of 27 months expiring in November 2028, and provides for total fixed lease payments of approximately $3.3 million over the initial term (see Note 5). During the nine months ended September 30, 2026, the Company paid approximately $0.2 million of rent in advance of lease commencement under the ARE Lease, which was included in the initial measurement of the operating lease right-of-use asset. The Company recognized lease expense of approximately $0.2 million under the ARE Lease for the three and nine months ended September 30, 2026.

Note 12. Net Loss Per Share

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive (in common stock equivalent shares):

	As of September 30,	
	2026	2025
Outstanding stock options	2,848,293	2,179,167
Unvested early exercised stock options	124,823	90,021
Series A-1 Convertible Preferred Stock	1,293,694	1,293,694
Series A-2 Convertible Preferred Stock	1,992,290	1,992,290
Series A-3 Convertible Preferred Stock	3,229,832	3,229,832
Series B Convertible Preferred Stock	11,226,401	7,039,280
Total	20,715,333	15,824,284

Note 13. Segment Information

The Company operates as a single reportable segment focused on autoimmune and inflammatory disease discovery. The Chief Executive Officer is the chief operating decision maker ("CODM"). The CODM evaluates net loss as the measure of segment profit or loss and total assets as the measure of segment assets.

Significant segment expenses regularly provided to the CODM were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Employee-related expenses, excluding stock-based compensation	$ 4,296	$ 3,419	$ 12,317	$ 10,333
Stock-based compensation	178	129	522	312
External research and development expenses	6,556	3,048	23,606	10,490
External general and administrative expenses	732	491	2,481	1,848
Other segment expenses*	2,154	1,626	6,008	4,954
Total operating expenses	13,916	8,713	44,934	27,937
Loss from operations	(13,916)	(8,713)	(44,934)	(27,937)
Interest income	768	853	2,523	2,421
Other expense, net	(3)	—	(6)	(66)
Total other income, net	765	853	2,517	2,355
Loss before provision for income taxes	(13,151)	(7,860)	(42,417)	(25,582)
Provision for income taxes	88	—	130	—
Net loss	$ (13,239)	$ (7,860)	$ (42,547)	$ (25,582)

*Other segment expenses include facility-related and office costs, information technology costs, depreciation and amortization and other operating expenses.

As of September 30, 2026 and December 31, 2025, all property and equipment and operating lease ROU assets were located in the United States.

Note 14. Subsequent Events

The Company evaluated subsequent events for recognition, remeasurement and disclosure through the date on which these unaudited condensed financial statements were issued. The events described below occurred after September 30, 2026 and are not reflected in the condensed financial statements as of and for the periods ended September 30, 2026. See Note 1 for information regarding the IPO, the conversion of the redeemable convertible preferred stock, and the amended and restated certificate of incorporation.

2026 Equity Incentive Plan

In October 2026, the Company's board of directors adopted, and its stockholders approved, the 2026 Plan, which became effective in connection with the IPO. The Company initially reserved 2,757,753 shares of its common stock for issuance under the 2026 Plan. The number of shares reserved will automatically increase on January 1 of each year from 2027 through 2036 by the lesser of:

(i) 5% of the shares of diluted stock outstanding as of the preceding December 31; and

(ii) a number of shares determined by the board of directors.

Upon the effectiveness of the 2026 Plan, the 768,560 shares then remaining available for grant under the 2024 Plan ceased to be available for issuance.

2026 Employee Stock Purchase Plan

In October 2026, the Company's board of directors adopted, and its stockholders approved, the 2026 Employee Stock Purchase Plan (the "ESPP"), which became effective in connection with the IPO. The Company initially reserved 275,775 shares of its common stock for issuance under the ESPP. The number of shares reserved will automatically increase on January 1 of each year beginning in 2027 by the lesser of:

(i) 1% of the shares of diluted stock outstanding as of the preceding December 31; and

(ii) a number of shares determined by the board of directors.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q and our audited financial statements and related notes for the year ended December 31, 2025 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on October 9, 2026 (the "IPO Prospectus"). This discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and the timing of events could differ materially from those discussed in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" in Part II, Item 1A of this Quarterly Report and elsewhere in this Quarterly Report. Our historical results are not necessarily indicative of results expected in any future period. See "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company focused on tissue regulatory T cell ("Treg") biology for the discovery and development of immunoregulatory medicines designed to restore immune balance and promote tissue repair to address unmet needs of patients with autoimmune and inflammatory diseases. Leveraging our Deep Biology drug discovery and design platform, we integrate tissue-level insights into human biology and Treg function to identify and characterize novel targets and approaches for therapeutic intervention.

Our most advanced wholly-owned product candidate, TRB-061, is an investigational tumor necrosis factor receptor 2 agonist designed to expand and activate Tregs in inflamed tissues. We initiated a Phase 1a clinical trial of TRB-061 in healthy volunteers in June 2025. The Phase 1a portion generated safety and biomarker data supporting proof-of-mechanism, and based on these results, we advanced TRB-061 into the Phase 1b portion of the trial in patients with moderate-to-severe atopic dermatitis ("AD") in April 2026. We expect to announce topline data in mid-2027. Our second wholly-owned product candidate, TRB-071, is an investigational agonist of TNF receptor superfamily member 8 (TNFRSF8, also known as CD30) designed to augment tissue Tregs and block inflammatory signaling axes. TRB-071 is currently in studies to enable an investigational new drug application ("IND") and, subject to regulatory allowance to proceed, is expected to enter a Phase 1 trial in the first half of 2027.

Beyond our lead product candidates, we are advancing multiple preclinical-stage programs focused on differentiated aspects of Treg biology. We also have an ongoing collaboration with Eli Lilly and Company ("Lilly") for TRB-051, a modulator of immune effector cells, first identified and advanced under a multi-year discovery collaboration leveraging our platform. In June 2024, we announced that Lilly initiated a Phase 1 first-in-human study for TRB-051. Lilly intends to advance TRB-051 into a Phase 2a clinical trial in lupus with cutaneous involvement.

Since inception, our operations have focused primarily on research and development, raising capital, business planning, staffing, intellectual property, manufacturing arrangements and administrative support. As of September 30, 2026, we had an accumulated deficit of $136.8 million. Our net losses were $13.2 million and $7.9 million for the three months ended September 30, 2026 and 2025, respectively, and $42.5 million and $25.6 million for the nine months ended September 30, 2026 and 2025, respectively. We expect to continue to incur significant losses for the foreseeable future as we advance our programs and operate as a public company.

We have historically financed our operations primarily with proceeds from the issuance of our redeemable convertible preferred stock and payments received under our strategic license and collaboration agreements and, most recently, through our initial public offering ("IPO"). In October 2026, we completed our IPO, in which we issued and sold an aggregate of 9,539,237 shares of our common stock at a public offering price of $14.00 per share, including 1,205,903 shares sold pursuant to the underwriters' partial exercise of their option to purchase additional shares. We received net proceeds of approximately $119.0 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Immediately prior to the closing of the IPO, all outstanding shares of our redeemable convertible preferred stock automatically converted into 17,742,217 shares of common stock.

As of September 30, 2026, we had cash, cash equivalents and marketable securities of $78.2 million. Based on our current operating plan, we believe these resources, together with the net proceeds from our IPO, will be sufficient to fund our operations and capital expenditure requirements into the second half of 2029. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect. See "Liquidity and Capital Resources."

Collaboration Agreements

Eli Lilly Research Collaboration and License Agreement

In January 2023, we entered into a Research Collaboration and License Agreement with Lilly (the "Lilly Collaboration Agreement"), under which we granted to Lilly exclusive worldwide rights to develop and commercialize certain program molecules and products. The research term for the Lilly Collaboration Agreement expired during the year ended December 31, 2024; however, our right to receive potential future milestone and royalty payments survives the expiration of the research term and remains in effect, unless earlier terminated in accordance with its terms. After giving effect to the $15.0 million development milestone payment received in July 2024, we are eligible to receive up to an additional $577.5 million in development, commercialization and sales milestone payments, as well as tiered royalties ranging from six to ten percent on annual aggregate net sales of licensed products, subject to specified adjustments. In June 2026, we and Lilly entered into the First Amendment to the Lilly Collaboration Agreement, which modified the achievement criteria for certain development milestones such that the applicable milestones are tied to specified clinical-development events. The amendment did not provide for any additional consideration. No development, commercialization or sales milestones were achieved during the three and nine months ended September 30, 2026 and 2025.

Components of Results of Operations

Collaboration Revenue

We have not generated revenue from product sales and do not expect to do so in the foreseeable future. Our collaboration revenue to date has been derived primarily from the Lilly Collaboration Agreement. We did not recognize collaboration revenue during the three and nine months ended September 30, 2026 and 2025, and we may not recognize additional revenue under the Lilly Collaboration Agreement unless and until additional milestone or royalty consideration qualifies for recognition in a future period.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Research and development expenses account for the largest component of our total operating expenses. Research and development expenses consist primarily of direct and unallocated costs incurred for the research and development of our product candidates.

A significant portion of our research and development costs has been external costs, which we track by product candidate once it has reached a certain stage of development. However, we do not track our unallocated costs on a product candidate specific basis because these costs are deployed across multiple projects and, as such, are not separately classified.

We expect that our research and development expenses will increase substantially in absolute dollars for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, as our product candidates advance into later stages of development, as we conduct ongoing and future clinical trials, as we seek regulatory approvals for any product candidates that successfully complete clinical trials, and as we incur expenses associated with hiring additional personnel to support our research and development efforts.

General and Administrative

General and administrative expenses consist primarily of personnel-related costs, costs related to maintenance and filing of intellectual property, legal fees related to corporate matters, professional fees paid for accounting, auditing, consulting, and tax services, insurance costs, general corporate expenses, and facility-related costs not otherwise included in research and development expenses. Personnel-related costs include salaries, bonuses, benefits, and stock-based compensation expense for our personnel in executive, finance and accounting, human resources, and other administrative functions.

We expect that our general and administrative expenses will increase substantially in absolute dollars for the foreseeable future as we continue to increase our headcount to support our business growth. We have incurred costs in connection with preparing to operate as a public company and, following the completion of our IPO in October 2026, we expect to incur significant additional expenses associated with operating as a public company, including expenses related to compliance with

the rules and regulations of the SEC and expenses related to audit, legal and regulatory services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs.

Other Income, Net

Other income, net primarily consists of interest earned on our cash equivalents and marketable securities during the period. Period-to-period changes generally reflect average invested balances, the weighted-average maturity of our investments and prevailing yields.

Provision for Income Taxes

We are subject to U.S. federal and state income taxes. Our provision for income taxes consists primarily of interest and penalties accrued on our liability for uncertain tax positions. We recognize interest and penalties related to uncertain tax positions as a component of our provision for income taxes. Due to our history of cumulative losses, we maintain a full valuation allowance against our net deferred tax assets, including our net operating loss and research and development tax credit carryforwards, because we have concluded that it is not more likely than not that these assets will be realized.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset future taxable income or taxes may be limited if we undergo an "ownership change." We have experienced ownership changes in the past that limit our use of certain of these attributes, and future changes in our stock ownership, some of which are outside our control, could result in additional limitations.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
Operating expenses:						
Research and development	$ 11,429	$ 6,969	$ 4,460	$ 37,459	$ 21,935	$ 15,524
General and administrative	2,487	1,744	743	7,475	6,002	1,473
Total operating expenses	13,916	8,713	5,203	44,934	27,937	16,997
Loss from operations	(13,916)	(8,713)	(5,203)	(44,934)	(27,937)	(16,997)
Interest income	768	853	(85)	2,523	2,421	102
Other expense, net	(3)	—	(3)	(6)	(66)	60
Total other income, net	765	853	(88)	2,517	2,355	162
Loss before provision for income taxes	(13,151)	(7,860)	(5,291)	(42,417)	(25,582)	(16,835)
Provision for income taxes	88	—	88	130	—	130
Net loss	(13,239)	(7,860)	(5,379)	(42,547)	(25,582)	(16,965)

Research and Development Expenses

The following table summarizes research and development expenses by direct and unallocated cost category (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
Direct costs:						
TRB-061	$ 3,548	$ 2,278	$ 1,270	$ 11,973	$ 6,774	$ 5,199
Other product candidates	3,008	770	2,238	11,633	3,716	7,917
Unallocated costs:						
Employee-related expenses, including stock-based compensation	2,964	2,468	496	8,441	7,026	1,415
Facility-related and office costs	784	430	354	1,699	1,310	389
Other costs	1,125	1,023	102	3,713	3,109	604
Total research and development expense	$ 11,429	$ 6,969	$ 4,460	$ 37,459	$ 21,935	$ 15,524

Research and development expenses were $11.4 million for the three months ended September 30, 2026, compared to $7.0 million for the three months ended September 30, 2025. The increase was primarily attributable to a $1.3 million increase in costs associated with TRB-061, resulting from higher clinical trial costs for the Phase 1b portion of the trial in patients with AD, which began in April 2026, and a $2.2 million increase in costs from increased preclinical development activity for our other product candidates.

Research and development expenses were $37.5 million for the nine months ended September 30, 2026, compared to $21.9 million for the nine months ended September 30, 2025. The increase was primarily attributable to a $5.2 million increase in costs associated with TRB-061, resulting from higher clinical trial costs associated with the Phase 1b portion of the trial in patients with AD, and a $7.9 million increase in costs associated with increased preclinical development activity for our other product candidates.

General and Administrative Expenses

General and administrative expenses were $2.5 million for the three months ended September 30, 2026, compared to $1.7 million for the three months ended September 30, 2025. The increase was primarily due to higher personnel-related costs resulting from increased headcount.

General and administrative expenses were $7.5 million for the nine months ended September 30, 2026, compared to $6.0 million for the nine months ended September 30, 2025. The increase was primarily due to higher personnel-related costs resulting from increased headcount and higher legal costs associated with the expansion of our intellectual property portfolio.

Other Income, Net

Total other income, net was $0.8 million and $2.5 million for the three and nine months ended September 30, 2026, respectively, compared to $0.9 million and $2.4 million for the three and nine months ended September 30, 2025, respectively. The changes primarily reflect lower yields on our cash equivalents and marketable securities, which were more than offset in the nine-month period by higher average balances following the sale of our Series B redeemable convertible preferred stock in January 2026.

Provision for Income Taxes

Provision for income taxes was $0.1 million for each of the three and nine months ended September 30, 2026, primarily attributable to interest and penalties accrued on our liability for uncertain tax positions. We did not record a provision for income taxes for the three and nine months ended September 30, 2025.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2026, we had cash, cash equivalents and marketable securities of $78.2 million. We have incurred net losses and negative cash flows from operations since inception, with the exception of the year ended December 31, 2023, during which we commenced the Lilly Collaboration Agreement, received a one-time upfront payment of $55.0 million from

Lilly and recognized total collaboration revenue of $41.9 million across our collaboration agreements, resulting in net income for the year and positive cash flows from operations. As of September 30, 2026, we had an accumulated deficit of $136.8 million.

We have historically funded our operations primarily through the issuance of shares of our redeemable convertible preferred stock and payments received under our strategic license and collaboration agreements. In January 2026, we issued and sold 16,182,795 shares of our Series B redeemable convertible preferred stock at a purchase price of $3.0897 per share for gross proceeds of $50.0 million (the "Series B Extension").

Subsequent to September 30, 2026, we completed our IPO, in which we issued and sold an aggregate of 9,539,237 shares of our common stock at a public offering price of $14.00 per share. We received net proceeds of approximately $119.0 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We expect to continue to incur substantial losses for the foreseeable future. Our ability to achieve and sustain profitability will depend on the successful development, regulatory approval and commercialization of any product candidates we may develop and our ability to generate sufficient revenue to support our cost structure. We may never achieve profitability and, unless and until we do, we will need to continue to raise additional capital to fund our ongoing research and development activities and maintain our operations.

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities, together with the net proceeds from our IPO, will be sufficient to fund our operations and capital expenditure requirements for at least 12 months from the date of issuance of our unaudited condensed financial statements. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

Our ability to access additional capital when needed is not assured. If sufficient capital is not available to us when needed, or is not available on terms acceptable to us, we could be required to delay, limit, reduce or terminate our research and product development activities or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, any of which could materially harm our business, financial condition and results of operations.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2026	**2025**
Net cash used in operating activities	$ (37,735)	$ (30,102)
Net cash used in investing activities	(7,637)	(33,476)
Net cash provided by financing activities	47,150	41,900
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 1,778	$ (21,678)

Net Cash Used in Operating Activities

We have not generated any revenue from product sales. Our cash flows from operating activities are primarily driven by our use of cash to fund research and development and general and administrative activities, and by changes in working capital, including the timing of payments to contract research organizations, contract manufacturers and other vendors.

Net cash used in operating activities for the nine months ended September 30, 2026 was $37.7 million and consisted of a net loss of $42.5 million, partially offset by net noncash adjustments of $0.3 million and a net change in operating assets and liabilities of $4.5 million. Noncash adjustments primarily included amortization of operating lease right-of-use assets of $1.0 million and stock-based compensation of $0.5 million, partially offset by net amortization of premiums and discounts on marketable securities of $1.4 million. The net change in operating assets and liabilities was mainly due to:

- an increase in accrued liabilities of $2.8 million, driven by higher accrued costs for nonclinical studies, clinical trials and contract manufacturing as our development activities expanded;
- a decrease in prepaid expenses and other current assets of $1.9 million, due to the utilization of prepayments for contract manufacturing, clinical trial and nonclinical study services; and
- an increase in accounts payable of $0.6 million, due to the timing of vendor payments.

These were partially offset by a decrease in lease liabilities of $0.8 million.

Net cash used in operating activities increased by $7.6 million during the nine months ended September 30, 2026, compared to the same period in 2025. The increase was primarily attributable to a $17.0 million increase in net loss, partially offset by a $9.3 million favorable change in operating assets and liabilities. The change in operating assets and liabilities resulted primarily from a $5.8 million change in accrued liabilities, reflecting increased development activities in 2026 and the prior-year payment of $2.0 million in income taxes accrued as of December 31, 2024; and a $2.4 million change in prepaid expenses and other current assets, driven by the utilization in 2026 of prepayments made as of December 31, 2025, compared to new clinical prepayments funded during the 2025 period. The remaining $1.1 million primarily reflected a $0.4 million change in other assets, as the 2025 period included a $0.5 million long-term pass-through prepayment to our contract research organization that will be held until the end of the study; a $0.4 million change in accounts payable due to the timing of vendor payments; and a combined $0.3 million change in lease liabilities and noncurrent income taxes payable.

Net Cash Used in Investing Activities

Our primary investing activities consist of purchases and maturities of marketable securities and, to a lesser extent, purchases of property and equipment.

Net cash used in investing activities for the nine months ended September 30, 2026 was $7.6 million, driven primarily by purchases of marketable securities of $81.5 million, partially offset by proceeds from maturities of marketable securities of $74.0 million.

Net cash used in investing activities decreased by $25.8 million during the nine months ended September 30, 2026, compared to the same period in 2025. The decrease was primarily due to a decrease in purchases of marketable securities of $18.9 million and an increase in proceeds from maturities of marketable securities of $7.0 million. Purchases in the prior-year period reflected the investment of proceeds from the second tranche of our Series B preferred stock financing in March 2025.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2026 was $47.2 million. This was primarily attributable to net proceeds of $49.8 million from the Series B Extension in January 2026, partially offset by payments of offering costs related to our IPO of $2.9 million.

Net cash provided by financing activities increased by $5.3 million during the nine months ended September 30, 2026, compared to the same period in 2025. The increase was mainly due to an increase in net proceeds from the issuance of redeemable convertible preferred stock of $8.1 million, reflecting the Series B Extension in 2026 compared to the second tranche of our Series B preferred stock financing in 2025. This was partially offset by payments of offering costs related to our IPO of $2.9 million.

Future Funding Requirements

Our primary use of cash is to fund research and development, clinical and preclinical activities, manufacturing and general corporate operations. The timing of cash use is affected by vendor billing, clinical enrollment, manufacturing schedules, prepaid amounts and accruals.

Our future funding requirements will depend on many factors, including:

- TRB-061 clinical scope, enrollment, dose escalation and expansion, data timing, clinical drug supply and other trial costs;
- TRB-071 IND-enabling, chemistry, manufacturing and controls, regulatory and clinical initiation activities, and development of other product candidates;
- manufacturing scale, raw materials, supply-chain availability, contract research organization and contract manufacturing organization commitments and inflation;
- potential milestone, royalty or other obligations under current and future license or collaboration agreements;
- personnel, facilities and public-company infrastructure, including SEC reporting, controls remediation, audit, legal, insurance and investor relations;
- patent prosecution, maintenance, enforcement and defense;
- acquisitions, in-licenses, collaborations or other strategic transactions; and
- any product approval, commercial readiness or commercialization activities.

Until such time, if ever, as we generate substantial product revenue, we expect to finance our operations through our existing cash, cash equivalents and marketable securities, the net proceeds from our IPO, public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements or other sources. Although completion of the IPO increased our available liquidity, we will require substantial additional capital to complete the development and potential commercialization of our product candidates.

Contractual Obligations and Other Commitments

In April 2026, we entered into an operating lease with a related party for approximately 33,780 square feet of laboratory and office space in South San Francisco, California. The lease commenced in August 2026, has an initial term of 27 months expiring in November 2028 and provides for total fixed lease payments of approximately $3.3 million over the initial lease term. As of September 30, 2026, the related operating lease liability was $2.8 million. Our prior lease of laboratory and office space from Lilly expired in August 2026. See Notes 5 and 11 to our unaudited condensed financial statements included in Part I, Item 1 of this Quarterly Report.

We enter into contracts in the normal course of business for contract research services, contract manufacturing services, professional services and other services and products used in our operations. These contracts generally provide for termination after a notice period, and, therefore, generally do not represent material noncancelable contractual commitments.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules and regulations or any holdings in variable interest entities.

Critical Accounting Estimates

This management's discussion and analysis is based on our unaudited condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these unaudited condensed financial statements requires us to make judgments and estimates that affect the reported amounts of revenue, the amount of stock-based compensation, the fair value of our common stock and the reported amounts of expenses during the reported periods. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be 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. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experiences. Actual results may differ from these estimates under different assumptions or conditions. The effects of material revisions in estimates, if any, will be reflected in the unaudited condensed financial statements prospectively from the date of change in estimates.

Our critical accounting estimates are described in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Estimates, Significant Judgments and Use of Estimates" in our IPO Prospectus. There have been no material changes to our critical accounting estimates since the filing of our IPO Prospectus.

Recent Accounting Pronouncements

See Note 2 to our unaudited condensed financial statements included in Part I, Item 1 of this Quarterly Report for information regarding recently issued and adopted accounting pronouncements.

Internal Control Over Financial Reporting

As previously disclosed in our IPO Prospectus, we identified a material weakness in our internal control over financial reporting related to the lack of sufficient internal technical accounting resources, which resulted in an overreliance on external advisors for complex accounting matters without maintaining adequate internal controls to review, validate and document the resulting accounting positions and disclosures. As of September 30, 2026, the material weakness had not been remediated. For additional information regarding the material weakness and our remediation plan, see Part I, Item 4, "Controls and Procedures."

Emerging Growth Company Status and Smaller Reporting Company Status

We qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to avail ourselves of this extended transition period and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of this election,

our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates.

We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We are also a smaller reporting company as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a "smaller reporting company" as defined in Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this Item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of September 30, 2026. Disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit 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 our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives.

Based on their evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2026, our disclosure controls and procedures were not effective at the reasonable assurance level because of the material weakness in our internal control over financial reporting described below.

Previously Reported Material Weakness

As previously disclosed in our IPO Prospectus, we identified a material weakness in our internal control over financial reporting related to the lack of sufficient internal technical accounting resources, which resulted in an overreliance on external advisors for complex accounting matters without maintaining adequate internal controls to review, validate and document the resulting accounting positions and disclosures. 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 our annual or interim financial statements will not be prevented or detected on a timely basis.

Notwithstanding the material weakness, management has concluded that the condensed financial statements included in this Quarterly Report present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. generally accepted accounting principles.

Remediation Plan

We are taking steps to remediate the material weakness, including hiring additional accounting and finance personnel with technical accounting and SEC reporting experience, enhancing our use of external specialists where appropriate, implementing improved review procedures and documentation requirements, and providing training to existing personnel. The material weakness will not be considered remediated until management completes the design and implementation of the related controls, the controls operate for a sufficient period of time, and management has concluded, through testing, that the controls are operating effectively. As of September 30, 2026, the material weakness had not been remediated. These measures may not be sufficient to remediate the material weakness or prevent additional material weaknesses from occurring in the future.

Changes in Internal Control over Financial Reporting

Other than the ongoing remediation efforts described above, including our engagement of a new third-party tax advisor during the quarter ended September 30, 2026, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may become involved in legal proceedings or claims arising in the ordinary course of our business. We do not believe that any such proceedings currently pending, if any, would have a material adverse effect on our business, financial condition, or results of operations.

Item 1A. Risk Factors.

You should carefully consider the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q, including in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our unaudited condensed financial statements and the related notes, and in our audited financial statements and related notes included in our IPO Prospectus. The risks and uncertainties set out below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially and adversely affect our business, financial condition, results of operations, liquidity and stock price. If any of the following events occur, our business, financial condition, and operating results could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Need for Capital

We are an early-stage biotech company with a limited operating history and no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability. We have incurred net losses in every year except one since our inception. We expect to continue to incur net losses in the future.

We are a clinical-stage biotechnology company with a limited operating history. Since our inception in 2018, we have invested most of our resources in developing our product candidates, building our intellectual property portfolio, conducting business planning, organizing and staffing our company, raising capital, conducting preclinical studies and, more recently, clinical trials and providing general and administrative support for these operations. Biopharmaceutical product development is a highly speculative undertaking, involving substantial upfront capital expenditure and significant risk. Any product candidate may fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable, despite substantial investment on development or commercialization. To date, we have not yet demonstrated our ability to successfully obtain regulatory approvals, manufacture a product on a commercial scale, or arrange for a third party to do so on its behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, 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 biopharmaceutical products. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each year since our inception except for the year ended December 31, 2023 during which we received a one-time upfront payment of $55.0 million from Eli Lilly and Company, and recognized total collaboration revenue of $41.9 million across our collaboration agreements. For the nine months ended September 30, 2026, we had a net loss of $42.5 million. As of September 30, 2026, we had an accumulated deficit of $136.8 million. We expect to continue to incur significant losses for the foreseeable future and expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our wholly-owned clinical-stage product candidates, TRB-061 and TRB-071, along with any other product candidates we may develop.

We anticipate that our expenses will increase substantially if, and as, we:

- continue the research and development of our clinical- and preclinical-stage product candidates and discovery-stage programs, including the continued development of our most advanced wholly-owned product candidates, TRB-061 and TRB-071;
- increase the amount of research and development activities to identify and develop product candidates to advance into clinical trial development;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts;
- establish sales, marketing and distribution infrastructure to commercialize any products for which we may obtain regulatory approval and intend to commercialize on our own or jointly with third parties;

- procure the manufacturing of preclinical, clinical and commercial supply of our current or any other product candidates;
- incur additional costs associated with operating as a public company following the closing of our IPO;
- establish agreements with contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"); and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies or trials, complex results, manufacturing challenges, safety issues or other regulatory challenges.

To become and remain profitable, we and any current or potential future collaborators must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, manufacturing our product candidates, either on our own or with our CMOs, obtaining regulatory approval for product candidates, marketing and selling any products for which we may obtain regulatory approval and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Our future results of operations will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

We will need substantial additional funding in order to maintain our operations and advance the development and commercialization of our product candidates. Failure to obtain this necessary capital when needed, or on acceptable terms, may force us to delay, reduce or eliminate certain of our product development or research operations.

The development of biopharmaceutical product candidates, including conducting preclinical studies and clinical trials, is a time-consuming, capital-intensive and uncertain process. Our operations have consumed substantial amounts of cash since inception. To date, we have funded our operations primarily with proceeds from the sale of our convertible preferred stock. We expect our expenses to increase in connection with our ongoing activities, particularly as we advance our Phase 1 trial of TRB-061 and continue to research, develop and initiate clinical trials of TRB-071 and our other product candidates. In addition, if we successfully develop and obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce, or eliminate our product development programs or any future commercialization efforts.

As of September 30, 2026, we had cash, cash equivalents, and marketable securities of approximately $78.2 million. Based on our current operating plan, we expect that our existing cash, cash equivalents, and marketable securities as of September 30, 2026, together with the net proceeds from our IPO, will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2029. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. We expect to attempt to raise additional cash in advance of exhausting our available capital resources.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for a product candidate, and we may not ever generate significant revenue or profits. In addition, we expect to incur costs associated with operating as a public company, including significant legal, accounting, investor relations, and other expenses that we did not incur prior to our IPO. If we obtain regulatory approval for a product candidate and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Because of the numerous risks and uncertainties, length of time and scope of activities associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements, both near and long-term, will depend on, and could increase significantly as a result of, many factors, including, but not limited to:

- the scope, timing, progress results and costs of our ongoing TRB-061 and TRB-071 clinical and preclinical studies and other research and development activities associated with the development of our other and future product candidates;
- the costs, timing and outcome of regulatory review of product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any product candidates for which we receive marketing approval;
- the costs of establishing and maintaining arrangements with third party manufacturers for the commercial supply of products that receive marketing approval, if any;
- the costs and timing of manufacturing for TRB-061, TRB-071, and other product candidates, including commercial manufacturing at sufficient scale, if any product candidate is approved, including as a result of inflation, any supply chain issues or component shortages;
- the revenue, if any, received from commercial sale of our products, should any product candidates receive marketing approval;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the cost and timing of attracting, hiring and retaining skilled personnel to support our operations and continued growth;
- the cost of being a public company, including implementing operational, financial and management systems to remediate an existing material weakness;
- 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 and maintain collaborations, strategic partnerships or marketing, distribution, licensing, or other strategic arrangements with third parties on favorable terms, if at all;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, current or future product candidates, if any; and
- the costs associated with operating as a public company following the completion of our IPO, including legal, accounting, or other expenses in operating our business.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms or at all. Until we can generate sufficient product or other revenue to finance our cash requirements, which we may never achieve, we expect to finance our future cash requirements through a combination of equity offerings, debt financings or other capital sources, including potential collaborations, out-licenses or dispositions and other similar arrangements.

Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. Market volatility resulting from geopolitical and economic instability, including as a result of trade policy, inflation and the wars between Russia and Ukraine and in the Middle East or other factors could also adversely impact our ability to access capital as and when needed. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or product candidates or we may be unable to take advantage of future business opportunities.

Raising additional capital may cause dilution to our stockholders and may restrict our operations or require us to relinquish rights to our product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potential collaborations, out-licenses or dispositions and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that may adversely affect the rights of our stockholders. Debt and equity financings, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as redeeming shares, making investments, incurring additional debt, making capital expenditures, declaring dividends or placing limitations on our ability to acquire, sell or license intellectual property rights.

If we raise additional capital through future collaborations, strategic alliances or third-party licensing arrangements, we may have to relinquish certain valuable rights to our intellectual property, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital when needed, we may be required to delay, limit, reduce or terminate our clinical development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Further, we may not be able to access a portion of our existing cash due to market conditions. If banks and financial institutions with whom we hold accounts enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash may be threatened and could have a material adverse effect on our business and financial condition.

Risks Related to Product Candidate Development and Commercialization

Preclinical and clinical development is lengthy and expensive, characterized by uncertain outcomes, with results of earlier studies and trials often failing to predict future trial results or results in other indications of a product candidate. We may incur additional costs or experience delays in completing, or fail to complete, the development and commercialization of our product candidates.

Our business is dependent on our ability to successfully complete preclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize our product candidates in a timely manner. We face substantial risk of failure with our product candidates, and we may fail to receive regulatory approval for any of our product candidates. To obtain the requisite regulatory approvals to commercialize any product candidate, we must demonstrate to the satisfaction of applicable regulatory authorities, through extensive preclinical studies and lengthy, complex and expensive clinical trials, that a product candidate is safe, pure and potent (or effective) for its intended uses. Clinical testing often takes many years to complete, and its outcome is inherently uncertain. The results of preclinical studies and early clinical trials of our product candidates may not predict results of later-stage clinical trials, and results in one indication may not predict results for the same product candidate in another target indication. Differences in trial design between early-stage clinical trials and later-stage clinical trials raise challenges for extrapolating the results of earlier clinical trials to later clinical trials.

A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. The results of our clinical trials for any product candidates may not achieve statistical significance or demonstrate a favorable risk-benefit profile. Further, negative clinical trial results for a product candidate with respect to one target indication may impact the potential or perceived potential of other target indications. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory approval of such product candidates.

Before commencing clinical trials of a product candidate in a jurisdiction, we must submit an investigational new drug application (“IND”) or foreign equivalent to the United States Food and Drug Administration (“FDA”) or comparable foreign regulatory authority. We may not be able to submit INDs to the FDA or similar regulatory submissions to foreign regulatory authorities for our product candidates on the timelines we expect. Additionally, we may experience manufacturing delays or other delays with IND-enabling studies, or the FDA or other comparable regulatory authorities may require additional preclinical studies that we did not anticipate. Moreover, we have had only limited interactions with the FDA, and we cannot be sure that submission of an IND or similar regulatory submissions will result in the FDA or other comparable regulatory authority allowing clinical trials to begin, or that, once begun, issues will not arise that result in a decision by us, by institutional review boards (“IRBs”) or independent ethics committees, or by the FDA or other comparable regulatory authorities to suspend or terminate clinical trials, including as a result of a clinical hold. Additionally, even if the FDA or other comparable regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or other similar regulatory submission, we cannot guarantee that they will not change their requirements or expectations in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to submit INDs

or similar regulatory submissions on the timelines we expect or to obtain regulatory authorization or allowance for our clinical trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. A high failure rate characterizes product candidates proceeding through clinical trials, and failure may occur at all stages of the clinical trial process. Most product candidates that commence clinical trials are never approved as products, and our current or future clinical trials ultimately may fail to support the approval of our current or any other product candidates.

We expect to continue to rely, in part, on collaborators, CROs and clinical trial sites to conduct our clinical trials, including participant enrollment, and we have limited influence over their performance. We or our collaborators may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay, prevent or terminate our clinical trials, or delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- the FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies or impose additional requirements before permitting us to initiate a clinical trial;
- the FDA or comparable foreign regulatory authorities, IRBs or ethics committees may disagree with our study design, may require that we modify or amend our clinical trial protocols, or may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site; we may experience delays in reaching, or fail to reach, agreement on acceptable terms with trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly;
- clinical investigators or clinical trial sites may deviate from trial protocols or Good Clinical Practice requirements ("GCPs") or drop out of a trial, and we may need to add new investigators or sites;
- we may be unable to add or be delayed in adding a sufficient number of clinical trial sites and obtaining IRB or ethics committee approval at each clinical trial site;
- the number of participants required for clinical trials may be larger than expected, enrollment in clinical trials may be slower than expected or participants may drop out or fail to return for post-treatment follow-up at a higher rate than expected;
- we may be required to evaluate clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- we may observe unexpectedly high placebo response rates;
- the cost of clinical trials and preclinical studies may be greater than we anticipate, or we may have insufficient funds to conduct such trial or study or to pay the substantial user fees required by the FDA upon the submission of a Biologics License Application ("BLA");
- our third-party contractors, including CROs and contract manufacturers, may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- we may be unable to obtain or be delayed in obtaining sufficient product supply of a product candidate for use in preclinical studies or clinical trials from third-party suppliers;
- our product candidates may have undesirable side effects or other unexpected characteristics that are viewed to outweigh their potential benefits;
- reports from clinical testing of other similar therapies may raise safety, tolerability or efficacy concerns about our product candidates; and
- clinical trials of our product candidates may fail to show appropriate safety, tolerability or efficacy, may produce negative or inconclusive results or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies or we may decide to abandon product candidate development.

If we are required to conduct additional preclinical studies or clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these studies, trials or tests are not positive or are only moderately positive or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such clinical trials are being conducted, by the data safety monitoring board, if any, for such clinical trial or by the FDA or other comparable regulatory authorities. Such authorities may suspend, place on clinical hold, or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or trial site by the FDA or other comparable regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from the product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur at any time, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to the FDA or comparable foreign regulatory authorities, or to IRBs and ethics committees for reexamination, which may impact the costs, timing, ability to proceed, or successful completion of a clinical trial.

To date we have conducted clinical trials only in Australia and New Zealand, and we have not conducted any clinical trials in the U.S. Conducting clinical trials in foreign countries, as we currently do and may do in the future, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks, including war, relevant to such foreign countries. It is also possible that the FDA or other regulatory authorities may not accept the clinical data generated in research conducted in a foreign country.

If we experience delays in the completion of, or the termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and regulatory approval process and jeopardize our ability to commence product sales and generate revenues.

We are substantially dependent on the success of our two most advanced wholly-owned product candidates, TRB-061 and TRB-071, and our clinical trials of such product candidates may not be successful.

Our future success is substantially dependent on our ability to timely obtain regulatory approval for, and then successfully commercialize, our two most advanced wholly-owned product candidates, TRB-061 and TRB-071. We are investing a majority of our efforts and financial resources into the research and development of these programs. We have initiated a Phase 1 clinical trial for TRB-061. The success of this program is dependent on observing adequate safety and tolerability results, in addition to early signs of clinical efficacy in AD patients. We have initiated a Good Laboratory Practice ("GLP") toxicology study for TRB-071. Our ability to advance this program into the clinic is dependent on observing adequate safety and tolerability results in our GLP studies. If we do not observe adequate safety, tolerability, or efficacy results in these studies such results would significantly and adversely affect the clinical and commercial potential of our programs.

Our programs will require additional clinical development, including further clinical, preclinical and manufacturing activities, receipt of regulatory approvals, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote these programs, or any other programs, before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approvals.

The success of our programs will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory review process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Accordingly, we may never be able to generate revenue through the sale of these programs, even if approved. If we are not successful in commercializing TRB-061, TRB-071 or our other programs, or are significantly delayed in doing so, our business will be materially harmed.

Delays or difficulties in the enrollment and dosing of patients in our clinical trials may cause delays or prevent receipt of necessary regulatory approvals.

The timing of our clinical trials depends on our ability to recruit patients to participate in our studies as well as the dosing of such patients and completion of required follow-up periods. Participant enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the number and location of clinical sites, the proximity of participants to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, patient referral practices of physicians, challenges in obtaining and maintaining participant consents, enrolled participants dropping out, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or biologics that may be approved for the indications being investigated by us.

In addition, our clinical trials currently, and may in the future, compete with other clinical trials for product candidates that address the same indications as those we are pursuing for our product candidates, and this competition reduces the number and types of participants available to us, because some participants who might have opted to enroll in our trials instead opt to enroll in a trial conducted by a competitor or elect to use a marketed therapy. We also could encounter delays if doctors face ethical challenges associated with enrolling participants in a clinical trial rather than prescribing an existing treatment with an established safety and efficacy profile.

If we or our collaborators are unable to enroll a sufficient number of eligible patients to participate in our clinical trials, we may not be able to initiate, continue or complete clinical trials for our product candidates. Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in enrollment may result in increased costs, delay completion or adversely impact the outcome of the trial.

Additionally, our ability to successfully initiate, enroll, and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including: difficulty in establishing or managing relationships with CROs and physicians; different standards for the conduct of clinical trials; different standard-of-care for patients with a particular disease; difficulty in locating qualified local consultants, physicians and partners; and potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

We have experienced participant discontinuations from our trials. Participants, including in any control groups, frequently withdraw from a clinical trial if they are not experiencing improvement in their underlying disease or condition or if they experience adverse side effects or other issues. Withdrawal of participants from our clinical trials may compromise the quality of our data.

Difficulties enrolling a sufficient number of patients to conduct our clinical trials as planned could require us to delay, limit or terminate clinical trials for our product candidates, or expand to additional jurisdictions, which could impose additional challenges on our company. Our assumptions used in determining expected clinical trial timelines may not be correct and we may experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines. Failure to successfully conduct our clinical trials as planned would have an adverse effect on our business, financial condition, results of operations and prospects.

Any significant adverse events or undesirable side effects caused by our product candidates may delay or prevent regulatory approval or market acceptance of our product candidates, or result in significant negative consequences following regulatory approval, if any.

If our product candidates are associated with serious or significant adverse side effects in clinical trials or have adverse safety findings in non-clinical studies, we may decide or be required to halt or delay their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe, or more acceptable from a benefit-risk perspective. The FDA or other comparable foreign regulatory authority or an institutional review board or ethics committee may also require that we suspend, discontinue, or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates, which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the indication, if approved.

Adverse events observed in preclinical studies or clinical trials could adversely affect our future clinical trial plans. For example, there were adverse findings observed in our preclinical studies for TRB-061, including one female cynomolgus monkey being dosed intravenously at 3 mg/kg/dose in a non-GLP dose-ranging toxicology study for TRB-061 who was found dead on day 29 of that study, and a male cynomolgus monkey being dosed subcutaneously at 3 mg/kg/dose in the currently ongoing 6 month GLP chronic toxicology study for TRB-061 who required early euthanasia on day 22. Our investigation of the findings in the 6 month TRB-061 study is ongoing, and the cause of death has not been determined. However, we believe

that the death in the non-GLP study of TRB-061 was likely related to generation of anti-drug antibodies ("ADA") and ADA-mediated immune complex formation. Such adverse findings in preclinical studies could result in the regulatory authorities imposing, or us proactively proposing, an exposure cap in our planned clinical trials, if otherwise allowed to proceed. Any of our current or other product candidates may be subject to new, partial or full clinical holds in the future.

We, the FDA or other applicable regulatory authorities, or an IRB, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Many potential product candidates developed in the biotechnology industry that initially showed promise in early-stage trials have later been found to cause side effects that prevented their further development and approval. Even if side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance. Adverse events or negative patient experiences may also result in negative publicity, including through social media, online forums or peer networks, which could damage our reputation and harm clinical trial enrollment and market acceptance of our product candidates, if approved.

Even if we successfully develop a product candidate and it receives regulatory approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of treatment outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to healthcare practitioners, restricted distribution methods, patient registries, extensive patient monitoring and other risk minimization tools that are highly controlled, restrictive, and more costly than what is typical for the industry. Furthermore, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates or those of our competitors may only be uncovered when a significantly larger number of patients have been exposed to the product candidate. If our product candidates receive regulatory approval and we or others identify undesirable side effects caused by such products (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such products;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to change the way such products are distributed or administered, conduct additional clinical trials or change the labeling of the products with the potential restriction of their clinical use;
- regulatory authorities may require a REMS to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may be required to suspend marketing of a product, or we may decide to remove such products from the marketplace;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be subject to personal injury claims, actions, lawsuits and proceedings that may arise from exposure to or taking our products;
- a product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us or our collaboration partners from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

We face potential competition from different sources that have made substantial investments into the rapid development of novel treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies, as well as public and private research institutions. Any product candidates that we successfully develop and commercialize, if approved, will compete with existing therapies and new therapies that may become available in the future.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their safety, efficacy, convenience, price, the level of generic competition, the existence of therapeutic alternatives and the availability of coverage and reimbursement from government and other third-party payors.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our current product candidates, initially under development for treatment of various autoimmune and inflammatory indications would, if approved, face competition from existing approved immunological treatments, many of which have achieved commercial success. For example, we are currently developing (i) TRB-061 for the treatment of moderate-to-severe AD and alopecia areata ("AA") and (ii) TRB-071 for inflammatory bowel disease ("IBD"). There are a number of products and product candidates in clinical development by other companies which may become available in the future, which treat AD, AA, and IBD.

To compete successfully, we need to disrupt currently marketed drugs, meaning we must demonstrate that the relative cost, method of administration, safety, tolerability and efficacy of our product candidates provides a better alternative to existing and new therapies. Our commercial opportunity and likelihood of success will be reduced or eliminated if our product candidates are not ultimately demonstrated to be safer, more effective, more conveniently administered or less expensive than the current standard of care or future competing products. Furthermore, even if our product candidates are able to achieve these attributes, acceptance of our products may be inhibited by the reluctance of physicians to switch from existing therapies to our products, or if physicians choose to reserve our products for use in limited circumstances.

Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of development and commercialization. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. If we are not able to effectively compete for any of the foregoing reasons, our business will be materially harmed.

Changes in product candidate manufacturing, formulation or analytical methods may result in additional costs or delay, which could adversely affect our business, financial condition, results of operations and prospects.

As product candidates are developed through preclinical studies to later-stage clinical trials toward approval and future commercialization, it is common that various aspects of the development program, such as manufacturing methods, formulation or analytical methods, are altered in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials or utilizing different analytical methods. Such changes also may require additional testing, or notification to, or authorization by, the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates or jeopardize our ability to commence product sales and generate revenue.

Interim, top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. Data from our clinical trials reported as of a measurement date may not be predictive of the effect, if any, of our product candidates at any later measurement date.

From time to time, we may publish interim, top-line or preliminary data from our clinical trials. Preliminary and interim data from our clinical trials may change as more patient data become available. Preliminary or interim data from our clinical trials are not necessarily predictive of final results. Preliminary and interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and we issue our final clinical trial report. Interim, top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary, top-line and interim data should be viewed with caution until the final data are available. Moreover, in connection with any data that is presented, caution should be exercised in drawing any conclusions from a comparison of data that does not come from head-to-head analysis. Additionally, data from a clinical trial as of any measurement date are only reflective of observations in such clinical trial at such date and should not be unduly used to predict any effect at a later measurement date.

Adverse differences between interim, topline, or preliminary data and final data could significantly harm our business prospects. Further, disclosure of such data could result in volatility in the price of our common stock. Further, others, including regulatory agencies, 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 delay or prevent regulatory approval of, or limit commercial prospects for, the particular product candidate and harm our business prospects. In addition, the information we choose to publicly disclose regarding a particular study or 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, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the preliminary and interim data that we report differ from actual results or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We may not realize the benefits of our current or future collaborations or licensing arrangements and may be unsuccessful in consummating future partnerships.

Our current or future collaborations or licensing arrangements may not be successful. Additionally, we have partnered, and intend to further partner, with third parties with respect to the clinical development and, if approved, may partner with respect to commercialization, of certain of our programs in certain regions outside the United States, and we may not be successful in identifying, negotiating and executing partnerships. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- agreements with collaborators may not provide exclusive rights to use their intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our other product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable other product candidates;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator’s sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize any product candidate in the United States or any other jurisdiction, and any such approval may be for a narrower indication than we seek.

Any product candidates we or our collaborators develop are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, record keeping, reporting, labeling, storage, pricing, advertising, promotion and distribution of drugs. Failure to obtain regulatory approval for a product candidate we may develop will prevent us from commercializing the product candidate in a given jurisdiction. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authorities. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that the product candidates we and our collaborators are developing will not obtain the regulatory approvals necessary for us or our collaborators to begin commercialization. Moreover, approval by the FDA does not ensure approval by any regulatory authority outside the U.S. and vice versa.

The time required to obtain FDA and other regulatory approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us are not always applied in a predictable or uniform manner and can change over time. Any analysis we perform of data from non-clinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We or our collaborators may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

If we or our collaborators complete clinical development and submit a BLA or other marketing application to the FDA or comparable foreign regulatory authority, such authorities may request additional clinical or other data or information in connection with the regulatory review of such marketing applications, including by issuing a complete response letter that may require that we or our collaborators submit additional clinical or other data or impose other conditions that must be met in order to secure approval of our or our collaborators' marketing applications, such as further inspections or reviews of manufacturing facilities. Even if such data and information are submitted, or any such inspection is completed, the FDA or foreign regulatory authority may ultimately decide that the BLA or other marketing application does not satisfy the criteria for approval.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions or contraindications with respect to conditions of use, or they may grant approval subject to the performance of costly post marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of any product candidates we may develop, or they may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and adversely affect our business, financial condition, results of operations, and prospects.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials or our interpretation of the resulting data;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective and have a positive risk-benefit profile for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations, or apparent improvement in trial participants receiving placebo;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;

- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the U.S. or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- the FDA or comparable foreign regulatory authorities may not approve our CMOs' manufacturing process or facilities;
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission;
- the FDA or comparable foreign regulatory authorities may not accept clinical data from trials conducted by individual investigators or in countries where the standard of care is potentially different from the U.S. or applicable foreign jurisdiction; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Regulatory approval for our product candidates may not be obtained without lengthy delays, if at all. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Additionally, TRB-061, TRB-071 and our other product candidates may be regulated as a combination product that consists of both a therapeutic biologic and medical device for delivery such as a prefilled syringe or autoinjector. Developing and obtaining regulatory approval for combination products can pose unique challenges because they involve components that are regulated under different types of regulatory requirements and potentially by different FDA centers. As a result, such product candidates may raise regulatory, policy and review management challenges. Differences in regulatory pathways for each component of a combination product can impact the regulatory processes for all aspects of product development and management, including clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, user fees and post approval modifications. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed.

From time to time, we may estimate the timing of the accomplishment of various scientific, clinical, regulatory, manufacturing and other product development goals. These milestones may include the commencement or completion of preclinical studies and clinical trials and the submission of regulatory filings, including IND and BLA submissions. From time to time, we may publicly announce the expected timing of such milestones. The achievement of these milestones is, and will be, based on a variety of assumptions. The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates.

We may develop our current or other product candidates in combination with other therapies, which would expose us to additional risks.

We may develop our current or potential other product candidates in combination with one or more currently approved therapies or therapies in development. Even if any of our current or other product candidates were to receive regulatory approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

We may also evaluate our current or other product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved therapies that do not ultimately obtain regulatory approval. In addition, developing combination regimens may require that we adequately demonstrate the efficacy of each therapy within the combination regimen, which may prove difficult and otherwise require us to generate more data than we would in connection with a monotherapy program.

Furthermore, we cannot be certain that we will be able to obtain a steady supply of such therapies for use in developing combinations with our product candidates on commercially reasonable terms or at all. Any failure to obtain such therapies for use in clinical development and the expense of purchasing therapies in the market may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If the FDA or comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or, if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or other product candidates, we may be unable to obtain approval of or successfully market any one or all of the current or other product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or other product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or other product candidates, or, if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We may expend our limited resources to pursue a particular product candidate in specific indications and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus our development efforts on certain selected product candidates in certain selected indications. For example, we are initially focused on our clinical stage product candidate, TRB-061, for the treatment of moderate-to-severe atopic dermatitis and other indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or other indications for our existing product candidates that later prove to have greater commercial potential. Additionally, negative clinical trial results with respect to one indication of a product candidate may impact the potential or perception of other indications of the product candidate. Our resource allocation decisions may result in our failure to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We are currently conducting, and may in the future conduct, clinical trials for current or other product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are currently conducting clinical trials outside the United States, including in Australia and New Zealand, and we expect to continue to conduct trials internationally in the future. The acceptance of data from clinical trials conducted outside the United States by the FDA, or data from clinical trials conducted outside a foreign jurisdiction by the applicable foreign regulatory authority, may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for approval in the United States, regardless of whether the applicable clinical trial was conducted pursuant to an IND, the FDA will generally not approve the application unless the data are applicable to the United States population and United States medical practice, the trials were performed by clinical investigators of recognized competence and pursuant to GCP and the FDA is able to validate the data through an onsite inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the trial was not otherwise subject to an IND, the FDA will not accept the data as support for a submission unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any applicable foreign authority will accept data from trials conducted outside of the United States or the applicable jurisdiction.

Even where the FDA or comparable foreign regulatory authority accepts such data, such regulatory authorities could require us to modify our planned clinical trials to receive allowance or authorization to initiate or continue such trials in the United States or the applicable foreign jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept data from trials conducted outside of the United States or the applicable jurisdiction, such non-acceptance would result in the need for additional trials that could be costly and time-consuming and could result in the product candidate not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the U.S. also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements including with respect to data privacy and security, which may impose heightened requirements and data transfer restrictions;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- inconsistent standards for reporting and evaluating clinical data and adverse events;
- varying standards of care;
- any pandemic, epidemic or public health emergencies;
- diminished protection of intellectual property in some countries; and
- political instability, civil unrest, war or similar events that may jeopardize our ability to commence, conduct or complete a clinical trial and evaluate resulting data.

Even if we receive regulatory approval for our current or other product candidates in the United States, we may never receive regulatory approval to market outside of the United States.

We plan to seek regulatory approval of our current or other product candidates outside of the United States including in the European Union ("EU") and United Kingdom ("UK"). In order to market any product outside of the United States we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other applicable jurisdictions. Regulatory approval processes vary among countries but generally implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval and can require additional product candidate testing and additional administrative review periods. In many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others and would impair our ability to market our current or other product candidates in such foreign markets. Any such impairment would limit the commercial potential of the product candidate, which could adversely affect our business, financial condition, results of operations and prospects.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities, government health benefit programs, private health insurance and other third-party payors establish broad coverage, adequate reimbursement levels and favorable pricing of such product.

The availability of coverage and the adequacy of reimbursement by governmental healthcare authorities or programs such as Medicare and Medicaid, private health insurance and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for any approved products will affect our ability to successfully commercialize those products. Even if we obtain coverage for a given product by a third-party payor, the reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the U.S. and there is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. The coverage determination process is often time consuming and costly and may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage will be obtained. Third-party payors may not provide or may limit coverage or may control utilization (e.g., by requiring that patients try other therapies first or that prescribers obtain specific approval of coverage on a patient by patient basis).

Third-party payors may deny or establish payment for any marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. We may be required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. More generally, we may need to offer price concessions to third-party payors to obtain favorable coverage or to purchasers to achieve sales.

Limited or no coverage or reimbursement or the offer of pricing concessions could have a negative impact on our ability to successfully commercialize any of our product candidates, if approved, and obtain a satisfactory financial return on our product candidates.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of products like our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, if approved. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be lower than in the United States and may be insufficient to generate meaningful revenue and profits.

We may seek accelerated approval for some of our product candidates but may not be able to obtain it as the sufficiency of our clinical trial results for accelerated approval are subject to the FDA's discretion.

We may explore strategies for our product candidates that involve use of the FDA's accelerated approval pathway. Obtaining accelerated approval requires demonstration of meaningful benefit over available therapies for a serious condition. The determination of what constitutes available therapy is wholly up to the FDA and is subject to change. Other therapeutics may receive full approval prior to our potential receipt of accelerated approval. If that were to occur, no assurance can be given that we would be successful in proving meaningful benefit over those later approved products. If we were unable to prove meaningful benefit over any such agents, we would be effectively blocked from receiving accelerated approval. If any of our drugs were ever to receive accelerated approval, we would be required to conduct a post-market confirmatory study, which we may not complete, or if completed, may prove unsuccessful. In such instance, the FDA can remove the product from the market.

We may seek fast track designation, breakthrough therapy designation and/or priority review designation from the FDA or similar designations from comparable foreign regulatory authorities for one or more of our product candidates. Even if one or more of our product candidates receive these designations, we may be unable to obtain or maintain the benefits associated with such designation.

The FDA has established various designations to facilitate more rapid and efficient development and approval of certain types of drugs intended to treat serious conditions that fill an unmet medical need. Such designations include fast track designation, breakthrough therapy designation, and priority review designation. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for a designation, the FDA could decide not to grant it. If any of our programs or product candidates receive any of these designations by the FDA or similar designations by comparable foreign regulatory authorities, we may not receive any benefits from such programs or that we will continue to meet the criteria to maintain such designation. Even if we obtain such designations, we may not experience a faster development process, review or approval compared to conventional procedures. A grant of these designations does not ensure that a product candidate will receive marketing approval or that approval will be granted within any particular timeframe. In addition, the FDA may withdraw any such designation if it believes that the designation is no longer supported by data from our clinical development program.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about clinical development activities, and we intend to utilize appropriate social media in connection with our commercialization efforts of our product candidates, if approved. Social media practices in the biotechnology and biopharmaceutical industries continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off-label marketing, promotion of an unapproved new drug, false or misleading advertising, or other prohibited activities and heightened scrutiny by the FDA, the Federal Trade Commission ("FTC"), the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing clinical trial or to report an alleged side effect or adverse event ("AE"). If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable AE reporting obligations or that we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive, personal or confidential information or negative or inaccurate posts or comments about us on any social networking website. In addition, we may encounter attacks on social media regarding us, our management, or any of our current or other product candidates. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, suffer reputational harm or incur other harm to our business.

Risks Related to Our Business and Operations

Our business depends entirely on the success of our product candidates, and we may fail to successfully develop, receive regulatory approval for, or successfully commercialize any or all of our product candidates.

We do not have any products approved for commercial sale. We have invested substantially all of our efforts and financial resources in the development of our product candidates, each of which is still in clinical development or preclinical studies, and we expect that we will continue to invest heavily in these product candidates and any other product candidates we may develop. Our business and our ability to generate revenue, which we do not expect will occur for many years, if ever, are substantially dependent on our ability to acquire, develop, obtain regulatory approval for and successfully commercialize our product candidates, which may never occur.

Our product candidates will require substantial additional clinical development time, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts and further investment before we can generate any revenue from product sales. We may not meet our timelines for our current or future clinical trials, which may be delayed or not completed for a number of reasons. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected AEs or failure to achieve primary endpoints in clinical trials.

Even if our product candidates are successful in clinical trials, we are not permitted to market or promote any product candidate before we receive regulatory approval from the FDA or comparable foreign regulatory authorities. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow commercialization, we will not be able to generate revenue from those product candidates in the United States or elsewhere in the foreseeable future, or at all.

We have never submitted a BLA for our product candidates to the FDA, or a similar marketing application to a comparable foreign regulatory authority, and our current or any other product candidates may not be successful in clinical trials or receive regulatory approval.

If approved for marketing by applicable regulatory authorities, our ability to generate revenue from our product candidates will depend on our ability to:

- receive regulatory approval for the targeted patient populations and claims that are necessary or desirable for successful marketing and maintain an acceptable safety profile for the products following approval;
- price our products competitively such that third-party and government reimbursement permits broad product adoption;
- obtain and maintain healthcare coverage and adequate reimbursement;
- achieve market acceptance of our products by patients, the medical community and third-party payors;
- demonstrate the superiority of our products compared to the standard of care, as well as other therapies in development;
- create market demand for our product candidates through our own marketing and sales activities or any co-promotion or other arrangements that we may otherwise establish;
- manufacture product candidates through CMOs in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establish sales and marketing capabilities, whether alone or through a collaboration, to support commercialization of our product candidates;
- establish and maintain agreements with wholesalers, distributors, pharmacies and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect and enforce patent and other intellectual property protection and regulatory exclusivity for our products;
- maintain compliance with applicable laws, regulations and guidance including interactions with healthcare professionals, patient advocacy groups and communication of healthcare economic information to payors and formularies;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and capable of timely product delivery; and
- assure that our product will be used as directed and that additional unexpected safety risks will not arise.

Any significant delays in obtaining approval for or inability to successfully commercialize our product candidates would adversely affect our business, financial condition, results of operations and prospects.

We are dependent on the services of our senior management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon the members of our senior management and clinical development teams. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates, if approved. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services. We do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses. If we are not able to attract, integrate, retain and motivate personnel necessary to accomplish our business objectives, we may experience constraints that significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.

As of September 30, 2026, we had 62 full-time employees. As our development and commercialization plans and strategies develop, and as we continue to operate as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with third parties to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures, and we may not be able to implement improvements in an efficient or timely manner or may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations and prospects.

The manufacturing of our product candidates is complex, and our third-party manufacturers may encounter difficulties in production. If our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain regulatory approval, or provide commercial supply of our products, if approved, could be delayed or halted.

Our product candidates are biopharmaceuticals and the process of manufacturing biopharmaceuticals is complex, time-consuming, highly regulated and subject to multiple risks. Our CMOs must comply with legal requirements, current Good Manufacturing Practices requirements ("cGMPs") and guidelines for the manufacturing of biopharmaceuticals used in clinical trials and, if approved, marketed products. Our CMOs may have limited experience in the manufacturing of cGMP batches of our products.

Manufacturing biopharmaceuticals is highly susceptible to drug product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. The impact of drug product loss is compounded by the long lead times needed to procure additional drug product due to plant capacity limitations or other restrictions at our CMOs. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product liability claims, or other supply disruptions. If microbial, viral or other contaminations are discovered at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely affect our business. Problems in third-party manufacturing process or facilities could restrict our ability to ensure sufficient clinical material for our clinical trials or delay or prevent us from obtaining regulatory approval.

Scaling up a biopharmaceutical manufacturing process is a difficult and uncertain task and involves additional risks, including cost overruns, process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of sufficient quantity of raw materials. Even if we obtain regulatory approval for any of our product candidates, manufacturers may not be able to manufacture the approved product to specifications acceptable to the FDA or

other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our third-party manufacturers are unable to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be a lengthy and expensive process. If our manufacturers are unable to produce sufficient quantities of drug substance and/or drug product for clinical trials or for commercialization we will need to identify and negotiate with other CMOs an agreement for clinical and/or commercial supply, and it is not certain we will be able to come to agreement timely or on terms acceptable to us, which would likely jeopardize our ability to provide any product candidates to study subjects in clinical trials and products to patients, if approved.

Any delay or interruption in clinical trial supplies will likely delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, could require new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, financial condition, results of operations and prospects.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate, proximity to global regions we intend to target or other reasons. Such changes may not achieve their intended objectives, and any of these changes could cause our current or other product candidates to perform differently or affect the results of our future clinical trials. In some circumstances, changes in the manufacturing process require us to perform *ex vivo* comparability studies and to collect additional data from participants prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a clinical trial to the product used in later clinical phases or later portions of the clinical trial. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

We currently have no marketing, sales or distribution capabilities, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing, sales or distribution capabilities or enter into agreements with third parties to perform such activities, we may not be able to generate product revenue.

We currently have no marketing, sales or distribution capabilities, nor have we commercialized a product, and we may need to invest significant resources to develop these capabilities. If we are unable to establish marketing, sales or distribution capabilities or enter into agreements with third parties to perform such activities, we may not be able to generate product revenue. If any of our product candidates ultimately receives regulatory approval, we will be required to build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in the markets that we target, which will be expensive and time-consuming, or to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Furthermore, we are currently developing product candidates for multiple indications in different medical specialties, which will require us to build different sales and marketing capabilities that are tailored to a given product or medical specialty. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. If we are not successful in

commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Revenue from our product candidates, if approved, will be limited if the product does not achieve broad market acceptance.

As a company, we have never commercialized a product candidate for any indication. Even if a product candidate is approved by the appropriate regulatory authorities for marketing and sale, it may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable.

The degree of market acceptance of any of our product candidates will depend on a number of factors, some of which are beyond our control, including:

- the safety, efficacy, tolerability and ease of administration of our product candidates;
- the prevalence and severity of side effects and AEs associated with our product candidates, and how the safety and tolerability profile of our product candidates compares to those of existing or emerging therapies;
- the clinical indications for which the product candidates may be approved and the approved claims that we may make for such products;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings that may be more restrictive than competitive products;
- distribution and use restrictions imposed by the FDA with respect to such product candidates or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- changes in the standard of care for the targeted indications for product candidates;
- cost of treatment as compared to the clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage and reimbursement by third-party payors including government authorities and government healthcare programs, including Medicare and Medicaid, and private health insurance;
- the extent and strength of our marketing and distribution of such product candidates;
- the safety, efficacy and other potential advantages of, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of such product candidates, as well as competitive products;
- the reluctance of physicians to switch their patients' current standard of care;
- the reluctance of patients to switch from their existing therapy regardless of the safety and efficacy of newer products;
- our ability to offer such product candidates for sale at competitive prices;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about our product candidates or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors as to the benefits of our product candidates may require significant resources and may never be successful. Even if the medical community accepts that our product candidates are safe and effective for their approved indications, physicians and patients may not be receptive to such product candidates and may be slow to adopt them as an accepted treatment. If our current or other product candidates are approved, but do not achieve an adequate level of acceptance among physicians, patients and third-party payors, we may not generate meaningful revenue from our product candidates and may never become profitable.

Misconduct or other improper actions, including noncompliance with regulatory standards and requirements, by our employees, independent contractors, consultants, commercial partners and vendors exposes us to potential noncompliance with regulatory standards and requirements.

Fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, vendors and any other third parties we may engage in connection with any research, development, regulatory manufacturing, distribution or marketing activities exposes us to liability. Misconduct by these parties could result from intentional, reckless and/or

negligent conduct or unauthorized activities that violate various laws, including failure to comply with FDA or other regulations, provide true, complete and accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, as will our costs associated with compliance. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct could also involve the improper use of information obtained in the course of clinical trials or creation of fraudulent data in preclinical studies or clinical trials, which could result in regulatory sanctions and serious harm to our reputation, as well as delay or prevent our ability to obtain or maintain regulatory approval for our product candidates.

Additionally, a person could allege fraud or other misconduct even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling known or unknown risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Any such actions instituted against us could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal or administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

Our estimates of commercial opportunities for product candidates and forecasts of market growth may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

We intend to initially focus our product candidate development on treatments for various autoimmune and inflammatory indications. Our projections of addressable patient populations within any particular disease state that may benefit from treatment with our product candidates are based on our estimates. Market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates. Our estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect in general or as to their applicability to our company. Further, new studies or trials may change the estimated incidence or prevalence of these diseases.

Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our commercial opportunity may also be limited by future competitor treatments that enter the market with such patients. If any of our estimates prove to be inaccurate, the commercial opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business. Even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Our future growth may depend, in part, on our ability to commercialize products in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of our product candidates. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our ability to realize the full commercial potential of our product candidates will be harmed. Failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be adversely affected. Moreover, even if we obtain regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different regulatory requirements for approval of drugs in foreign countries;

- reduced protection for intellectual property rights in some foreign countries;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Strategic transactions could impact our liquidity, increase our expenses and present significant distractions to our management.

We may enter into strategic transactions, which could include acquisitions of companies, asset purchases and in-licensing and out-licensing of intellectual property. We have entered into a research and collaboration agreement with Lilly pursuant to which Lilly is advancing TRB-051 in a clinical study for autoimmune and inflammatory diseases. The expected synergies in development programs, pipelines and other areas of focus between us and our licensors and collaborators may not be realized on a timely basis or at all, and there may be risks associated with these transactions that we did not previously anticipate, such as unanticipated liabilities.

We also may enter into a variety of other business arrangements, including strategic collaborations, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our business, financial condition, liquidity and results of operations.

Future acquisitions may require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business or assets may be disruptive, complex, risky and costly and we may never realize the full benefits of the acquisition.

Recent and future changes to tax laws could adversely affect our company.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could adversely affect our company. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, the Inflation Reduction Act of 2022 (the "IRA"), and the One Big Beautiful Bill Act, introduced many significant changes to the United States tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. For example, the IRA includes provisions that will impact the United States federal income taxation of certain corporations, including imposing a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock.

Additionally, the U.S. government may enact other significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, the imposition of minimum taxes or surtaxes on certain types of income, significant changes to the taxation of income derived from international operations, and further limitations on the deductibility of business interest.

We are unable to predict what changes to the tax laws of the United States and other jurisdictions may be proposed or enacted in the future or what effect such changes would have on our business. New, changed, modified, or newly interpreted or applied tax laws could increase our compliance, operating, and other costs. Further, these events could decrease the capital we have available to operate our business. Any of these or similar developments or changes to tax laws or rulings (which changes may apply retroactively) could adversely affect our effective tax rate and our results of operations and financial condition.

If our internal information technology systems, or those used by our CROs, contract development and manufacturing organizations ("CDMOs"), clinical sites or other third parties, are or were compromised, become unavailable or suffer security incidents, loss or leakage of data or other disruptions, we could suffer material adverse consequences, including operational or service interruption, harm to our reputation, litigation, fines, penalties, compromise of sensitive information related to our business and other adverse consequences.

In the ordinary course of our business, we, and the third parties upon which we rely, process sensitive data including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and other sensitive third-party data (collectively, confidential information). We also rely on computer systems, hardware, software, technology infrastructure and online sites and networks for both internal and external operations that are critical to our business (collectively, "IT systems"). We own and manage some of these IT systems but also rely on third parties for a range of IT systems and related products and services, including cloud computing services.

Our IT systems and those of our CROs, CDMOs, clinical sites and other contractors and consultants, and the confidential information within these systems, are vulnerable to cyberattacks, computer viruses, bugs, worms, or other malicious codes, malware (including as a result of advanced persistent threat intrusions) and other attacks by computer hackers, cracking, application security attacks, social engineering (including through phishing attacks), supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks (such as credential stuffing), credential harvesting, ransomware attacks, personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods and other similar threats.

Such threats are prevalent and continue to rise, are increasingly difficult to detect and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), AI-driven bots, sophisticated nation states and nation-state-supported actors. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of confidential information, loss of income, significant extra expenses to restore IT systems or confidential information, reputational loss and the diversion of funds. To alleviate the negative impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments, or our insurance carrier objects to payment).

Some actors, including nation-state actors, also engage in cyber-attacks for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely are vulnerable to a heightened risk of these attacks, including cyber-attacks, that could materially disrupt our systems and operations, supply chain, critical infrastructure, and ability to conduct our development activities, including clinical trials. Nation-state weapons may also impact us even if we are not targeted. In addition to experiencing a security incident, third parties may gather, collect or infer sensitive information about us from public sources or other means that reveals competitively sensitive details about our organization and could be used against us.

Additionally, remote work increases risks to our IT systems and confidential information, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. We may be vulnerable to attacks as a result of vulnerabilities introduced through our supply chain, including vendors we engage to provide us with security and other technologies, or to the critical infrastructure that supports communications, transportation, and payments.

Furthermore, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities present in acquired or integrated entities' systems and technologies, including security issues that are not identified during due diligence. Additionally, it may be difficult to integrate companies into our IT systems and security program.

We may not be able to detect and remediate all vulnerabilities and the threats and techniques used to exploit such vulnerabilities change frequently and are often sophisticated in nature. AI-driven cyber-attackers may be able to create, find, or exploit vulnerabilities faster than our systems can respond, even if our defenses are also using AI-driven systems. Therefore, vulnerabilities could be exploited but may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

We rely on third-party service providers and technologies to operate critical business systems to process confidential information in a variety of contexts, including cloud-based infrastructure, encryption and authentication technology, employee email and other functions. We also rely on third-party service providers to assist with our clinical trials, provide other products or services or otherwise to operate our business. Our ability to perform diligence on or monitor third parties' information security practices is limited, and third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us,

any award may be insufficient to cover our damages, insurance may not be available, or we may be unable to recover such award. If the IT systems of our CROs, CDMOs, clinical sites and other contractors and consultants become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our IT systems (including our services) or the third-party IT systems that support us.

A security incident or other interruption could result in unauthorized, unlawful or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our confidential information or our IT systems, or those of the third parties upon whom we rely, any of which could disrupt our ability (and that of third parties upon whom we rely) to advance clinical development or commercial activities for any products, if approved. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in our regulatory approval efforts, significantly increase our costs to recover or reproduce the data or limit our ability to effectively execute a product recall, if required. In addition, we could incur liability if any disruption or security incident results in the loss of or damage to our confidential information or applications. Applicable data privacy and security obligations also may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. A disruption or security incident could result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, damage to our reputation or a loss of confidence in us and our ability to conduct clinical trials, and/or significant incident response, system restoration or remediation and future compliance costs, which could delay the clinical development of our product candidates. Any or all of the foregoing could materially adversely affect our business, results of operations, and financial condition. Finally, we cannot guarantee that any costs and liabilities incurred in relation to an attack or incident will be covered by our existing insurance policies or that applicable insurance will be available to us in the future on economically reasonable terms or at all.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could adversely affect our business, financial condition, results of operations and prospects.

As we conduct clinical trials of our current or other product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of new therapies. Product liability claims could delay or prevent completion of our development programs. If we succeed in obtaining approval to market any product candidate, product liability claims could result in FDA or other investigation of the safety and effectiveness of our other product candidates, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product candidates, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants or inability to enroll participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize any products that we may develop, and a decline in our stock price. We may require higher levels of product liability insurance for later stages of clinical development or marketing any of our product candidates, and our insurance may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could adversely affect our business, financial condition, results of operations and prospects.

Public opinion and scrutiny of autoimmune and inflammatory disease treatments may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business and our business plans.

Public perception may be influenced by claims, such as claims that our product candidates are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to autoimmune and inflammatory disease treatments in general could result in greater government regulation and stricter labeling requirements of products to treat autoimmune and inflammatory diseases, including any of our product candidates, if approved, and could cause a decrease in the demand for any product candidates we may develop. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. AEs in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in withdrawal of clinical trial participants or impact our ability to enroll participants or lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. More restrictive government regulations or negative public opinion could have an adverse effect on our business, financial condition,

results of operations and prospects, and may delay or impair the development and, if approved, commercialization of our product candidates or demand for any products we may develop.

We or the third parties upon whom we depend may be adversely affected by earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

If earthquakes, fires, other natural disasters, terrorism and similar events beyond our control prevent us from using all or a significant portion of our headquarters or other facilities, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which could have a material adverse effect on our business. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical manufacturing and distribution industry in particular are unclear, and changes in the supply, demand or available sources of energy and the regulatory and other costs associated with energy production and delivery may affect the availability or cost of goods and services, including raw materials and other natural resources, necessary to run our business. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business.

Risks Related to Government Regulation

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we or our existing or future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and adverse event reporting, storage, import, export, advertising, promotion and record keeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information, to require post-market studies or clinical trials to evaluate safety risks related to the use of a product, or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, including biologics. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory authorities, including for continued compliance with cGMPs. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. We will not have complete control over compliance with applicable rules and regulations by such manufacturers.

The FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of products to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. Although physicians are generally permitted, based on their medical judgment, to prescribe products for indications other than those approved by the applicable regulatory agency, manufacturers are prohibited from promoting their products for such off-label uses. If we promote our products in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action, including issuance of a warning or untitled letter, injunction, seizure, and significant fines and criminal penalties. The United States federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Even if it is later determined we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions, and have to divert significant management resources from other matters.

The failure by us or our collaborators to comply with applicable regulatory requirements in the United States or foreign jurisdictions in which we seek to market our product candidates may result in, among other things, fines, warning or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA or comparable foreign regulatory authorities to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution. The occurrence of any such event or penalty may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response, and could generate negative publicity.

Moreover, the FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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 be subject to enforcement action and we may not achieve or sustain profitability.

Disruptions at the FDA and other government agencies, including as a result of funding shortages or staffing limitations, could hinder their ability to hire, retain or deploy key leadership and other personnel or otherwise prevent product candidates from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and applicable foreign authorities to review and approve new product candidates can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees and statutory, regulatory and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies 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 drugs to be reviewed and approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government shut down several times and certain regulatory agencies, such as the FDA, furloughed or laid off critical employees and ceased critical activities. Additionally, the current U.S. presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with administrative agencies, including the FDA, which have led to substantial personnel changes, and it remains unclear the degree to which these efforts or the resulting changes in FDA personnel may limit or otherwise adversely affect the FDA's ability to conduct routine activities. If a prolonged government shutdown occurs, or if funding shortages or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, such events could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain regulatory approval for and commercialize our product candidates and may affect the prices we set.

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare and containing or lowering the cost of healthcare. For example, in March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the "Affordable Care Act" or "ACA"), which, among other things, expanded health care coverage through Medicaid expansion and included a number of changes to the coverage and reimbursement of drug products under government healthcare programs.

Other health care reform initiatives, including legislative, administrative and executive actions, have taken place in the United States since the Affordable Care Act was enacted. A number of changes have focused on drug pricing and payment. For example, changes to Medicaid effective in 2024 eliminated the statutory cap on drug manufacturers' Medicaid drug rebate liability and changes to certain Medicare price reporting requirements for drugs beginning in 2026 will likely increase the administrative and compliance burden for manufacturers. More broadly, the IRA includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the Affordable Care Act Medicare Part D coverage gap discount program) and a drug price negotiation program for certain high spend Medicare Part B and D drugs (with negotiated prices for the first set of drugs taking effect in 2026). The IRA has had and will likely continue to have significant impact on the pharmaceutical industry.

In April 2025, President Trump issued an Executive Order with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying

prescription drugs as over-the-counter drugs; and increasing drug importation. In May 2025, President Trump issued another executive order that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients); prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the United States; and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. In the wake of the executive orders and related executive initiatives, a number of pharmaceutical manufacturers announced direct-to-consumer offerings with discounted prices and/or reached agreement with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. A website sponsored by the federal government that offers pharmaceutical direct-to-consumer channels has also been launched. Federal agencies are developing new drug pricing pilot programs, such as a voluntary Medicaid initiative which would authorize the federal government to negotiate Medicaid supplemental rebates with participating manufacturers on behalf of state Medicaid programs, in exchange for standardized coverage criteria for participating manufacturer drugs, and proposed Medicare Part B and Part D pilot models that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model. Many of these reform initiatives would require additional legal and/or administrative action to implement and may be subject to legal challenge.

Other federal healthcare reform efforts or actions may affect access to healthcare coverage or the funding of health care benefits, although the full impact of such efforts or actions cannot be predicted. For example, the One Big Beautiful Bill Act of 2025 imposed significant reductions in Medicaid funding, additional work requirements for certain Medicaid beneficiaries and more frequent eligibility redeterminations. These changes are expected to place increased pressure on state Medicaid budgets and could reduce enrollment, utilization and reimbursement levels for prescription drugs, including our products, which could adversely affect our business.

Other more general federal government actions may also affect prices or payments for prescription drugs. For example, federal legislation passed in early 2026 is intended to reform the pharmacy benefit manager industry by restricting compensation and requiring greater transparency and is anticipated to have an impact on drug pricing and market access. As another example, President Trump issued an executive order in April 2026 to establish a tariff framework for certain patented pharmaceuticals and associated pharmaceutical ingredients, with some tariffs taking effect as early as July 31, 2026. As yet another example, the Budget Control Act, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 that remain in effect through 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Some measures are designed to encourage importation from other countries and bulk purchasing. These types of initiatives may result in additional reductions in healthcare funding, and may otherwise affect the prices we may obtain for our product candidates, if approved. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition, and prospects. In addition, hospitals and health systems are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition, and prospects.

Health care reform initiatives at the federal or state level could affect demand for, or pricing of, our current or other product candidates if approved for sale. Healthcare reform efforts have been and may continue to be subject to scrutiny, legal challenge and subsequent amendment, creating further uncertainty. We cannot, however, predict the ultimate content, timing or effect of any federal and state reform efforts. Federal or state health care reform may adversely affect our future business and financial results.

If we fail to comply with healthcare and other regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

Our business operations, including our interactions with healthcare professionals and other healthcare providers, third-party payors, patients and other third-parties in the healthcare industry are or may in the future be subject to a wide range of federal and state healthcare laws and regulations that may constrain our business and/or financial arrangements, including how we research, market, sell and distribute our product candidates, if approved. Restrictions under applicable federal and state

healthcare laws and regulations, some of which will apply only if and when we receive regulatory approval for a product candidate, include the following:

- federal healthcare program Anti-Kickback Statute, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for an item or service or the purchasing, ordering or recommending of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. 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;
- federal false claims, false statements and civil monetary penalties laws which prohibit, among other activities, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement material to an obligation to pay money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements to obtain money or property from a health benefit program. 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 Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to calculate, certify, and report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called "federal sunshine" law, which requires certain pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians (as defined by statute), certain non-physician healthcare practitioners (such as physician assistants and nurse practitioners) and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members to the federal government for re-disclosure to the public;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and
- analogous state and foreign laws and regulations, such as state anti-bribery, anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers;
- state laws that require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to healthcare providers or marketing expenditures; state laws that require pharmaceutical companies to file reports relating to pricing and marketing information, and state and local laws may require registration of pharmaceutical sales representatives; and other state laws that require licensure for, or otherwise regulate, the manufacture and distribution of, pharmaceutical products.

Efforts to ensure that our business arrangements with third-parties comply with applicable healthcare laws and regulations will involve substantial costs. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including significant civil, criminal and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and

prospects. Further, defending against any such actions can be costly, time consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

The U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* 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 guidance issued by federal agencies, including FDA and the Center for Medicare & Medicaid Services, 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 action or as a result of legal challenges, either in the United States or abroad. 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, our business could be materially harmed.

We are and in the future may be subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, and policies related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; 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.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process or processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, employee data, intellectual property, data we collect about trial participants in connection with clinical trials, and other sensitive third-party data (collectively, sensitive data). We also depend on a number of third-party vendors in relation to the operation of our business, including our CROs, CDMOs and other service providers, a number of which process sensitive data on our behalf.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements, regulations, industry standards, privacy policies, contractual requirements, and other obligations governing the collection, use, disclosure, retention, and security of sensitive data, such as information that we may collect in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business.

For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information from third parties, such as research institutions with which we collaborate, that are subject to privacy and security requirements under HIPAA. Although we do not believe that we are directly subject to HIPAA, other than potentially with respect to providing certain employee benefits, we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA. Additionally, the California Consumer Privacy Act ("CCPA") applies to personal information of California consumers, business representatives, and employees, and among other things requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, including the right to opt out of certain disclosures of their information. At least 19 other states have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these state privacy laws, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self- regulatory standards that may place additional burdens on us.

In addition, the U.S. Department of Justice "Data Security Program" regulations issued pursuant to Executive Order 14117, "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern," restrict, and in some cases prohibit, data transfers involving countries of concern or covered persons, including the People's Republic of China (including Hong Kong and Macau), Russia, Iran, North Korea, Cuba and Venezuela that involve certain U.S. government-related data and bulk human 'omic, geolocation, biometric, health, financial, and other sensitive personal data. The Data Security Program applies even to data that has been de-identified, anonymized or encrypted. Entities organized under the laws of the United States as well as U.S. persons are restricted in their ability to provide access to such data to such countries as well as "covered persons" that have certain nexuses to such countries, and they are also required to prohibit foreign parties from making an "onward transfer" of such data to countries of concern and covered persons. These restrictions may inhibit or preclude our ability to fully realize the value of such data, to use such data effectively or efficiently, or to engage in some data transactions that would otherwise be available to entities not subject to the Data Security Program. Compliance with the Data Security Program may require us to invest heavily in data security and compliance measures, such as implementing and complying with the Cybersecurity and Infrastructure Security Agency's guidelines and other burdensome

recordkeeping, reporting, and auditing requirements. It may also require us to implement new processes, stop or restrict certain data transfers, alter the geographic scope of our operations, cease doing business with certain third parties or using certain tools or vendors, or change how data flows throughout our business, any of which could materially impact our business operations or hinder our ability to grow our business. Non-compliance with the Data Security Program could result in significant civil or criminal penalties, which could materially adversely affect our business, results of operations, and financial condition.

There are also various laws and regulations in other jurisdictions outside the United States relating to data privacy and security, with which we may need to comply. For example, the EU GDPR and the UK's equivalent ("UK GDPR" and collectively, "GDPR"), impose strict requirements for processing personal data. Notably, the EU GDPR and UK GDPR impose large penalties for noncompliance, including the potential for fines of up to €20 million under the EU GDPR / £17.5 million under the UK GDPR, or 4% of the annual global revenue of the noncompliant entity, whichever is greater. The EU GDPR and UK GDPR also provide for private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Additionally, EU member states and other jurisdictions may introduce further conditions, including limitations, and make their own laws and regulations further limiting the processing of special categories of personal data, including personal data related to health, biometric data used for unique identification purposes and genetic information, which could limit our ability to collect, use and share data from the EU and other jurisdictions, and could cause our compliance costs to increase, ultimately adversely affecting our business, financial condition, results of operations and prospects.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the UK have significantly restricted the transfer of personal data to countries whose privacy laws it believes are inadequate. Case law from the Court of Justice of the European Union ("CJEU"), however, states that reliance on the standard contractual clauses-a standard form of contract approved by the European Commission as an adequate personal information transfer mechanism-alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. In October 2022, President Biden signed an Executive Order that introduced new mechanisms and safeguards to address the concerns raised by the CJEU in relation to data transfers from the EEA to the United States and which formed the basis of the new EU-US Data Privacy Framework (and corresponding UK data protection framework, collectively the "DPF"), as released on December 13, 2022. The European Commission adoption of its Adequacy Decision means the DPF is effective as an EU GDPR transfer mechanism to U.S. entities self-certified under the DPF. While we have certified as a participant in the DPF, we cannot guarantee that the validity of the DPF will not undergo further legal challenge as occurred with previous transfer mechanisms like the EU/US Privacy Shield.

Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses and the recently approved DPF, these mechanisms are subject to legal challenges, and we may not satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

Each of these laws, rules, regulations and contractual obligations relating to data privacy and security, and any other such changes or new laws, rules, regulations or contractual obligations could impose significant limitations, require changes to our business, or restrict our collection, use, storage or processing of sensitive data, which may increase our compliance expenses and make our business more costly or less efficient to conduct. In addition, any such changes could compromise our ability to develop an adequate marketing strategy and pursue our growth strategy effectively or even prevent us from providing certain products in jurisdictions in which we currently operate and in which we may operate in the future or incur potential liability in an effort to comply with such legislation, which, in turn, could adversely affect our business, financial condition, results of operations and prospects. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any data privacy or security laws, whether by us, one of our CROs or CDMOs, or another third party, could adversely affect our business, financial condition, results of operations and prospects, including but not limited to: investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent

orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; reputational damage; and injunctive relief. The implementation of the CCPA, GDPR and other similar laws have increased our responsibility and liability in relation to sensitive data that we process and we may in the future be required to put in place additional mechanisms to ensure compliance with these and other applicable laws and regulations, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

Any actual or perceived failure by us or our third-party service providers to comply with any federal, state or foreign laws, rules, regulations, regulatory guidance, orders to which we may be subject or other legal obligations relating to privacy, data protection, data security could adversely affect our reputation, brand and business. We may also be contractually required to indemnify and hold harmless third parties from the costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure of sensitive data that we store or handle as part of operating our business. Any of these events could adversely affect 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 sensitive data 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 substantial changes to our business model or operations.

Our CROs, CDMOs or other third-party service providers with access to our or our suppliers', manufacturers', trial participants' and employees' sensitive data for which we are responsible may breach contractual obligations imposed by us, or they may experience data security incidents, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, financial condition, results of operations and prospects. Our contractual measures and our own privacy and security-related safeguards may not protect us from the risks associated with the third-party processing of such information. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

We also publicly post our privacy policies and practices concerning our collection, use, disclosure and other processing of the personal information provided to us by our website visitors and by our customers. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be perceived to have failed to do so. Our publication of our privacy policies and other statements we publish that provide promises and assurances about privacy and security can subject us to potential state and federal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any actual or perceived failure by us to comply with federal, state or foreign laws, rules or regulations, industry standards, contractual or other legal obligations, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of personal information or other data, may result in enforcement actions and prosecutions, private litigation, significant fines, penalties and censure, claims for damages by customers and other affected individuals, regulatory inquiries and investigations or adverse publicity and could cause our customers to lose trust in us, any of which could adversely affect our business, financial condition, results of operations and prospects.

Our contracts may not contain limitations of liability, and even where they do, the limitations of liability in our contracts may not be sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Further, the successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

We do not own or operate and currently have no plans to establish any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. Currently, several of our suppliers are located outside of the United States. We also rely on specialized laboratory equipment, supplies and materials, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts.

Current or future tariffs could result in increased research and development expenses, including with respect to increased costs associated with active pharmaceutical ingredients, raw materials, laboratory equipment and research materials and components. In addition, such tariffs could increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating entirely domestically or in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, results of operations and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions or

deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this Quarterly Report.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Our Reliance on Third Parties

We rely, and expect to continue to rely, on third parties, including independent clinical investigators, contracted laboratories and CROs, to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We rely and intend to continue to rely on third-party clinical investigators, CROs and clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current and other product candidates. Because of this reliance, we have less control over the timing, quality and other aspects of preclinical studies and clinical trials than if we conduct them ourselves. Third parties are not our employees and we have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties have contractual relationships with other entities, some of which may be our competitors, which may divert time and resources from our programs.

Our reliance on third parties reduces our control over our development activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards. For example, we remain responsible for ensuring that certain of our preclinical studies are conducted in accordance with GLPs, and clinical trials are conducted in accordance with GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once a BLA is submitted to the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CROs. If we, our CROs, clinical trial sites or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If our third party contractors do not successfully carry out their contractual duties, meet deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed or terminated, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding contractors involves cost, takes time and diverts management's attention. In addition, there is a natural transition period when a new third party commences work. Delays could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely,

which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. We may be required to report some of these relationships to the FDA, and the FDA may conclude that a financial relationship between us and/or a principal investigator has created a conflict of interest or otherwise affects interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

We currently rely and expect to rely in the future on third parties to manufacture our product candidates, and we may rely on third parties to produce and process our products, if approved. Our business could be adversely affected if the third-party manufacturers encounter difficulties in production.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing and must currently rely on CMOs to manufacture our product candidates. We have not yet caused our product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved. We currently have sole source relationships for our supply of TRB-061 and TRB-071. If there should be any disruption in such supply arrangement, including any adverse events affecting our sole suppliers, it could have a negative effect on the clinical development of our product candidates and other operations while we work to qualify an alternate supply source. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or comparable foreign regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have no control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and materially adversely affect our ability to develop, obtain regulatory approval for or market our programs, if approved. Similarly, our failure, or the failure of our CMOs, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of programs or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our programs or drugs and harm our business and results of operations.

Moreover, our CMOs may experience manufacturing difficulties due to resource constraints, supply chain issues, or as a result of labor disputes or unstable political environments. If any CMOs on which we will rely fail to manufacture quantities of our programs at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected. In addition, our CMOs are responsible for transporting temperature-controlled materials that can be inadvertently degraded during transport due to several factors, rendering certain batches unsuitable for trial use for failure to meet, among others, our integrity and purity specifications. We and any of our CMOs may also face product seizure or detention or refusal to permit the import or export of products. Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our anticipated timelines, potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the completion of our preclinical studies and clinical trials or the approval of any of our programs by the FDA, result in higher costs or adversely impact commercialization of our product candidates.

We may have conflicts with our current or future licensors or collaborators that could delay or prevent the development or commercialization of our product candidates.

We are currently party to license and collaboration agreements, and we expect to enter into similar strategic transactions in the future. Our current or any future collaborators may act in a manner that is adverse to our best interests and our interests may conflict with theirs, including concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. Any disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenue: disputes regarding milestone payments or royalties; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of a product candidate, including providing us with data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and

commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights related to our product candidates, or data from third parties, we could lose such rights that are important to our business.

Our licensors may have relied upon, and any future licensors may rely upon, third-party companies, consultants or collaborators, or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize our current or other product candidates that are or may be the subject of such licensed rights could be adversely affected. Further development and commercialization of our product candidates and development of any other product candidates may require us to enter into additional license or collaboration agreements. Our future licenses may not provide us with exclusive rights to use the licensed patent rights and other intellectual property licensed thereunder or may not provide us with exclusive rights to use such patent rights and intellectual property in all relevant fields of use and in all territories in which we wish to develop or commercialize our current or other product candidates.

In spite of our efforts, our licensors or any future licensors might conclude that we are in material breach of obligations under our license agreements and may therefore have the right to terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by such license agreements. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors would have the freedom to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in-licenses could prevent us from developing or commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses and compete with our existing product candidates. Any of these events could adversely affect our business, financial condition, results of operations, and prospects.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- the extent to which our processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- the inventorship or 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
- the priority of invention of patented technology.

In addition, our license agreements are, and future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could adversely affect our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could adversely affect our business, financial condition, results of operations, and prospects.

The operations of our suppliers, some of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

Currently, certain of our suppliers primarily operate outside of the United States. As a result, we are subject to risks associated with doing business abroad, including:

- geopolitical tensions, political unrest, terrorism, labor disputes and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions and safety standards, information and data transfer, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA or comparable foreign regulatory authorities;
- reduced protection for intellectual property rights, including trade secret protection, in some countries;
- disruptions in operations due to global, regional, or local epidemics, pandemics and other public health crises, or other emergencies or natural disasters;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all and inhibit our suppliers' ability to procure certain materials, any of which could delay our clinical trials or otherwise harm our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates or any other product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely impacted.

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our product candidates and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidates and their uses, as well as our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others. We seek to protect our proprietary position by filing and licensing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. Our pending and future patent applications may not result in patents being issued. Issued patents may not afford sufficient protection of our product candidates or their intended uses against competitors, and the patents issued may be infringed, designed around, invalidated by third parties, or may not effectively prevent others from unauthorized use, unauthorized reverse engineering, or otherwise commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to obtain patents and to enforce patent rights in the future. As a

result, the issuance, scope, validity, enforceability and commercial value of any patent rights are highly uncertain. Our pending and future owned and in-licensed patent applications may not result in patents being issued which protect our product candidates, effectively prevent others from commercializing our product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. The coverage claimed in a patent application can also be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. For example, the legal systems of certain countries, particularly China and certain other developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology.

The patent application process is subject to numerous risks and uncertainties, and we may not be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own or our licensors' patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our or our licensors' patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our or our licensors' pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our or our licensors' pending patent applications may be subject to third-party pre-issuance submissions of prior art to the United States Patent and Trademark Office ("USPTO") or our issued patents may be subject to post-grant review proceedings, oppositions, derivations, reexaminations, interferences, *inter partes* review proceedings or other similar proceedings, in the United States or elsewhere, challenging our or our licensors' patent rights or the patent rights of others. In some cases, such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one or more of our owned or licensed pending patent applications. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

A third party may also claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any legal proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our technology, products or product candidates without infringing third-party patent rights.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could adversely affect our business, financial condition, results of operations and prospects.

We may not obtain or maintain necessary rights to our product candidates through acquisitions and in-licenses.

The growth of our business depends in part on our ability to acquire, in-license, or use third-party proprietary rights, and we may not be able to do so on commercially reasonable terms or at all. Licenses may be on nonexclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, or could require us to make substantial licensing and royalty payments. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources or greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or

maintain the existing intellectual property rights we have obtained, we may have to abandon development of the relevant program or product candidate, which could adversely affect our business, financial condition, results of operations, and prospects.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our licensors or collaboration partners. If any of our current or future licensors or collaboration partners fails to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Patent rights relating to inventions described and claimed in our or our licensors' pending patent applications may not issue and patents based on our or our licensors' patent applications could be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and we, our licensors, or any of our potential future collaborators may not be successful in protecting our product candidates by obtaining and defending patents. We and our licensors have several pending U.S. and foreign patent applications in our portfolio. We cannot predict:

- if and when patents may issue based on our and our licensors' patent applications;
- the scope of protection of any patent issuing based on our and our licensors' patent applications;
- whether the claims of any patent issuing based on our and our licensors' patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our and our licensors' patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our and our licensors' patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our and our licensors' patent rights which will be costly whether we win or lose;
- whether the patent applications that we own will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries; or
- whether we may experience patent office interruption or delays to our ability to timely secure patent coverage to our product candidates due to global pandemics and epidemics.

The claims in our or our licensors' pending patent applications directed to our product candidates may not be considered patentable by the USPTO or by patent offices in foreign countries, and any such patent applications may not issue as granted patents. One aspect of the determination of patentability of our and our licensors' inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our or our licensors' patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our or our licensors' patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. For example, there may be prior art not considered by the patent office that is raised by a third party to challenge the validity of any patents that issue from our or our licensors' patent applications. Furthermore, even if they are unchallenged, patents in our and our licensors' portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

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

Patents are of national or regional effect. Filing, prosecuting and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive, and our and our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. 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 United States, 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 United States, even in jurisdictions where we or our licensors do pursue patent protection, or from selling or importing products made using our or our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our or our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with our product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our proprietary rights.

Various countries outside the United States 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. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we or our licensors 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. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our product candidates. While we will endeavor to try to protect our product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and unpredictable.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the pending patent applications that we own or the patents or patent applications that we license;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing or otherwise violating our owned or licensed intellectual property rights;
- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we either own or have exclusively licensed may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;

- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our and our licensors' patent applications, including whether the patent applications that we own, presently in-license, or, in the future, in-license will result in issued patents with claims that are directed to our product candidates or uses thereof in the United States or in other foreign countries;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents, if they issue in the future, are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent applications.

Should any of these or similar events occur, they could significantly harm our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we or one of our licensing partners may file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our or our licensors' pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents or our licensors' patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours or our licensors is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our or our licensors' patent claims do not cover the invention, or decide that the other party's use of our or our licensors' patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our or our licensors' patents could limit our ability to assert our or our licensors' patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive position, business, financial condition, results of operations or prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks

we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also 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 adversely affect the price of shares of our common stock. Moreover, we may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in- license needed technologies or other product candidates or enter into development partnerships that would help us bring our product candidates to market.

We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Intellectual property rights of third parties could adversely affect our ability to commercialize our current or other product candidates, and we, our licensors or collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or obtain licenses from third parties in order to develop or market our current or other product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Our commercial success depends on our ability to develop, manufacture, market and sell our product candidates without infringing, misappropriating or otherwise violating the valid intellectual property and other proprietary rights of third parties. Identifying third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments which could adversely affect the market price of our common stock and harm our reputation. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property

portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely affect our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. We cannot be certain that our product candidates will not infringe existing or future valid patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of their merit. We may decide in the future to seek a license to such third-party patents or other intellectual property rights, but we might not be able to do so on reasonable terms. Proving patent invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. As this burden is a high one, a court of competent jurisdiction may not invalidate the claims of any such United States patent or find that our product candidates do not infringe any such claims. If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing technology or product candidate. Further, we may be required to redesign the technology or product candidate in a non-infringing manner, which may not be commercially feasible. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. In addition, 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 our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may choose to challenge the enforceability or validity of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex-parte* reexamination, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office ("EPO"), or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates. Further, third-party patents or other intellectual property rights may be enforced against our current technology, including our research programs, product candidates, and their respective methods of use, manufacture and formulations thereof, which could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the United States, numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology, products and enforce our intellectual property rights. Subsequent rulings may adversely impact our patents or patent applications. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once granted.

Depending on decisions by the U.S. Congress, the federal courts and the USPTO, and similar legislative and regulatory bodies in other countries in which we may pursue patent protection, the laws and regulations governing patents could change in unpredictable ways, particularly with respect to pharmaceutical patent protection, that would weaken our ability to obtain new patents or to enforce our or our licensors' or collaborators' existing patents and patents that we might obtain in the future.

We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

In 2012, the European Union Patent Package (the "EU Patent Package") regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court ("UPC") for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC, unless otherwise opted out. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our owned or licensed European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our owned or licensed future European patents from the UPC but doing so may preclude us from realizing the benefits of the UPC. Moreover, if the patent owner of our owned or licensed future European patents do not meet all of the formalities and requirements for opt-out under the UPC, said future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our owned or licensed European patents and allow for the possibility of a competitor to obtain a pan-European injunction in UPC member states. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and any other product candidates due to increased competition and, resultantly, on our business, financial condition, results of operations and prospects in Europe. The UPC and Unitary Patent are significant changes 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 in the UPC.

We may become subject to claims challenging the inventorship or ownership of our or our licensors' patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our or our licensors' patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could adversely affect our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the

ownership of what we regard as our intellectual property. Such claims could adversely affect our business, financial condition, results of operations, and prospects.

Patent terms may be inadequate to protect our competitive position on products or product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products or product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of products or new product candidates, patents protecting such products or candidates might expire before or shortly after such products or candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient and continuing rights to exclude others from commercializing products similar or identical to ours. For example, the patents covering TRB-061 and TRB-071's composition of matter expire in September 2044 and June 2046, respectively, excluding any extension of patent term that may be available.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated as a result of noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and patent applications. We rely on our outside counsel or our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could adversely affect our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA approval of any of our product candidates, one or more of our or our licensors' issued U.S. patents or issued U.S. patents that we may own in the future may be eligible for limited patent term extension ("PTE") under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"), which permit a PTE of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate. However, we may not be granted any extensions for which we apply because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

If approved, our product candidates that are regulated as biological products ("biologics"), may face competition from biosimilars approved through an abbreviated regulatory pathway.

Regulatory authorities in some jurisdictions, including the U.S. and Europe, allow for abbreviated approval processes for generic and/or biosimilar products. In the United States, the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") was enacted as part of the ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable with an FDA-licensed reference biologic product. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic. Under the BPCIA the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop

and receive approval of a competing biologic using that company's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product, so long as their BLA does not rely on the reference product or sponsor's data or submit the application as a biosimilar application. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty, and any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidate to be a reference product for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. For example, in recent years, the FDA has sought to reduce the data required for biosimilar product sponsors to demonstrate biosimilarity to, or interchangeability with, a biologic reference product.

The approval of a biosimilar of our product candidates could have a material adverse impact on our business due to increased competition and pricing pressure. If competitors are able to obtain regulatory approval for biosimilars referencing our product candidates, our product candidates may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Laws and regulations outside the United States differ, including the length and extent of patent and exclusivity protection and pathways for competition to enter the market. Other countries may have significantly shorter or longer periods of exclusivity. In addition, other countries may have different standards in determining similarity to a reference product. Any market entry of competing products to our product candidates in these other regions could adversely affect our business in those regions. To the extent that we do not receive any anticipated periods of regulatory exclusivity for our product candidates it could adversely affect our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know-how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially viable terms, then we may not be able to launch our product candidate. Additionally, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets, and the criteria for protection of trade secrets can vary among different jurisdictions. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, our trade secrets and other confidential proprietary information could be disclosed or competitors could otherwise gain access to our trade secrets.

We try to protect the confidential nature of our proprietary information by maintaining physical security of our premises and electronic security of our information technology systems. Our security measures may not prevent an employee, consultant or other third party from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copyor reverse engineer certain aspects of our products or services that we consider proprietary. Enforcing aclaim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. If the steps we have taken to maintain our trade secrets are deemed inadequate,we may have insufficient recourse against third parties for misappropriating the trade secret. If any of our intellectual property rights or confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our

applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark.

Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

We may be subject to claims asserting that our employees, consultants, advisors or other third parties have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants, advisors or other third parties have in the past and may in the future be employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our product candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which could adversely affect our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, former employees, consultants, advisors or other third parties may assert an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our product candidates. Such challenges may also result in our inability to develop, manufacture or commercialize our product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or other product candidates. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

Rights to improvements to our product candidates may be held by third parties.

In the course of testing our current or other product candidates, we have entered and may enter into agreements with third parties to conduct clinical testing, which do and may provide that improvements to our product candidates may be owned solely by a third party or jointly between the parties. If we determine that rights to such improvements owned solely by a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing the product

candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby potentially giving our competitors and other third parties access to the same technologies licensed to us. Failure to obtain a license on commercially reasonable terms or at all, or to obtain an exclusive license, could prevent us from commercializing our current or other product candidates or force us to cease some of our business operations, which could materially harm our business. If we determine that rights to improvements jointly owned between us and a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such improvements, such co-owners may be able to license their rights to other parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our intellectual property in order to enforce such intellectual property against other parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our intellectual property licensed from third parties may be subject to retained rights.

Our future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

Government agencies may provide funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property. The United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses could result in the loss of significant rights and could harm our ability to commercialize licensed products. Co-developed intellectual property may be subject to government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

Risks Related to Ownership of Our Common Stock

An active and liquid trading market for our common stock may not be sustained.

Our common stock is listed on The Nasdaq Global Select Market under the symbol "TRXB." If an active or liquid trading market for our common stock is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall. Furthermore, an inactive market may reduce the fair market value of your shares, impair our ability to raise capital by selling shares of our common stock in the future, and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

The market price of our common stock may be volatile, which could result in substantial losses for investors.

Since shares of our common stock were sold in our IPO in October 2026 at a price of $14.00 per share and through October 31, 2026, the per share price of our common stock has ranged from $13.10 to $16.56. Some of the factors that may cause the market price of our common stock to fluctuate include:

- volatility in our operating results or the failure of our operating results to meet the expectations of investors or securities analysts;
- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical and clinical studies for any product candidates that we may develop;
- failure or discontinuation of any of our product development and research programs;
- our failure to commercialize our product candidates;
- the success of the development of companion diagnostics, if required, for use with our product candidates;

- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs or product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- announcement or expectation of additional financing efforts;
- sales or perceived potential sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreements;
- any changes to our relationship with manufacturers, suppliers, collaborators or other strategic partners;
- manufacturing or supply shortages;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- press reports, whether or not true, about our business;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- changes in the structure of healthcare payment systems;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- the inability to obtain additional funding;
- market conditions in the pharmaceutical and biotechnology sectors;
- general global economic, industry, political and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control; and
- the other factors described in this “Risk Factors” section and elsewhere in this Quarterly Report, including those which are outside of our control.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. The market price of our common stock may decline, and you may lose some or all of your investment. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future.

A significant portion of our total outstanding shares is restricted from immediate resale but may be sold into the market upon expiration of the lock-up agreement entered into in connection with our IPO, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales upon the expiration of the lock-up agreements entered into by holders of substantially all of our common stock outstanding immediately prior to our IPO, the early release of the lock-ups, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of November 5, 2026,

we had 28,788,654 shares of common stock outstanding. Of these shares, the 9,539,237 shares we sold in our IPO may be resold in the public market immediately, unless held by our affiliates. The remaining shares are currently restricted under securities laws or as a result of lock-up or other agreements, subject in some cases to applicable volume limitations under Rule 144 beginning after the close of trading on April 6, 2027.

Moreover, holders of an aggregate of 17,541,654 shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also registered all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements entered into in connection with our IPO. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Insiders have substantial influence over us, which could limit your ability to affect the outcome of key transactions, including a change of control.

As of October 31, 2026, our directors, executive officers and greater than 5% stockholders and their affiliates, in the aggregate, beneficially owned shares representing approximately 54.6% of our outstanding common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. The interests of these holders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of our other stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our common stock in the foreseeable future.

We are an emerging growth company ("EGC") and a smaller reporting company, and the reduced reporting requirements applicable to EGCs and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and we may remain an emerging growth company until December 31, 2031. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. In our annual report on Form 10-K and in our periodic reports, we will not include all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period, or (ii) no longer qualify as an emerging growth company. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934, (as amended, the "Exchange Act"). We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250.0 million

measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Provisions in our Fourth Amended and Restated Certificate of Incorporation (our "Restated Charter"), our Second Amended and Restated Bylaws (our "Restated Bylaws") and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our Restated Charter, Restated Bylaws, and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our Restated Charter and Restated Bylaws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- do not permit stockholders to cumulate votes at any election of directors;
- expressly authorize our board of directors to make, alter, amend or repeal our Restated Bylaws; and
- require super-majority votes of all holders of our common stock to amend provisions of our Restated Charter and Restated Bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware ("DGCL") which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our Restated Charter, Restated Bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our Restated Charter designates specific courts as the sole and exclusive forum for certain claims or causes of action that may be brought by our stockholders, which could discourage lawsuits against us and our directors and officers.

Our Restated Charter provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware (or, if, and only if, the Court of Chancery of the State of Delaware dismisses a Covered Claim (as defined below) for lack of subject matter jurisdiction, any other state or federal court in the State of Delaware that does have subject matter jurisdiction) will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for the following types of claims: (i) any derivative claim brought in the right of the Company, (ii) any claim asserting a breach of a fiduciary duty to the Company or the Company's stockholders owed by any current or former director, officer or other employee or stockholder of the Company, (iii) any claim against the Company arising pursuant to any provision of the DGCL, our Restated Charter or Restated Bylaws, (iv) any claim to interpret, apply, enforce or determine the validity of our Restated Charter or Restated Bylaws, (v) any claim against the Company governed by the internal affairs doctrine, and (vi) any other claim, not subject to exclusive federal jurisdiction and not asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act"), brought in any action asserting one or more of the claims specified in clauses (i) through (v) above (each a "Covered Claim"). This provision does not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Our Restated Charter further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In addition, our Restated Charter provides that any person or entity purchasing or otherwise acquiring any interest in the shares of capital stock of the Company will be deemed to have notice of and consented to these choice-of-forum provisions and waived any argument relating to the inconvenience of the forums in connection with any Covered Claim.

The choice of forum provisions contained in our Restated Charter may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid, it is possible that a court of law in another jurisdiction could rule that the choice of forum provisions contained in our Restated Charter are inapplicable or unenforceable if they are challenged in a proceeding or otherwise, which could cause us to incur additional costs associated with resolving such action in other jurisdictions. The choice of forum provisions may also impose additional litigation costs on stockholders who assert that the provisions are not enforceable or invalid.

General Risk Factors

Unstable economic and market conditions may have serious adverse consequences on our business, financial condition and stock price.

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, fluctuating inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, tariffs and uncertainty about economic and geopolitical stability (for example, related to the ongoing Russia-Ukraine conflict and conflict in the Middle East). The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. Further deterioration in economic or market conditions may occur, and challenges may persist for an unknown period of time. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

If securities or industry analysts do not publish research or reports about our business, or if they publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts continue to cover of us, or if analysts cease coverage of us, we could lose visibility in the financial markets, and the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

We have incurred, and will continue to incur, increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company we have incurred, and particularly after we are no longer an emerging growth company, we will incur, significant legal, accounting and other expenses that we did not incur as a private company. The Securities Act, the Exchange Act, Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time

as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Failure to establish and maintain effective internal control over financial reporting could adversely affect our business and if investors lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be negatively affected.

As a public company, we are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and, beginning with our second annual report on Form 10-K, provide an annual management report on the effectiveness of internal control over financial reporting. Although we are required to disclose changes made in our internal control over financial reporting on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting until our second annual report on Form 10-K. However, as an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm would need to issue a report that is adverse in the event that there are material weaknesses in our internal control over financial reporting.

We do not currently have an internal audit function. To comply with the requirements of being a public company, we have undertaken various actions, and will need to take additional actions, such as implementing numerous internal controls and procedures and hiring additional accounting or internal audit staff or consultants. Testing and maintaining internal controls can divert our management's attention from other matters that are important to the operation of our business.

We have identified a material weakness in our internal control over financial reporting. If we are unable to implement and maintain the effectiveness of our internal control over financial reporting, our investors may lose confidence in the accuracy and completeness of our financial reports, which could adversely affect our stock price.

We identified a material weakness in our internal control over financial reporting. 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 will not be prevented or detected on a timely basis. The material weakness is related to the lack of sufficient internal technical accounting resources, which resulted in an overreliance on external advisors for complex accounting matters without maintaining adequate internal controls to review, validate, and document the resulting accounting positions and disclosures.

We are in the process of remediating this material weakness by hiring additional accounting and finance personnel with technical accounting and SEC reporting experience, enhancing our use of external specialists where appropriate, implementing improved review procedures and documentation requirements, and providing training to existing personnel. These measures may not remediate the material weakness in a timely manner and additional material weaknesses may be identified in the future. The material weakness will not be considered remediated until management completes the design and implementation of the controls and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. The measures we are taking may not be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not remediate the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected.

Our management will not be required to evaluate the effectiveness of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act until our second annual report on Form 10-K. As part of that evaluation, we may identify additional control deficiencies that are determined to constitute one or more material weaknesses. In addition, our remediation efforts may not be successful, our internal control over financial reporting may not be effective as a result of these efforts, and any future control deficiencies identified may be material weaknesses that would be required to be reported in future periods.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

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

We are subject to the periodic reporting requirements of the Exchange Act. We must design 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 that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related person transaction disclosures. 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.

We may not be able to satisfy the continued listing requirements of Nasdaq or maintain a listing of our common stock on Nasdaq.

If we fail to satisfy Nasdaq's continued listing requirements, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, there may not be any action we can take to restore compliance with listing requirements that would allow our common stock to become listed again on the Nasdaq or any other securities exchange, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

While we maintain commercial insurance at a level we believe is appropriate against certain risks commonly insured in the industry in which we operate, there is no guarantee that our insurer will cover costs or that we will be able to obtain the desired level of coverage on acceptable terms in the future. Some of the policies we currently maintain include general liability, crime insurance, products liability, workers' compensation, cyber, directors' and officers', employment practices and fiduciary liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Changes in the market conditions and our business operations may necessitate the addition of new insurance policies or change of our existing insurance policies. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

We also expect that operating as a U.S. public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, on our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition and results of operations.

We could be subject to securities class action litigation or other litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the trading price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements and damages awarded to plaintiffs.

From time to time we may also be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal data, contractual relations with collaborators and licensors and intellectual property rights. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources.

We could be subject to changes in tax rates, the adoption of new tax legislation or could otherwise have exposure to additional tax liabilities, which could harm our business.

As discussed above, changes to tax laws or regulations, or to the interpretation of such laws or regulations, in the jurisdictions in which we operate could significantly increase our effective tax rate and materially affect our financial condition. In addition, other factors or events, including business combinations and investments, changes in our stock-based compensation, changes in the valuation of our deferred tax assets and liabilities, adjustments to our taxes upon finalization of any of our various tax returns or as a result of deficiencies asserted by taxing authorities against us, increases in any of our expenses that are not deductible for tax purposes, changes in our available tax credits, and changes in the apportionment of our income and our activities among tax jurisdictions, could also increase our effective tax rate. Our tax filings are subject to review or audit by the U.S. Internal Revenue Service (the "IRS"), and state, local and foreign taxing authorities. We may also be liable for taxes in connection with businesses we acquire. Our determinations in respect of our tax liabilities are not binding on the IRS or any other taxing authorities, and accordingly the final determination in an audit or other proceeding may be materially different than the treatment reflected in our tax provisions, accruals and returns. An assessment of additional taxes because of an audit or other proceeding could harm our business.

Our ability to use certain net operating loss ("NOL") carryforwards and certain other tax attributes may be limited.

As of December 31, 2025, we had federal NOL carryforwards of approximately $96.1 million. Federal NOL carryforwards generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely but are permitted to be used in any taxable year to offset only up to 80% of taxable income in such taxable year, if any. It is uncertain if and to what extent various states will conform to federal law.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code") if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income and taxes may be limited. Similar rules may apply under state tax laws. In general, an "ownership change" occurs if there is a cumulative change in ownership of the corporation by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. We have completed an analysis of Section 382 ownership changes in our stock through December 31, 2024 and have concluded that, as of December 31, 2024, we have experienced ownership changes that will result in limitations in our ability to use certain of our NOL carryforwards and other tax attributes. We may also experience an ownership change upon future issuances of our stock or due to secondary trading of our stock which may be outside of our control. If we were to undergo an additional ownership change in the future, further limitations could be imposed on our ability to utilize our NOL carryforwards and other tax attributes. Any of these ownership changes and their resulting limitations on our ability to use NOL carryforwards and other tax attributes could adversely impact our business, financial condition, results of operations and cash flows.

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

(a) During the three months ended September 30, 2026, we issued an aggregate of 131,853 shares of our common stock (as adjusted to reflect the reverse stock split) to certain of our employees. These shares were issued upon the exercise of stock options granted under our 2024 Equity Incentive Plan, as amended, at a weighted-average exercise price of $1.14 per share, for aggregate cash consideration of approximately $0.2 million. These issuances were exempt from registration under Rule 701 promulgated under the Securities Act, as transactions under compensatory benefit plans and contracts relating to compensation, or, alternatively, under Section 4(a)(2) of the Securities Act, as transactions by an issuer not involving a public offering. No underwriters were involved in these issuances.

(b) On October 13, 2026, we completed our initial public offering, or IPO, pursuant to our Registration Statement on Form S-1 (File No. 333-299018), which was declared effective by the Securities and Exchange Commission on October 8, 2026. In connection with the IPO, we issued and sold 8,333,334 shares of our common stock at a public offering price of $14.00 per share. On October 19, 2026, we sold an additional 1,205,903 shares of our common stock at the public offering price, less underwriting discounts and commissions, pursuant to the underwriters' partial exercise of their option to purchase additional shares. The offering terminated after the sale of the 9,539,237 shares registered pursuant to the Registration Statement. J.P. Morgan Securities LLC and Evercore Group L.L.C. acted as representatives of the underwriters for the offering.

The aggregate gross proceeds from the IPO, including the option shares, were approximately $133.5 million. After deducting underwriting discounts and commissions of approximately $9.3 million and estimated offering expenses of approximately $5.2 million paid or payable by us, the net proceeds from the IPO were approximately $119.0 million.

No underwriting discounts and commissions or other offering expenses were paid, directly or indirectly, to any of our directors or officers or their associates, to persons owning 10% or more of any class of our equity securities, or to any of our affiliates.

As of September 30, 2026, we had not used any of the net proceeds from the IPO, which closed after the end of the period. There has been no material change in the planned use of proceeds from the IPO as described in our IPO Prospectus.

(c) None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the three months ended September 30, 2026, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Fourth Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on October 13, 2026).
3.2	Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on October 13, 2026).
4.1	Specimen stock certificate evidencing shares of common stock (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Registration Statement on Form S-1 filed on October 5, 2026).
4.2†	Amended & Restated Investors' Rights Agreement, dated November 7, 2024, by and among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to the Registration Statement on Form S-1 filed on October 5, 2026).
10.1†	Lease Agreement, by and between the Registrant and ARE-San Francisco No. 46, LLC, dated April 15, 2026 (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-1 filed on September 18, 2026).
10.2#	Employment Agreement, by and between the Registrant and M. Johnston Erwin, Jr., dated October 2, 2026 (incorporated by reference to Exhibit 10.4 to Amendment No. 1 to the Registration Statement on Form S-1 filed on October 5, 2026).
10.3#	Employment Agreement, by and between the Registrant and Ali Zarrin, dated October 2, 2026 (incorporated by reference to Exhibit 10.5 to Amendment No. 1 to the Registration Statement on Form S-1 filed on October 5, 2026).
10.4#	Employment Agreement, by and between the Registrant and Laura Berner, dated October 2, 2026 (incorporated by reference to Exhibit 10.6 to Amendment No. 1 to the Registration Statement on Form S-1 filed on October 5, 2026).
10.5#	TRex Bio, Inc. 2026 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to Amendment No. 1 to the Registration Statement on Form S-1 filed on October 5, 2026).
10.6#	Form of Non-Statutory Stock Option Agreement for Employees under the 2026 Equity Incentive Plan (incorporated by reference to Exhibit 10.11 to Amendment No. 1 to the Registration Statement on Form S-1 filed on October 5, 2026).
10.7#	Form of Incentive Stock Option Agreement under the 2026 Equity Incentive Plan (incorporated by reference to Exhibit 10.12 to Amendment No. 1 to the Registration Statement on Form S-1 filed on October 5, 2026).
10.8#	Form of Non-Statutory Stock Option Agreement for Directors under the 2026 Equity Incentive Plan (incorporated by reference to Exhibit 10.13 to Amendment No. 1 to the Registration Statement on Form S-1 filed on October 5, 2026).
10.9#	TRex Bio, Inc. 2026 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.14 to Amendment No. 1 to the Registration Statement on Form S-1 filed on October 5, 2026).
10.10#	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.15 to Amendment No. 1 to the Registration Statement on Form S-1 filed on October 5, 2026).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2+	Certification of 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 – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
# Management contract or compensatory plan or arrangement.
+ This certification is deemed not filed for purposes of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.
† Annexes, schedules and/or exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant agrees to furnish supplementally a copy of any omitted attachment to the SEC upon request.

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.

TRex Bio, Inc.

Date: November 13, 2026

By: /s/ M. Johnston Erwin, Jr.
M. Johnston Erwin, Jr.
Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2026

By: /s/ Brandon Hants
Brandon Hants
Chief Financial Officer
((Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, M. Johnston Erwin, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TRex 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)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: November 13, 2026

By: /s/ M. Johnston Erwin, Jr.
M. Johnston Erwin, Jr.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brandon Hants, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of TRex 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)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: November 13, 2026

By: /s/ Brandon Hants
Brandon Hants
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of TRex Bio, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: November 13, 2026

By: /s/ M. Johnston Erwin, Jr.
M. Johnston Erwin, Jr.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of TRex Bio, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: November 13, 2026

By: /s/ Brandon Hants
Brandon Hants
Chief Financial Officer
(Principal Financial and Accounting Officer)