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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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: 001-39594

Spruce Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**81-2154263**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
611 Gateway Boulevard, Suite 740 South San Francisco, California	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 343-5986

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, par value $0.0001 per share	SPRB	Nasdaq Capital Market

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

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

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

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

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

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

As of May 11, 2026, the registrant had 2,752,278 shares of common stock, $0.0001 par value per share, outstanding.

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SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

We face risks and uncertainties associated with our business, many of which are beyond our control. Some of the material risks associated with our business include the following:

- We will need substantial additional financing to develop our product candidates and implement our operating plan. If we fail to obtain additional financing, including as a result of geopolitical uncertainty and macroeconomic events, we may be forced to delay, reduce or eliminate our product development programs or commercialization efforts, which could significantly harm our business, financial condition, results of operations and prospects.
- We have a limited operating history, have incurred significant net losses since our inception, and anticipate that we will continue to incur significant net losses for the foreseeable future, and such net losses are expected to increase as we continue our clinical development of, and seek regulatory approvals for, our product candidate, tralesinidase alfa enzyme replacement therapy ("TA-ERT"), and our other current and future product candidates.
- If we are unable to advance our product candidates in clinical development, obtain regulatory approval, and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Our clinical trials may fail to adequately demonstrate that our product candidates are well tolerated and provide sufficient clinical benefits for patients, which could prevent or delay regulatory approval and commercialization.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- Preclinical and clinical drug development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of TA-ERT and our other current and future product candidates.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Any delays in the commencement or completion, or termination or suspension, of our clinical trials could result in increased costs to us, delay or limit our ability to generate revenue, and adversely affect our commercial prospects.
- TA-ERT and our other current and future product candidates will be subject to extensive regulation and compliance obligations, which are costly and time-consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize TA-ERT and our other current and future product candidates.
- Interim, topline, 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.
- If the market opportunities for TA-ERT and our other current and future product candidates are smaller than we believe they are, our future revenue, if any, may be adversely affected and our business may suffer.
- We currently have no marketing and sales organization and have yet to commercialize a product. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell TA-ERT and our other current and future product candidates, we may not be able to generate any product revenues.
- Unfavorable U.S. and global economic and geopolitical conditions could adversely affect our business, financial condition, results of operations and prospects.
- International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- Coverage and reimbursement may be limited or unavailable in certain market segments for TA-ERT and our other current and future product candidates, which could make it difficult for us to sell TA-ERT and our other current and future product candidates profitably.
- If we fail to develop and commercialize additional product candidates, we may be unable to grow our business.

- We depend on intellectual property licensed from others, the termination of which could result in the loss of significant rights, which would harm our business.
- We rely on third parties to conduct our 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 TA-ERT and our other current and future product candidates.
- We rely completely on third parties to manufacture our preclinical and clinical drug supplies and we intend to rely on third parties to produce commercial supplies of TA-ERT and our other current and future product candidates, if approved, and these third parties may fail to obtain and maintain regulatory approval for their facilities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.
- If we are unable to obtain and maintain sufficient intellectual property protection for TA-ERT and our other current and future product candidates, and other proprietary technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize TA-ERT, our other current and future product candidates or other proprietary technologies, if approved, may be adversely affected.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

SPRUCE BIOSCIENCES, INC.
CONDENSED BALANCE SHEETS
(unaudited)
(in thousands, except share and per share amounts)

	March 31, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 54,080	$ 48,906
Prepaid expenses	864	353
Other current assets	88	2,853
Total current assets	55,032	52,112
Right-of-use assets	595	666
Other assets	539	243
Total assets	$ 56,166	$ 53,021
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,683	$ 943
Accrued expenses and other current liabilities	8,101	9,143
Debt, current portion	1,000	—
Total current liabilities	11,784	10,086
Lease liabilities, net of current portion	332	419
Debt, net of current portion	5,464	—
Warrant liability	3,938	—
Total liabilities	21,518	10,505
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of March 31, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of March 31, 2026 and December 31, 2025; 1,372,278 and 1,372,043 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	336,148	331,750
Accumulated deficit	(301,500)	(289,234)
Total stockholders' equity	34,648	42,516
Total liabilities and stockholders' equity	$ 56,166	$ 53,021

See accompanying notes to the condensed financial statements.

SPRUCE BIOSCIENCES, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2026	2025
Operating expenses:		
Research and development	$ 7,575	$ 10,837
General and administrative	4,412	3,655
Total operating expenses	11,987	14,492
Loss from operations	(11,987)	(14,492)
Interest expense	(674)	(36)
Interest and other income, net	486	329
Change in fair value of warrant and conversion option liabilities	(91)	158
Net loss and comprehensive loss	(12,266)	(14,041)
Net loss per share, basic and diluted	$ (8.94)	$ (23.95)
Weighted-average shares of common stock outstanding, basic and diluted	1,372,084	586,142

See accompanying notes to the condensed financial statements.

SPRUCE BIOSCIENCES, INC.
CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of January 1, 2026	1,372,043	$ —	$ 331,750	$ (289,234)	$ 42,516
Issuance of common stock related to vesting of restricted stock units, net of tax withholdings	235	—	(10)	—	(10)
Reclassification of embedded conversion option	—	—	3,719	—	3,719
Stock-based compensation	—	—	689	—	689
Net loss	—	—	—	(12,266)	(12,266)
Balance as of March 31, 2026	1,372,278	$ —	$ 336,148	$ (301,500)	$ 34,648

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of January 1, 2025	563,042	$ —	$ 279,089	$ (250,268)	$ 28,821
Stock-based compensation	—	—	544	—	544
Net loss	—	—	—	(14,041)	(14,041)
Balance as of March 31, 2025	563,042	$ —	$ 279,633	$ (264,309)	$ 15,324

See accompanying notes to the condensed financial statements.

SPRUCE BIOSCIENCES, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2026	2025
Cash flows from operating activities		
Net loss	$ (12,266)	$ (14,041)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	689	544
Depreciation and amortization	252	6
Non-cash lease expense	71	65
Change in fair value of warrant and conversion option liabilities	91	(158)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,054	492
Other assets	64	—
Accounts payable	1,700	584
Accrued expenses and other current liabilities	(1,300)	140
Other liabilities	(87)	(359)
Net cash used in operating activities	(8,732)	(12,727)
Cash flows from investing activities		
Purchases of property and equipment	(10)	—
Net cash used in investing activities	(10)	—
Cash flows from financing activities		
Proceeds from debt, gross	14,146	—
Repayment of debt	—	(405)
Payment of debt and equity offering costs	(220)	(6)
Tax withholding payments on restricted stock units	(10)	—
Net cash provided by (used in) financing activities	13,916	(411)
Net increase (decrease) in cash, cash equivalents, and restricted cash	5,174	(13,138)
Cash, cash equivalents, and restricted cash at beginning of period	48,942	38,788
Cash, cash equivalents, and restricted cash at end of period	$ 54,116	$ 25,650
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 54,080	$ 25,615
Restricted cash, long-term (included in other assets)	36	35
Total cash, cash equivalents, and restricted cash	$ 54,116	$ 25,650
Supplemental cash flow data:		
Cash paid for interest on term loan	$ 158	$ 30
Supplemental disclosure of non-cash investing and financing activities:		
Allocation of debt to warrant liability for warrant and embedded conversion option	$ 7,566	$ —
Reclassification of debt embedded conversion option to additional paid-in capital	$ 3,719	$ —
Deferred offering costs included in accounts payable and accrued expenses	$ 298	$ —

See accompanying notes to the condensed financial statements.

SPRUCE BIOSCIENCES, INC.
NOTES TO THE CONDENSED FINANCIAL STATEMENTS
(unaudited)

1. Organization and Principal Activities

Description of Business

Spruce Biosciences, Inc. (the "Company") is a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for neurological disorders with significant unmet medical need. The Company is located in South San Francisco, California and was incorporated in the state of Delaware in April 2016.

April 2026 Public Offering

On April 22, 2026, the Company closed its previously announced underwritten public offering of 1,150,000 shares of its common stock at a public offering price of $50.00 per share and pre-funded warrants to purchase up to 50,000 shares of its common stock at a public offering price of $49.99 per pre-funded warrant (which equals the public offering price per share of common stock, less the $0.01 per share exercise price of each pre-funded warrant). In addition, the Company granted the underwriters a 30-day option to purchase up to 180,000 additional shares of common stock at the public offering price, less underwriting discounts and commissions, which was exercised in full. The gross proceeds to the Company from the offering, before deducting underwriting discounts and commissions and estimated offering expenses payable by the Company, were approximately $69.0 million. The pre-funded warrants were fully exercised in April 2026.

Open Market Sales Agreement

In November 2025, the U.S. Securities and Exchange Commission ("SEC") declared effective a registration statement on Form S-3 (the "Shelf Registration"), covering the sale of up to $300.0 million of the Company's securities. Also, in March 2026, the Company entered into an Open Market Sales Agreement℠ (the "Sales Agreement") with Jefferies LLC ("Jefferies") pursuant to which it may elect to issue and sell, from time to time, shares of common stock having an aggregate offering price of up to $75.0 million under the Shelf Registration through Jefferies acting as the sales agent and/or principal. As of March 31, 2026, the Company has not issued any shares of common stock under the Sales Agreement.

Reverse Stock Split

Effective April 29, 2025, the Company's common stock was delisted from the Nasdaq Capital Market as a result of the Company's ongoing failure to comply with the minimum bid price requirement under the Nasdaq Capital Market. As a result, the Company's common stock began trading publicly on the over-the-counter market on April 29, 2025 under its symbol "SPRB".

Subsequently on August 4, 2025, the Company effected a one-for-seventy-five (1:75) reverse stock split of its outstanding common stock (the "Reverse Stock Split"). The Company's common stock began trading on the OTCQB on a split-adjusted basis on August 7, 2025 (the "Split Effective Date") under the ticker symbol "SPRBD". The Company's common stock resumed trading on the Nasdaq Capital Market on September 15, 2025 under the ticker symbol "SPRB".

At the Split Effective Date, every 75 shares of the Company's issued and outstanding common stock were automatically converted into one issued and outstanding share of common stock, without any change in authorized common stock or par value per share. The Reverse Stock Split affected all shares of the Company's common stock outstanding immediately prior to the effective time of the Reverse Stock Split, as well as the number of shares of common stock available for issuance under the Company's equity incentive plans and employee stock purchase plan. In addition, the Reverse Stock Split effected a reduction in the number of shares of common stock issuable upon the exercise of warrants, stock options and restricted stock units outstanding immediately prior to the effectiveness of the Reverse Stock Split with a corresponding increase in the exercise price per share applicable to such warrants and stock options. No fractional shares were issued because of the Reverse Stock Split. Stockholders who were otherwise entitled to receive a fractional share received a cash payment in lieu thereof.

All of the outstanding common stock share numbers (including shares of common stock subject to the Company's options), share prices, exercise prices and per share amounts contained in the financial statements have been retroactively adjusted in the financial statements to reflect this Reverse Stock Split for all periods presented.

Liquidity and Capital Resources

The Company has incurred significant losses and negative cash flows from operations. During the three months ended March 31, 2026, the Company incurred a net loss of $12.3 million and used $8.7 million of cash in operations. As of March 31, 2026, the Company had an accumulated deficit of $301.5 million and does not expect positive cash flows from operations in the foreseeable future. The Company has funded its operations primarily through the issuance and sale of equity securities, debt and collaboration revenue.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which assumes the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company believes that based on its current operating plan, its cash and cash equivalents of $54.1 million as of March 31, 2026 and the net proceeds from its April 2026 underwritten public offering of common stock and pre-funded warrants will be sufficient to fund its planned operations and debt obligations for at least 12 months following the issuance date of these financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the SEC for interim reporting. As permitted under those rules and regulations, certain notes or other financial information normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. The condensed balance sheet as of March 31, 2026, the condensed statements of operations and comprehensive loss for the three months ended March 31, 2026 and 2025, the condensed statement of stockholders' equity for the three months ended March 31, 2026 and 2025, and the condensed statements of cash flows for the three months ended March 31, 2026 and 2025 are unaudited. The interim condensed financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal, recurring adjustments that are necessary to present fairly the Company's results for the interim periods presented. The condensed balance sheet as of December 31, 2025 is derived from the Company's audited financial statements. The results of operations for the three months ended March 31, 2026 are not necessarily indicative of the results to be expected for the year ending December 31, 2026, or for any other future annual or interim period.

These interim condensed financial statements should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on March 9, 2026 ("Annual Report").

Certain prior period amounts on the condensed statement of operations and comprehensive loss for the three months ended March 31, 2025 have been reclassified to conform to the current period presentation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses as well as related disclosure of contingent assets and liabilities. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, accrued research and development expenses, warrant liability, stock-based compensation, and uncertain tax positions. The Company bases its estimates on its historical experience and on assumptions that it believes are reasonable; however, actual results could significantly differ from those estimates.

Risks and Uncertainties

Any product candidates developed by the Company will require approvals from the U.S. Food and Drug Administration or foreign regulatory agencies prior to commercial sales. There can be no assurance that the Company's current and future product candidates will meet desired efficacy and safety requirements to obtain the necessary approvals. If approval is denied or delayed, it may have a material adverse impact on the Company's business and its financial statements.

The Company is subject to a number of risks similar to other late-stage biopharmaceutical companies including, but not limited to, dependency on the clinical success of the Company's product candidates, ability to obtain regulatory approval of its product candidates, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and consumers, significant competition, untested manufacturing capabilities, and dependence on key individuals and sole source suppliers.

Global economic and business activities continue to face widespread macroeconomic and geopolitical uncertainties, including global trade disputes, labor shortages, declines in consumer confidence, inflation and monetary supply shifts, recession risks, potential disruptions from the ongoing wars in Ukraine and the Middle East and related sanctions, declines in economic growth, tariffs and related legal challenges, the recent U.S. government shutdown and uncertainty about economic stability. The Company continues to actively monitor the impact of these macroeconomic and geopolitical factors on its financial condition, liquidity, operations, and workforce. The extent of the impact of these factors on the Company's operational and financial performance, including its ability to execute its business strategies and initiatives in the expected time frame, will depend on future developments, which are uncertain and cannot be predicted; however, any continued or renewed disruption resulting from these factors could negatively impact the Company's business.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash and cash equivalents. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and cash equivalents to the extent recorded in the condensed balance sheets.

Segment Reporting

The Company operates and manages its business as one reportable and operating segment, which is the business of developing and commercializing novel therapies for serious neurological disorders with significant unmet medical need. The Company's chief executive officer, who is the chief operating decision maker ("CODM"), reviews financial information on an aggregate basis for allocating and evaluating financial performance. All long-lived assets are maintained in the United States of America.

The CODM assesses performance and decides how to allocate resources based on net loss. Net loss is used to monitor budget versus actual results. The measure of segment net loss and segment expenses is reported on the condensed statements of operations and comprehensive loss. The measure of segment assets is reported on the condensed balance sheet as total assets.

Significant Accounting Policies

There have been no significant changes to the significant accounting policies during the three months ended March 31, 2026, as compared to the significant accounting policies described in the Annual Report.

Recent Accounting Pronouncements - Not Yet Adopted

In November 2024, the FASB issued Accounting Standards Update 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which requires disaggregated information about certain income statement expense line items on an annual and interim basis. ASU 2024-03 is effective for annual periods beginning after December 15, 2026 and interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted and can be applied prospectively or retrospectively. The Company is evaluating the impact of the adoption of this standard on the Company's financial statements and related disclosures.

3. Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date. Fair value measurement establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value.

The Company determined the fair value of financial assets and liabilities using the fair value hierarchy that describes three levels of inputs that may be used to measure fair value, as follows:

Level 1 — Quoted prices in active markets for identical assets and liabilities;

Level 2 — Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company classifies money market funds as Level 1 instruments as the Company uses quoted prices in active markets for identical assets to determine the fair value.

The following table summarizes the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	March 31, 2026			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Cash equivalents:				
Money market funds	$ 45,618	$ 45,618	$ —	$ —
Total	$ 45,618	$ 45,618	$ —	$ —
Financial liabilities:				
Warrant liability	$ 3,938	$ —	$ —	$ 3,938
Total	$ 3,938	$ —	$ —	$ 3,938

	December 31, 2025			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Cash equivalents:				
Money market funds	$ 48,458	$ 48,458	$ —	$ —
Total	$ 48,458	$ 48,458	$ —	$ —

The Company did not have any financial liabilities recorded at fair value as of December 31, 2025.

Debt

The gross amount of debt approximates its fair value as of March 31, 2026 as the debt bears interest at a variable rate that includes a component based on the prime rate, which is a market-observable rate. As a result, the stated coupon rate is consistent with current market rates for similar instruments and therefore the carrying amount is considered to approximate fair value.

Warrant and Conversion Option Liabilities

The Company classified its warrant and conversion option liabilities as Level 3 instruments as they were valued using the Monte Carlo Method. See Note 6 “Debt” for further information.

4. Balance Sheet Components

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	March 31, 2026	December 31, 2025
Accrued research and development expenses	$ 5,301	$ 3,496
Accrued general and administrative expenses	1,834	3,556
Accrued compensation and benefits	640	1,774
Lease liabilities, current portion	326	317
Total accrued expenses and other current liabilities	$ 8,101	$ 9,143

Accrued research and development expenses were primarily related to clinical development.

5. Leases

The Company leases space under a non-cancelable operating lease, which requires the Company to pay base rent, real estate taxes, insurance, general repairs, and maintenance. In December 2022, the Company entered into a non-cancelable operating lease for approximately 6,500 square feet of office space in South San Francisco, California, which commenced in December 2022 and expires in February 2028 (the “South San Francisco Lease”). The Company has an option to extend the lease term of the South San Francisco Lease for an additional three years which has not been included in the lease term as it is not reasonably certain that the Company will exercise this option.

6. Debt

Avenue Loan

On January 7, 2026 (the "Avenue Closing Date"), the Company entered into a Loan and Security Agreement (the "Avenue Loan and Security Agreement") and a Supplement to the Loan and Security Agreement (together with the Avenue Loan and Security Agreement, the "Avenue Loan Agreement"), with Avenue Capital Management II, L.P., as administrative agent and collateral agent (the "Agent") and Avenue Venture Opportunities Fund II, L.P., as lender (the "Lender", together with the Agent, "Avenue").

The Avenue Loan Agreement makes available to the Company term loans in an aggregate principal amount of up to $50.0 million with (i) $15.0 million funded within 5 business days after the Avenue Closing Date ("Tranche 1"), (ii) up to $10.0 million to be made available to the Company between March 1, 2026 and September 30, 2026, subject to, among other things, the Company's achievement of a key regulatory milestone related to the Company's development of TA-ERT for the treatment of Sanfilippo Syndrome Type B ("MPS IIIB") ("Tranche 2") and (iii) up to $15.0 million to be made available to the Company between September 1, 2026 and March 31, 2027, subject to, among other things, the Company's achievement of an additional key regulatory milestone with respect to the Company's development of TA-ERT for the treatment of MPS IIIB ("Tranche 3"). The Lender may make additional term loans of up to an additional $10.0 million (the "Discretionary Tranche 4" and collectively with Tranche 1, Tranche 2 and Tranche 3, the "Avenue Loans"), to be funded between October 1, 2027 and June 30, 2028, subject to, among other things, (i) the Company's achievement of a certain commercial milestone and (ii) the mutual written agreement of the Company and the Lender (upon the Lender's investment committee approval). The Avenue Loans bear interest at an annual rate equal to the greater of (x) the sum of 5.25% plus the prime rate as reported in The Wall Street Journal and (y) 12.25%. The Avenue Loans are secured by a lien upon and security interest in all of the Company's assets, including intellectual property, subject to agreed exceptions. The maturity date of the Avenue Loans is July 1, 2029 (the "Avenue Maturity Date"). The Avenue Loan Agreement does not contain any minimum cash requirement or other financial covenants. As of March 31, 2026, the stated interest rate of the Avenue Loans was 12.25%.

The Company will make interest only payments on the Avenue Loans until the 12-month anniversary of the Avenue Closing Date, subject to (i) a 6-month extension, so long as at least $5.0 million from Tranche 2 has been funded and (ii) an additional 12-month extension if the Company achieves the Tranche 3 milestone. The Avenue Loans principal is repayable in equal monthly installments from the end of interest only period to the Avenue Maturity Date.

The Company may, at its option at any time, prepay the Avenue Loans in their entirety by paying the then-outstanding principal balance and all accrued and unpaid interest on the Avenue Loans, subject to a prepayment fee equal to (i) 3.0% of the principal amount outstanding if the prepayment occurs on or prior to the first anniversary following the Avenue Closing Date, (ii) 2.0% of the principal amount outstanding if the prepayment occurs after the first anniversary following the Avenue Closing Date, but on or prior to the second anniversary following the Avenue Closing Date, and (iii) 1.0% of the principal amount outstanding if the prepayment occurs after the second anniversary following the Avenue Closing Date. The Company will pay a final payment of 4.0% of the aggregate commitment amounts for Tranche 1, Tranche 2 and Tranche 3, which shall be increased to include the commitment amount of Discretionary Tranche 4 upon the funding of such tranche, on the earlier of (x) the Avenue Maturity Date and (y) the date that the Company prepays all of the outstanding principal amount of the Avenue Loans in full ("Avenue Final Payment"). On the Avenue Closing Date, the Company paid to the Lender a commitment fee of $0.4 million.

The Avenue Loan Agreement contains customary representations, warranties and covenants, including covenants by the Company limiting additional indebtedness, liens, guaranties, mergers and consolidations, substantial asset sales, investments and loans, certain corporate changes, transactions with affiliates and fundamental changes. The Avenue Loan Agreement provides for events of default customary for term loans of this type, including but not limited to non-payment, breaches or defaults in the performance of covenants, insolvency, bankruptcy and the occurrence of a material adverse effect on the Company. After the occurrence of an event of default, the Agent may (i) accelerate payment of all obligations, impose an increased rate of interest, and terminate the Lender's commitments under the Avenue Loan Agreement and (ii) exercise any other right or remedy provided by contract or applicable law. As of March 31, 2026, the Company was in compliance with all covenants under the Avenue Loan Agreement.

Pursuant to the Avenue Loan Agreement, following the filing of the Company's annual report on Form 10-K for the fiscal year ending December 31, 2025 which occurred on March 9, 2026, the Lender has the right to convert up to $4.0 million of the outstanding principal of the Avenue Loans (the "Avenue Conversion Option") at a price of $60.00 per share, subject to certain terms and conditions, including beneficial ownership limitations. In addition, subject to applicable law, the Lender had the right to participate in certain equity financing transactions of the Company in an aggregate amount of up to $1.0 million on the same terms, conditions and pricing offered by the Company to other investors participating in such financing transaction (such right, the "Participation Right"). The Participation Right terminated in April 2026.

At issuance of the Avenue Loans, the Company recorded the debt net of debt discount and costs which included $7.6 million for the grant date fair value of the Avenue Warrant and Avenue Conversion Option (discussed below), Avenue Final Payment of $1.6 million and issuance costs of $1.2 million.

As of March 31, 2026, the carrying value of the Avenue Loans was $6.5 million, consisting of the outstanding principal under Tranche 1 of $15.0 million, plus the Avenue Final Payment of $1.6 million, less unamortized debt discount and costs of $10.1 million, which are being amortized using the effective interest method over the life of the Avenue Loans.

As of March 31, 2026, future payments of principal and interest of the Avenue Loans are as follows (in thousands):

Year ending December 31,		
2026 (remaining 9 months)	$	1,404
2027		7,020
2028		6,778
2029		5,207
Total	$	20,409
Less: interest		(3,809)
Debt, gross	$	16,600
Less: unamortized debt discount and costs		(10,136)
Less: debt, current portion		(1,000)
Debt, net of current portion	$	5,464

Avenue Warrant

In connection with the Avenue Loans, the Company issued to the Lender a warrant (the "Avenue Warrant") to purchase up to $3.2 million worth of shares of the Company's common stock on March 9, 2026. Prior to the issuance of the Avenue Warrant, the Lender was entitled to receive a payment of $6.4 million in the event a change of control had occurred prior to the issuance of the Avenue Warrant (the "Success Fee"). The obligation to pay the Lender the Success Fee terminated upon the issuance of the Avenue Warrant. The Avenue Warrant will expire on January 31, 2031 (the "Avenue Warrant Expiration Date") and has an exercise price equal to $50.00 per share, provided that any exercise of such Avenue Warrant is subject to certain beneficial ownership limitations. In addition, upon a change of control, the Lender is entitled to receive the shares of the Company's common stock underlying the Avenue Warrant without payment of the exercise price.

The Lender may exercise the Avenue Warrant at any time, or from time to time up to and including the Avenue Warrant Expiration Date, by making a cash payment equal to the exercise price multiplied by the quantity of shares. The Lender may also exercise the Avenue Warrant on a cashless basis by receiving a net number of shares calculated pursuant to the formula set forth in the Avenue Warrant. The Avenue Warrant is subject to anti-dilution adjustments for stock dividends, stock splits, and reverse stock splits.

Avenue Warrant Liability

Although the Avenue Warrant wasn't legally issued until March 9, 2026 (the "Avenue Warrant Issue Date"), the Avenue Warrant was considered issued and outstanding as of the Avenue Closing Date for accounting purposes. The Avenue Warrant met the criteria for a derivative classification under ASC 815. As of the Avenue Closing Date, the Avenue Warrant did not have a fixed number of shares to be issued and therefore did not qualify for equity classification and was accounted for as a derivative liability at an initial fair value of $3.8 million under the Monte Carlo Method, with changes in fair value recognized on the condensed statements of operations and comprehensive loss during the three months ended March 31, 2026.

Upon legal issuance of the Avenue Warrant on March 9, 2026, the shares into which the Avenue Warrant will be issued became fixed and therefore the Company reassessed its accounting treatment under ASC 815-40-15-7 using the prescribed two-step analysis. The Company concluded that Section 4.3 of the Avenue Warrant, which provides for automatic exchange of the Avenue Warrant for a fixed number of shares without payment of the exercise price upon a change of control, precludes the Avenue Warrant from being considered indexed to the Company's own stock under Step 2 of ASC 815-40-15-7C through 7E. As such, the Avenue Warrant remains a derivative liability and was remeasured to fair value with changes in fair value recognized on the condensed statements of operations and comprehensive loss during the three months ended March 31, 2026.

Avenue Conversion Option

As discussed above, the Avenue Conversion Option allows the Lender to convert up to $4.0 million of the outstanding principal of the Avenue Loans at a price of $60.00 per share. At inception on the Avenue Closing Date, this feature was initially accounted for as an embedded derivative liability due to variable settlement terms at an initial fair value of $3.7 million under the Monte Carlo Method, with changes in fair value recognized on the condensed statements of operations and comprehensive loss during the three months ended March 31, 2026.

Upon legal issuance of the Avenue Warrant on March 9, 2026, the Company reassessed its accounting treatment under ASC 815-40-15-7 using the prescribed two-step analysis and concluded that the Avenue Conversion Option qualified for equity

classification because the settlement terms became fixed and the Avenue Conversion Option satisfied both the indexation and classification criteria. As such, the derivative liability was remeasured to fair value of $3.7 million and reclassified to additional paid-in capital, with no further remeasurement required thereafter.

The Avenue Warrant and Avenue Conversion Option was measured using the Monte Carlo Method with the following inputs as of the periods noted:

	Avenue Warrant		Avenue Conversion Option	
	Grant Date 1/7/2026	Quarter End 3/31/2026	Grant Date 1/7/2026	Issue Date 3/9/2026
Warrant exercise price / Conversion price max	$ 89.21	$ 54.60	$ 4,000,000	$ 4,000,000
Expected term (in years)	5.1	5.1	3.5	3.3
Expected stock price volatility	178.8%	179.3%	178.8%	179.3%
Risk-free interest rate	3.7%	3.7%	3.7%	3.7%
Expected dividend rate	0.0%	0.0%	0.0%	0.0%

The following table provides a roll forward of the aggregate fair value of the Company's warrant and conversion option liability (in thousands):

	Avenue Warrant	Avenue Conversion Option	Total
Fair value as of December 31, 2025	$ —	$ —	$ —
Grant date fair value	3,819	3,747	7,566
Change in fair value	119	(28)	91
Reclass to additional paid-in capital	—	(3,719)	(3,719)
Fair value as of March 31, 2026	$ 3,938	$ —	$ 3,938

As of the date of this filing, 64,000 shares remain outstanding under the Avenue Warrant at an exercise price of $50.00 and Avenue had not exercised the Avenue Conversion Option.

7. License Agreements

BioMarin Pharmaceutical, Inc.

On October 4, 2024, the Company entered into that certain Asset Purchase Agreement (the "Allievex Purchase Agreement") with AVX (ABC), LLC, a Delaware limited liability company, in its sole and limited capacity as the assignee for the benefit of creditors of Allievex Corporation ("Allievex"). Pursuant to the Allievex Purchase Agreement, the Company acquired all intellectual property and inventory relating to Allievex's product candidates and that certain Exclusive License Agreement, by and between BioMarin Pharmaceutical Inc. ("BioMarin") and Allievex, dated October 22, 2019 (the "BioMarin License Agreement").

As consideration, the Company paid $5.0 million to Allievex in November 2024. The Company also assumed certain liabilities of Allievex of $7.8 million, which have been fully paid as of March 31, 2026. The Company also recorded an estimated receivable of $2.6 million in other current assets on the balance sheet related to the completed Allievex bankruptcy proceedings which was fully collected by the Company in January 2026.

The Company also assumed the obligations of Allievex to pay BioMarin up to $25.5 million for the first MPS IIIB product and up to an aggregate of $100.0 million per licensed product upon the achievement of certain sales milestones. In addition, the Company is required to pay to BioMarin certain (i) high-single digit to low-double digit tiered royalties on aggregate annual net sales of licensed MPS IIIB products during the applicable royalty term, subject to certain customary reductions and floors. No amounts were paid by the Company to BioMarin nor were any due as of March 31, 2026.

The Company may terminate the BioMarin License Agreement at any time for convenience upon prior written notice provided within a specified period of time. BioMarin may terminate the BioMarin License Agreement upon written notice if the Company (i) challenges the validity, enforceability or scope of any of the patents licensed by the Company under the BioMarin License Agreement, subject to certain conditions, or (ii) ceases all material research and development activity for any licensed product for a specified period of time, subject to certain exceptions. Either the Company or BioMarin may also terminate the BioMarin License Agreement (i) in the event the other party shall have materially breached its obligations thereunder and such default shall have continued for a specified period after written notice thereof or (ii) upon the bankruptcy or insolvency of the other party.

HBM Alpha Therapeutics, Inc.

On January 15, 2025, the Company entered into a collaboration and license agreement (the "HBM License Agreement") with HBM Alpha Therapeutics, Inc. ("HBM"). Under the terms of the HBM License Agreement, HBM granted the Company a limited exclusivity, royalty bearing, and sublicensable license to certain technology, patent rights, manufacturing rights, know-how, and proprietary materials relating to SPR202.

As consideration, the Company made a one-time upfront payment to HBM of $5.0 million in February 2025. Additionally, in January 2025, the Company issued pre-funded warrants to HBM and its affiliates that in total were to be equal to 4.99% of the Company's outstanding common stock as of the date of exercise of such pre-funded warrants. In June 2025, the Company amended the pre-funded warrants to extend the exercise period to December 2025. In December 2025, these pre-funded warrants were fully exercised.

The Company concluded that the rights acquired under the HBM License Agreement have no alternative future use. Therefore, the consideration paid of $5.0 million, along with the initial fair value of the pre-funded warrants issued of $0.7 million, was recognized as acquired in-process research and development expense, which was reported as a component of research and development expense for the three months ended March 31, 2025.

The Company is also obligated to pay HBM up to an aggregate of $390.0 million upon the achievement of certain development, regulatory, and sales milestones. In addition, the Company is required to pay to HBM certain mid to high-single digit tiered royalties on aggregate annual net sales of licensed products during the applicable royalty term, subject to certain customary reductions.

The Company may terminate the HBM License Agreement on a licensed product-by-licensed product basis or in its entirety at any time for convenience upon prior written notice provided within a specified period of time. Either the Company or HBM may also terminate the HBM License Agreement (i) in the event the other party shall have materially breached its obligations thereunder and such default shall have continued for a specified period after written notice thereof or (ii) upon the bankruptcy or insolvency of the other party. HBM may terminate the HBM License Agreement upon prior written notice if the Company (i) ceases all development or commercialization activities for a specified period of time, subject to certain exceptions, or (ii) challenges the validity, enforceability or scope of any of the patents licensed by the Company to HBM under the HBM License Agreement, subject to certain conditions.

8. Commitments and Contingencies

The Company's industry is characterized by frequent claims and litigation, including claims regarding intellectual property. As a result, the Company may be subject to various legal proceedings from time to time. The results of any future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources and other factors. As of March 31, 2026, the Company was not subject to any material legal proceedings and management is not aware of any pending or threatened litigation that, individually or in the aggregate, could have a material adverse effect on the Company's business, financial condition or results of operations.

9. Capital Structure

Common Stock

As of March 31, 2026 and December 31, 2025, the Company was authorized to issue 200,000,000 shares of common stock $0.0001 par value per share. Holders of common stock are entitled to dividends if and when declared by the board of directors of the Company. The holder of each share of common stock is entitled to one vote. As of March 31, 2026, no dividends were declared.

Common stock reserved for future issuance, on an as converted basis, consisted of the following:

	March 31, 2026	December 31, 2025
Common stock warrants, issued and outstanding	227,755	169,147
Stock options, issued and outstanding	40,674	42,421
Restricted stock units, issued and outstanding	106,384	47,200
Shares available for future issuance under 2020 Equity Incentive Plan	52,480	19,715
Shares available for future issuance under 2020 Employee Stock Purchase Plan	18,414	12,531
Total shares reserved	445,707	291,014

10. Stock-Based Compensation Expense

The following table summarizes the components of stock-based compensation expense recognized in the Company's condensed statements of operations and comprehensive loss during the three months ended March 31, 2026 and 2025 (in thousands):

	Three Months Ended March 31,	
	2026	2025
Research and development	$ 154	$ 126
General and administrative	535	418
Total stock-based compensation expense	$ 689	$ 544

Restricted Stock Units ("RSUs")

During the three months ended March 31, 2026, the Company granted 62,350 RSUs with a weighted-average grant date fair value of $79.37 per unit, of which 36,900 RSUs are subject to performance-based vesting conditions related to the satisfaction of a regulatory milestone. As of March 31, 2026, the Company had 38,920 RSUs outstanding subject to performance-based vesting conditions, of which none are considered probable of achievement.

11. Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per share (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2026	2025
Numerator:		
Net loss	$ (12,266)	$ (14,041)
Denominator:		
Weighted-average shares of common stock outstanding	1,372,084	586,142
Net loss per share, basic and diluted	$ (8.94)	$ (23.95)

Basic net loss per share was the same as diluted net loss per share for all periods as the inclusion of potentially dilutive securities would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations were as follows:

	March 31,	
	2026	2025
Shares subject to outstanding common stock warrants	227,755	169,154
Shares subject to outstanding common stock options	40,674	43,776
Shares subject to outstanding RSUs	106,384	30,393
Estimated shares issuable under the 2020 Employee Stock Purchase Plan	5,918	3,319
Total	380,731	246,642

12. Related Party Transactions

Effective December 20, 2024, Kirk Ways, M.D., a member of the board of the directors, began serving as the Company's interim Chief Medical Officer pursuant to a consulting agreement. During the three months ended March 31, 2026 and 2025, the Company recognized compensation expense of $0.3 million and $0.3 million, respectively, which is included in research and development expenses on the condensed statement of operations and comprehensive loss. As of March 31, 2026, the Company accrued compensation expense of $0.1 million which is included in accrued expenses and other current liabilities on the condensed balance sheet.

13. Subsequent Events

April 2026 Public Offering

See Note 1 “Organization and Principal Activities — April 2026 Public Offering” for further information.

Adoption of 2026 Inducement Plan

In May 2026, the Company's Board of Directors adopted the Spruce Biosciences, Inc. 2026 Inducement Plan (the “Inducement Plan”). The Inducement Plan was adopted without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4), which provides an exception to the stockholder approval requirement for the issuance of securities as an inducement material to an individual entering into employment with the Company.

The Company has reserved 75,000 shares of its common stock for issuance pursuant to awards granted under the Inducement Plan. Awards under the Inducement Plan may consist of non-qualified stock options, restricted stock units, restricted stock awards, stock appreciation rights, and other stock-based awards. In accordance with Nasdaq Listing Rule 5635(c)(4), awards under the Inducement Plan may only be made to an employee who has not previously been an employee or director of the Company, or following a bona fide period of non-employment, in each case as a material inducement to the individual's entering into employment with the Company.

In May 2026, the Company granted 7,000 restricted stock units under the Inducement Plan to two newly hired employees, effective as of the day following the filing of a registration statement on Form S-8 covering the shares issuable thereunder. The restricted stock units vest over four years in equal annual installments. The awards have a contractual term of 10 years.

The Company will recognize stock-based compensation expense related to awards granted under the Inducement Plan over the requisite service period in accordance with ASC 718, Compensation — Stock Compensation.

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 in conjunction with our unaudited condensed financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q (the "Quarterly Report") and our audited financial statements and notes thereto and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2025 filed with the Securities and Exchange Commission ("SEC") on March 9, 2026 (the "Annual Report"). Unless otherwise indicated, all references in this Quarterly Report to "Spruce," the "company," "we," "our," "us" or similar terms refer to Spruce Biosciences, Inc.

Forward-Looking Statements

In addition to historical financial information, this Quarterly Report contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A below. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "should," "will" or the negative of these terms or other similar expressions.

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

Overview

We are a biopharmaceutical company focused on developing and commercializing novel therapies for neurological disorders with significant unmet medical need. We have a diverse portfolio of product candidates aimed at addressing diseases with high unmet medical need and clear biology for treatment, for which there are either no approved therapies treating the underlying disease or suboptimal treatment options. We were founded in April 2016 and are led by a management team experienced in the development and commercialization of groundbreaking therapeutics.

Since inception, we have focused primarily on raising capital, establishing and protecting our intellectual property portfolio, organizing and staffing our company, business planning, and conducting preclinical and clinical development of, and manufacturing development for, our product candidates. Since November 2024 we have shifted our focus to the development of tralesinidase alfa enzyme replacement therapy ("TA-ERT"), an investigational treatment for mucopolysaccharidoses type IIIB ("MPS IIIB"), or Sanfilippo Syndrome Type B. In October 2025, TA-ERT received breakthrough therapy designation from the U.S. Food and Drug Administration ("FDA") for the treatment of Sanfilippo Syndrome Type B. TA-ERT has received Rare Pediatric Disease Designation, Fast Track Designation, Breakthrough Therapy Designation, and Orphan Drug Designation in the United States and European Union ("EU"). We anticipate submitting a biologics license application of TA-ERT for the treatment of Sanfilippo Syndrome Type B in the fourth quarter of 2026. Currently, there is no FDA-approved therapy for the treatment of MPS IIIB, and disease management consists of limited palliative care.

We have no products approved for commercial sale and have not generated any product revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development of TA-ERT and our other current and future product candidates.

Since inception, we have incurred significant losses and negative cash flows from operations. During the three months ended March 31, 2026 and 2025, we incurred net losses of $12.3 million and $14.0 million, respectively, and used $8.7 million and $12.7 million of cash in operations, respectively. As of March 31, 2026, we had an accumulated deficit of $301.5 million, and we do not expect positive cash flows from operations for the foreseeable future. We expect to continue to incur significant and increasing losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of expenditures on our planned research and development activities.

Since inception through the date of this filing, we have raised aggregate gross proceeds of $427.1 million, including $103.5 million from our initial public offering in October 2020, $116.0 million from the sale of our redeemable convertible preferred stock, $103.6 million from private placement financings, $69.0 million from the April 2026 underwritten public offering, $20.0 million from the issuance of debt, and $15.0 million upfront payment from Kaken Pharmaceutical Co., Ltd. received in April 2023. As of March 31, 2026, we had cash and cash equivalents of $54.1 million.

We believe that based on our current operating plan, our cash and cash equivalents of $54.1 million as of March 31, 2026 and

the net proceeds from our April 2026 underwritten public offering of common stock and pre-funded warrants will be sufficient to fund our planned operations and debt obligations for at least 12 months following the issuance date of these financial statements included elsewhere in this Quarterly Report.

We expect our expenses will increase significantly in connection with our ongoing activities, as we:

- pursue regulatory approval of TA-ERT in patients with MPS IIIB;
- build a highly specialized commercial organization to support the commercialization of TA-ERT, if approved, in the United States;
- seek strategic collaborations to benefit from the resources of biopharmaceutical companies specialized in either relevant disease areas or geographies in markets outside the United States;
- advance TA-ERT through a planned confirmatory study in patients with MPS IIIB and expanded access programs;
- expand manufacturing capacity to accommodate anticipated global demand of TA-ERT, if approved, for the treatment of MPS IIIB;
- advance pre-clinical and clinical development of SPR202 in congenital adrenal hyperplasia ("CAH");
- implement operational, financial, and management information systems;
- hire additional personnel; and
- obtain, maintain, expand, and protect our intellectual property portfolio.

In November 2025, the U.S. Securities and Exchange Commission ("SEC") declared effective a registration statement on Form S-3 (the "Shelf Registration"), covering the sale of up to $300.0 million of our securities. Also, in March 2026, we entered into an Open Market Sales Agreement℠ (the "Sales Agreement") with Jefferies LLC ("Jefferies") pursuant to which we may elect to issue and sell, from time to time, shares of common stock having an aggregate offering price of up to $75.0 million under the Shelf Registration through Jefferies acting as the sales agent and/or principal. As of March 31, 2026, we have not issued any shares of common stock under the Sales Agreement.

Additionally, on April 22, 2026, we closed our previously announced underwritten public offering of 1,150,000 shares of our common stock at a public offering price of $50.00 per share and pre-funded warrants to purchase up to 50,000 shares of our common stock at a public offering price of $49.99 per pre-funded warrant (which equals the public offering price per share of common stock, less the $0.01 per share exercise price of each pre-funded warrant). In addition, we granted the underwriters a 30-day option to purchase up to 180,000 additional shares of common stock at the public offering price, less underwriting discounts and commissions, which was exercised in full. The gross proceeds to us from the offering, before deducting underwriting discounts and commissions and estimated offering expenses payable by us, were approximately $69.0 million.

Global economic and business activities continue to face widespread macroeconomic uncertainties, including global trade disputes, labor shortages, declines in consumer confidence, inflation and monetary supply shifts, recession risks, potential disruptions from the ongoing wars in Ukraine and the Middle East and related sanctions, declines in economic growth, tariffs and related legal challenges, and uncertainty about economic stability.

The extent of the impact of these factors on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected time frame, will depend on future developments, which are uncertain and cannot be predicted; however, any continued or renewed disruption resulting from these factors could negatively impact our business.

Reverse Stock Split

We effected a one-for-seventy-five (1:75) reverse stock split of our outstanding common stock (the "Reverse Stock Split") on August 4, 2025.

All of the outstanding common stock share numbers (including shares of common stock subject to our options), share prices, exercise prices and per share amounts contained in the financial statements have been retroactively adjusted in the financial statements to reflect this Reverse Stock Split for all periods presented.

Material Agreements

Loan Agreement with Avenue

On January 7, 2026 (the "Avenue Closing Date"), we entered into a Loan and Security Agreement (the "Avenue Loan and Security Agreement") and a Supplement to the Loan and Security Agreement (together with the Avenue Loan and Security

Agreement, the "Avenue Loan Agreement"), with Avenue Capital Management II, L.P., as administrative agent and collateral agent (the "Agent") and Avenue Venture Opportunities Fund II, L.P., as lender (the "Lender", together with the Agent, "Avenue").

The Avenue Loan Agreement makes available to us term loans in an aggregate principal amount of up to $50.0 million with (i) $15.0 million funded within 5 business days after the Avenue Closing Date ("Tranche 1"), (ii) up to $10.0 million to be made available to us between March 1, 2026 and September 30, 2026, subject to, among other things, our achievement of a key regulatory milestone related to our development of TA-ERT for the treatment of MPS IIIB ("Tranche 2") and (iii) up to $15.0 million to be made available to us between September 1, 2026 and March 31, 2027, subject to, among other things, our achievement of an additional key regulatory milestone with respect to our development of TA-ERT for the treatment of MPS IIIB ("Tranche 3"). The Lender may make additional term loans of up to an additional $10.0 million (the "Discretionary Tranche 4" and collectively with Tranche 1, Tranche 2 and Tranche 3, the "Avenue Loans"), to be funded between October 1, 2027 and June 30, 2028, subject to, among other things, (i) our achievement of a certain commercial milestone and (ii) the mutual written agreement of us and the Lender (upon the Lender's investment committee approval). The Avenue Loans bear interest at an annual rate equal to the greater of (x) the sum of 5.25% plus the prime rate as reported in The Wall Street Journal and (y) 12.25%. The Avenue Loans are secured by a lien on and security interest in all of our assets, including intellectual property, subject to agreed exceptions. The maturity date of the Avenue Loans is July 1, 2029 (the "Avenue Maturity Date"). The Avenue Loan Agreement does not contain any minimum cash requirement or other financial covenants. As of March 31, 2026, the outstanding principal was $15.0 million under Tranche 1.

We will make interest only payments on the Avenue Loans until the 12-month anniversary of the Avenue Closing Date, subject to (i) a 6-month extension, so long as at least $5.0 million from Tranche 2 has been funded and (ii) an additional 12-month extension if we achieve the Tranche 3 milestone. The Avenue Loan principal is repayable in equal monthly installments from the end of interest only period to the Avenue Maturity Date.

We may, at our option at any time, prepay the Avenue Loans in their entirety by paying the then-outstanding principal balance and all accrued and unpaid interest on the Avenue Loans, subject to a prepayment fee equal to (i) 3.0% of the principal amount outstanding if the prepayment occurs on or prior to the first anniversary following the Avenue Closing Date, (ii) 2.0% of the principal amount outstanding if the prepayment occurs after the first anniversary following the Avenue Closing Date, but on or prior to the second anniversary following the Avenue Closing Date, and (iii) 1.0% of the principal amount outstanding if the prepayment occurs after the second anniversary following the Avenue Closing Date. We will pay a final payment of 4.0% of the aggregate commitment amounts for Tranche 1, Tranche 2 and Tranche 3, which shall be increased to include the commitment amount of Discretionary Tranche 4 upon the funding of such tranche, on the earlier of (x) the Avenue Maturity Date and (y) the date that we prepay all of the outstanding principal amount of the Avenue Loans in full. On the Avenue Closing Date, we paid to the Lender a commitment fee of $0.4 million.

The Avenue Loan Agreement contains customary representations, warranties and covenants, including covenants by the company limiting, among other things, additional indebtedness, liens, guaranties, mergers and consolidations, substantial asset sales, investments and loans, certain corporate changes, transactions with affiliates and fundamental changes. The Avenue Loan Agreement provides for events of default customary for term loans of this type, including but not limited to non-payment, breaches or defaults in the performance of covenants, insolvency, bankruptcy and the occurrence of a material adverse effect on the company. After the occurrence of an event of default, the Agent may (i) accelerate payment of all obligations, impose an increased rate of interest, and terminate the Lender's commitments under the Avenue Loan Agreement and (ii) exercise any other right or remedy provided by contract or applicable law, including a foreclosure on our assets.

Components of Results of Operations

Operating Expenses

We classify operating expenses into two main categories: (i) research and development expenses and (ii) general and administrative expenses.

Research and Development Expenses

Our research and development expenses consist of external and internal expenses incurred in connection with our research activities and development programs.

These expenses include:

- external expenses, consisting of:
  - clinical development—expenses associated with clinical research organizations ("CROs") engaged to manage and conduct clinical trials, in-process research and development and other outside services;
  - preclinical studies—expenses associated with preclinical studies and clinical pharmacology;

- manufacturing—expenses associated with contract manufacturing; labeling, packaging, and distribution of clinical trial supplies, and other outside services;
- other research and development—expenses associated with business operations, quality and regulatory compliance; and

▪ internal expenses, consisting of personnel, including expenses for salaries, bonuses, benefits, stock-based compensation, as well as allocation of certain expenses.

To date, these expenses have been incurred primarily to develop TA-ERT. We expect that these expenses will primarily consist of personnel costs, expenses for the conduct of clinical trials, manufacturing costs for clinical drug supply, and in-process research and development. We expect that significant additional spending will be required to progress TA-ERT through clinical development and potential regulatory approval and advancing our other investigational product candidates through clinical and pre-clinical development.

Research and development expenses are recognized as they are incurred, including licenses of intellectual property that have no alternative future use at the time of the acquisition. If deposits are required by external vendors, a portion of the deposit is included as a prepaid expense until the activity has been performed or when the goods have been received to amortize the deposit to expense in the statements of operations and comprehensive loss.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits, and stock-based compensation expense, for executive, finance, and other administrative functions. General and administrative expenses also include legal fees, professional fees, insurance costs, facility costs not otherwise included in research and development expenses, and public company expenses such as costs associated with compliance with the rules and regulations of the SEC, and those of the Nasdaq Stock Market LLC listing rules.

We expect that our general and administrative expenses will continue to increase in the foreseeable future as additional administrative personnel and services are required to manage these functions of a public company, and as we advance TA-ERT through potential regulatory approval.

Interest Expense

Interest expense consists of interest incurred and non-cash amortization of debt discount and issuance costs in connection with our debt.

Interest and Other Income, Net

Interest and other income, net primarily consists of interest income earned on our cash and cash equivalents.

Change in Fair Value of Warrant and Conversion Option Liabilities

Change in fair value of warrant and conversion option liabilities consists of the change in the fair value of the warrant liability and debt conversion option.

Results of Operations

Comparisons of the Three Months Ended March 31, 2026 and 2025

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

	Three Months Ended March 31,		
	2026	2025	Change
Operating expenses:			
Research and development	$ 7,575	$ 10,837	$ (3,262)
General and administrative	4,412	3,655	757
Total operating expenses	11,987	14,492	(2,505)
Loss from operations	(11,987)	(14,492)	2,505
Interest expense	(674)	(36)	(638)
Interest and other income, net	486	329	157
Change in fair value of warrant and conversion option liabilities	(91)	158	(249)
Net loss	$ (12,266)	$ (14,041)	$ 1,775

Research and Development Expenses

The following table sets forth research and development expenses for the periods presented (in thousands):

	Three Months Ended March 31,		
	2026	2025	Change
External expenses:			
Clinical development	$ 4,645	$ 8,593	$ (3,948)
Manufacturing	1,480	382	1,098
Preclinical studies	5	(49)	54
Other research and development	200	262	(62)
Internal expenses:			
Personnel	1,190	1,568	(378)
Facilities and other	55	81	(26)
Total research and development expenses	$ 7,575	$ 10,837	$ (3,262)

Research and development expenses decreased by $3.3 million during the three months ended March 31, 2026 compared to the three months ended March 31, 2025. The decrease in clinical development expenses of $3.9 million was primarily related to lower acquisition related costs of $5.7 million, the discontinuation of the tildacerfont CAH development program of $1.9 million, offset by increased expenses for TA-ERT of $3.7 million. The increase in manufacturing expenses of $1.1 million was primarily related to TA-ERT.

We anticipate that research and development expenses will increase into the foreseeable future as we advance TA-ERT through an anticipated biologics license application submission in the fourth quarter of 2026 and potential FDA approval.

For a description of the terms of our license agreements, see Note 7 to our unaudited condensed financial statements “License Agreements” presented elsewhere in this Quarterly Report.

General and Administrative Expenses

General and administrative expenses increased by $0.8 million during the three months ended March 31, 2026 compared to the three months ended March 31, 2025 primarily due to an increase in professional fees of $0.5 million and an increase in personnel related costs of $0.2 million.

Interest Expense

Interest expense increased by $0.6 million during the three months ended March 31, 2026 compared to the three months ended March 31, 2025 due to an increase in our debt and its related interest rate and an increase in amortization of debt discount and issuance costs.

Interest and Other Income, Net

Interest and other income, net increased by $0.2 million during the three months ended March 31, 2026 compared to the three months ended March 31, 2025 primarily due to higher yield earned on money market fund balances.

Change in Fair Value of Warrant and Conversion Option Liabilities

Change in fair value of warrant and conversion option liabilities decreased by $0.2 million during the three months ended March 31, 2026 compared to the three months ended March 31, 2025. In the prior period, the change in fair value was for pre-funded warrants issued to HBM Alpha Therapeutics, Inc. In the current period, the change in fair value relates to warrants and the conversion option under the Avenue Loan Agreement.

Liquidity and Capital Resources

Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from operations. We anticipate that we will continue to incur net losses for the foreseeable future. As of March 31, 2026 and December 31, 2025, we had an accumulated deficit of $301.5 million and $289.2 million, respectively. As of March 31, 2026 and December 31, 2025, we had cash and cash equivalents of $54.1 million and $48.9 million, respectively.

Since inception through the date of this filing, we have raised aggregate gross proceeds of $427.1 million, including $103.5 million from our initial public offering in October 2020, $116.0 million from the sale of our redeemable convertible preferred stock, $103.6 million from private placement financings, $69.0 million from the April 2026 underwritten public offering, $20.0 million from the issuance of debt, and $15.0 million upfront payment from Kaken Pharmaceutical Co., Ltd. received in April 2023. As of March 31,

2026, we had cash and cash equivalents of $54.1 million. We believe that based on our current operating plan, our cash and cash equivalents of $54.1 million as of March 31, 2026 and the net proceeds from our April 2026 underwritten public offering of common stock and pre-funded warrants will be sufficient to fund our planned operations and debt obligations for at least 12 months following the issuance date of these financial statements included elsewhere in this Quarterly Report.

Until we can generate sufficient revenue, if ever, to fund our operations, we will need to finance future cash needs through the sale of a priority review voucher, if received, public or private equity offerings, license agreements, debt financings or restructurings, collaborations, strategic alliances and marketing or distribution arrangements, and there can be no assurance that such arrangements will be available to us on a timely basis, or, if available, will be available on terms acceptable to us.

Shelf Registration and Sales Agreement

In November 2025, the SEC declared effective the Shelf Registration covering the sale of up to $300.0 million of our securities. Also, in March 2026, we entered into the Sales Agreement with Jefferies, pursuant to which we may elect to issue and sell, from time to time, shares of common stock having an aggregate offering price of up to $75.0 million under the Shelf Registration through Jefferies acting as the sales agent and/or principal (the "ATM Offering"). We have also filed a prospectus supplement with the SEC in connection with the ATM Offering under the Shelf Registration. Upon delivery of an issuance notice and subject to the terms and conditions of the Sales Agreement, Jefferies may sell the shares at market prices by any method deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act, including sales made directly on or through The Nasdaq Global Select Market ("Nasdaq"), the existing trading market for our common stock. As of March 31, 2026, we have not issued any shares of common stock pursuant to the Sales Agreement. We have agreed to pay Jefferies commissions for its services of acting as agent of 3.0% of the gross proceeds from the sale of the shares pursuant to the Sales Agreement. We have also agreed to provide Jefferies with customary indemnification and contribution rights.

Funding Requirements

To date, we have not generated any product revenue. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval and commercialize TA-ERT or any other current or future product candidates, and we do not know when, or if at all, that will occur. We will continue to require additional capital to develop and launch TA-ERT and fund operations for the foreseeable future. Our primary uses of cash are to fund our operations, which consist primarily of research and development expenses related to our clinical development programs, and to a lesser extent, general and administrative expenses.

At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, TA-ERT or any of our other current or future product candidates. We expect our research and development expenses to increase significantly in the foreseeable future as we continue to invest in activities related to the clinical development and commercialization of TA-ERT and as we pursue regulatory approval of TA-ERT for the treatment of MPS IIIB. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and we may never succeed in achieving regulatory approval for TA-ERT in patients with MPS IIIB.

We may seek to raise capital through the sale of a priority review voucher, if received, equity or debt financings, collaborative agreements, potentially including agreements to out-license rights to develop and commercialize TA-ERT, or other arrangements with other companies, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the progress, costs, trial design, results of, and timing of our ongoing and planned clinical trials of our product candidates;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the number and characteristics of product candidates that we may pursue;
- our ability to manufacture sufficient quantities of our product candidates;
- our plan to expand our research and development activities;
- the costs associated with manufacturing our product candidates and establishing clinical and commercial supplies, and sales, marketing, and distribution capabilities;
- our ability to enter into favorable out-licensing agreements for the development and commercialization of our product candidates;
- the costs associated with commercialization;
- the costs of acquiring, licensing, or investing in product candidates;

- our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or other intellectual property rights;
- our need and ability to retain key management and hire scientific, technical, business, and medical personnel;
- the effect of competing products and product candidates and other market developments;
- the timing, receipt, and amount of sales from our product candidates and any future product candidates, if approved;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the economic and other terms, timing of, and success of any collaboration, licensing, or other arrangements which we may enter in the future; and
- the effects of the disruptions to and volatility in the credit and financial markets in the United States and worldwide from geopolitical and macroeconomic events, including global trade disputes, labor shortages, declines in consumer confidence, inflation and monetary supply shifts, recession risks, tariffs and related legal challenges, and the ongoing wars in Ukraine and the Middle East and related sanctions.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. If we raise additional capital through debt financing, we may be subject to covenants that restrict our operations including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from macroeconomic events, global trade disputes, labor shortages, declines in consumer confidence, inflation and monetary supply shifts, recession risks, potential disruptions from the wars in Ukraine and the Middle East and related sanctions, declines in economic growth, tariffs and related legal challenges, and uncertainty about economic stability. If the equity and credit markets continue to deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back, or discontinue the development or commercialization of our product candidates or other research and development initiatives. We also could be required to seek collaborators for our product candidates and any future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates and any future product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

The amount and timing of our future funding requirements will depend on many factors including the pace and results of our development efforts. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Material Cash Requirements

As of March 31, 2026, future payments of principal and interest on the Avenue Loans, which matures in July 2029, were $20.4 million. For a description of the terms of the Avenue Loans, see the section titled “Material Agreements — Loan Agreement with Avenue” above.

As of March 31, 2026, the total undiscounted lease payments for our non-cancelable operating lease for office space, which terminates in February 2028 unless renewed, was $0.7 million.

We enter into contracts in the normal course of business with third-party contract manufacturing organizations and CROs for clinical trials, non-clinical studies, drug substance and product manufacturing and other services for operating purposes. These contracts are generally cancelable by us upon prior written notice after a certain period, except for certain contracts with contract manufacturing organizations containing minimum purchase obligations. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation.

We have also entered into license and collaboration agreements under which we are obligated to make aggregate milestone payments upon the achievement of specified milestones as well as royalty payments. As of March 31, 2026, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. For a description of the terms of our license and collaboration agreements, see Note 7 to our unaudited condensed financial statements “License Agreements” presented elsewhere in this Quarterly Report.

Summary Statements of Cash Flows

The following table sets forth the primary sources and uses of cash, cash equivalents, and restricted cash for the periods presented below (in thousands):

	Three Months Ended March 31,		
	2026	2025	Change
Net cash used in operating activities	$ (8,732)	$ (12,727)	$ 3,995
Net cash used in investing activities	(10)	—	$ (10)
Net cash provided by (used in) financing activities	13,916	(411)	14,327
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 5,174	$ (13,138)	$ 18,312

Operating Activities

Net cash used in operating activities decreased by $4.0 million during the three months ended March 31, 2026 compared to the three months ended March 31, 2025 primarily due to lower payments driven by decreased clinical development activities and receipt of $2.6 million related to the Allievex Purchase Agreement due to the completed Allievex bankruptcy proceedings.

For a description of the terms of our license agreements, see Note 7 to our unaudited condensed financial statements “License Agreements” presented elsewhere in this Quarterly Report.

Investing Activities

For the three months ended March 31, 2026, net cash used in investing activities was related to purchase of property and equipment.

Financing Activities

For the three months ended March 31, 2026, net cash provided by financing activities was $13.9 million, consisting primarily of net proceeds from the Avenue Loans of $14.0 million.

For the three months ended March 31, 2025, net cash used in financing activities was $0.4 million, consisting primarily of principal payments on debt of $0.4 million.

Critical Accounting Estimates

Our condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these condensed financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities and expenses, as well as the related disclosure of contingent assets and liabilities as of the date of the financial statements. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Our critical accounting estimates are described in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Estimates” in the Annual Report. During the three months ended March 31, 2026, there were no changes to our critical accounting estimates from those discussed in the Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Our cash and cash equivalents as of March 31, 2026 consisted of $54.1 million in bank deposits and money market funds. Previously, we have held U.S. treasury securities and corporate bonds. Such interest-earning instruments carry a degree of interest rate risk. The goals of our investment policy are capital preservation, liquidity, safeguarding of capital and total return. We do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. Additionally, the interest rates for our loans are variable.

As of March 31, 2026 and December 31, 2025, a hypothetical 1% change in interest rates would not have a material effect on our financial statements. We do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Foreign Currency Exchange Rate Risk

Our operations primarily consist of activities in the United States. In addition, we contract with vendors that are located outside of the United States and certain invoices are denominated in foreign currencies. While our operating results are exposed to changes in foreign currency exchange rates between the U.S. dollar and various foreign currencies, there was no material impact on our results of operations for any periods presented herein.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation and changing prices had a significant impact on our results of operations for any periods presented herein. While we are seeing, and expect to continue to see, high inflation due to geopolitical and macroeconomic uncertainties, as of March 31, 2026, we do not expect anticipated changes in inflation to have a material effect on our business, financial condition or results of operations for future reporting periods.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our President and Chief Financial Officer, have evaluated 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 the end of the period covered by this Quarterly Report. Based on that evaluation, our Chief Executive Officer and President and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and President and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended March 31, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitation on the Effectiveness of Disclosure Controls and Procedures

In designing and evaluating our disclosure controls and procedures and internal control over financial reporting, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures and internal control over financial reporting must reflect the fact that there are resource constraints and our management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs. The design of any disclosure controls and procedures and internal control over financial reporting also are based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report, including our unaudited condensed financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the risks described below could harm our business, financial condition, results of operations, growth prospects, and/or stock price or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (*) those risk factors that reflect changes from the similarly titled risk factors included in the Annual Report.

Risks Related to Our Business and Industry

We will need substantial additional financing to develop our product candidates and implement our operating plan. If we fail to obtain additional financing, including as a result of geopolitical uncertainty and macroeconomic events, we may be forced to delay, reduce or eliminate our product development programs or commercialization efforts, which could significantly harm our business, financial condition, results of operations and prospects.*

Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to continue the clinical development of, and seek regulatory approval for, TA-ERT and our other current and future product candidates. We will require significant additional amounts in order to prepare for commercialization, and, if approved, to launch and commercialize TA-ERT and our other current and future product candidates.

As of March 31, 2026, we had cash and cash equivalents of $54.1 million. In October 2020, we consummated our initial public offering and issued 92,000 shares of common stock for net proceeds of $93.4 million. In February 2023, we completed a private placement for net proceeds of $50.9 million. In April 2023, we received a $15.0 million upfront payment under a collaboration and license agreement with Kaken Pharmaceutical Co. Ltd. In October 2025, we entered into a Securities Purchase Agreement with certain institutional investors to sell and issue (i) 502,181 shares of common stock and (ii) pre-funded warrants to purchase up to 233,144 shares of common stock in a private placement transaction, which were exercised in full by December 31, 2025. Our total net proceeds were $46.6 million. On January 7, 2026, we entered into the Avenue Loan Agreement, which makes available to the company term loans in an aggregate principal amount of up to $50.0 million, subject to the company's achievement of certain regulatory milestones, which we may not achieve. Additionally, on April 22, 2026, we closed our previously announced underwritten public offering of 1,150,000 shares of our common stock and pre-funded warrants to purchase up to 50,000 shares of our common stock, and we granted the underwriters a 30-day option to purchase up to 180,000 additional shares of common stock, which was exercised in full. The gross proceeds to us from the offering were approximately $69.0 million.

Changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control.

We will require additional capital for the further development and commercialization of TA-ERT and our other current and future product candidates and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. Additional funding may not be available on acceptable terms, or at all.

Further, as a result of geopolitical uncertainty and macroeconomic events, including global trade disputes, tariffs and resulting legal challenges, and the ongoing wars in Ukraine and the Middle East and related sanctions, the global credit and financial markets have experienced and may in the future experience volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly or more dilutive. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back, or discontinue the development or commercialization of TA-ERT or other research and development initiatives. We also could be required to seek collaborators for our current product candidates and any future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, or relinquish or license on unfavorable terms our rights to our current product candidates and any future product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, financial condition, results of operations and prospects, and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates.*

We may seek additional capital through a combination of equity offerings, debt financings, strategic partnerships and alliances, and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. For example, on January 7, 2026, we entered into the Avenue Loan Agreement, which contains covenants restricting, among other things, our ability to incur additional indebtedness, liens, guaranties, mergers and consolidations, substantial asset sales, investments and loans, certain corporate changes, transactions with affiliates and fundamental changes. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or current or future product candidates, or grant licenses on terms unfavorable to us.

We have a limited operating history, have incurred significant net losses since our inception, and anticipate that we will continue to incur significant net losses for the foreseeable future, and such net losses are expected to increase as we continue our clinical development of, and seek regulatory approvals for, our product candidate, TA-ERT, and our other current and future product candidates.*

We are a late-stage biopharmaceutical company founded in 2014, and our operations to date have focused primarily on raising capital, establishing and protecting our intellectual property portfolio, organizing and staffing our company, business planning, and conducting preclinical and clinical development of, and manufacturing development for, our product candidates. Additionally, as an organization, we have not yet demonstrated an ability to successfully complete clinical development, obtain regulatory approvals, manufacture a commercial-scale product, or conduct sales and marketing activities necessary for successful commercialization. As we build our capabilities and expand our organization, we have not yet demonstrated an ability to overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Consequently, any predictions about our future performance may not be as accurate as they would be if we had a history of successfully developing and commercializing biopharmaceutical products.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effectiveness in the targeted indication or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any product revenue to date, and 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 significant net losses since our inception. If our product candidates are not successfully developed and approved, we may never generate any revenue. For the three months ended March 31, 2026 and 2025, we reported net losses of $12.3 million and $14.0 million, respectively. As of March 31, 2026, we had an accumulated deficit of $301.5 million.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our clinical development of, seek regulatory approvals for, and commercially launch, if approved, TA-ERT and our other current and future product candidates. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. Our prior net losses and expected future net losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of increased expenses, or when, if at all, we will be able to achieve profitability.

If we are unable to advance our product candidates in clinical development, obtain regulatory approval, and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

The success of TA-ERT and our other current and future product candidates will depend on various factors, including the following:

- successful enrollment, site expansion and activation and patient engagement in our ongoing and planned clinical trials;
- successful completion of our ongoing and planned clinical trials with favorable results;
- acceptance by the U.S. Food and Drug Administration ("FDA") and European Medicines Agency ("EMA") of the clinical trial design of our planned and ongoing clinical trials of TA-ERT and our other current and future product candidates;

- demonstrating safety and efficacy to the satisfaction of applicable regulatory authorities;
- the outcome, timing, and cost of meeting regulatory requirements established by the FDA, the European Commission, EMA, and other comparable foreign regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities, including one or more new drug applications ("NDAs") from the FDA, and maintaining such approvals;
- establishing commercial manufacturing capabilities and receiving/importing commercial supplies approved by the FDA and other regulatory authorities from any future third-party manufacturer;
- establishing sales, marketing, and distribution capabilities and commercializing TA-ERT and our other current product candidates, if approved, whether alone or in collaboration with others;
- establishing and maintaining patent and trade secret protection and regulatory exclusivity for TA-ERT and our other current and future product candidates;
- maintaining an acceptable safety profile of TA-ERT and our other current product candidates following approval; and
- maintaining and growing an organization of people who can develop and, if approved, commercialize, market, and sell TA-ERT and our other current product candidates to physicians, patients, healthcare payors, and others in the medical community.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to obtain regulatory approvals or commercialize our product candidates, if approved.

Even if regulatory approvals are obtained, we may never be able to successfully commercialize our product candidates. In addition, we will need to transition at some point from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. Accordingly, we may not be able to generate sufficient revenue through the sale of TA-ERT and our other current product candidates, if approved, to continue our business.

We intend to seek FDA approval of TA-ERT for MPS IIIB through the accelerated approval pathway. If we are unable to obtain accelerated approval, we may be required to conduct additional preclinical studies or clinical trials beyond the confirmatory Phase 3 trial that we currently contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approval.*

We intend to submit a biologics license application ("BLA") seeking accelerated approval of TA-ERT for MPS IIIB based on existing clinical data, however there can be no assurance that such submission or application will be accepted for filing by the FDA or that approval will be granted on a timely basis, or at all. For example, in March 2024, in a type C meeting with the FDA, the FDA confirmed that CSF HS-NRE is deemed to be a biomarker reasonably likely to predict clinical benefit and could serve as a basis for accelerated approval. The FDA also confirmed that the completed clinical and nonclinical studies of TA-ERT were sufficient for a BLA submission and provided guidance around key design elements of a confirmatory trial (placebo-controlled 5-year study in 14 patients), which must be initiated prior to potential accelerated approval of TA-ERT.

We also held two Type B meetings with the FDA ahead of our anticipated BLA submission for TA-ERT; the first in December 2025 to discuss our clinical data and regulatory strategy, and the second in January 2026 to discuss CMC requirements. During the December 2025 meeting, the FDA confirmed that the integrated study data from interventional clinical studies of TA-ERT and the available natural history data could potentially serve as an adequate and well-controlled study for purposes of the FDA's review of the effects of TA-ERT on CSF HS-NRE, which could serve as a RLSE to support an accelerated approval. Following the January 2026 CMC meeting, the FDA considered the company's plan to address DP PPQ batch requirements for the BLA submission, and in the official meeting minutes, the FDA shared its requirement for one DP PPQ batch at the time of BLA submission and data from a second DP PPQ batch prior to midcycle of BLA review.

Based, in part, on these discussions, we intend to submit the BLA for TA-ERT for the treatment of MPS IIIB in the fourth quarter of 2026, and if successful and FDA approval is received, potentially commercially launch in mid-2027. However, even if we submit the BLA as planned, we may be unsuccessful in providing sufficient evidence of CSF HS-NRE as a RLSE to predict clinical benefit in support of an accelerated approval, and after reviewing our BLA submission, the FDA may ultimately reject CSF HS-NRE as a RLSE. For example, the FDA has in the past rejected accelerated approval following submission of a BLA under accelerated approval pathway by another company focusing on the treatment of an ultra-rare neurodegenerative disease, in part due to uncertainty regarding the appropriateness of the designated RLSE, and the FDA may reject similar BLA applications in the future. If our BLA submission is viewed as having similarities to another BLA submission that was previously rejected by the FDA, this could impact the likelihood of success of our BLA application or could influence investor perception of our likelihood of success, which could cause the price of our common stock to decline, and could harm our business, financial condition, results of operations and prospects. If the FDA rejects CSF HS-NRE as a RLSE, we may be required to conduct longer-term follow up, to enroll additional patients in our

current study, or to perform a new clinical study, all of which could be challenging with an ultra-rare and fatal genetic disease like MPS IIIB and could make us experience significant delays in, or could prevent us from, obtaining accelerated regulatory approval. Failure to obtain accelerated approval would result in a longer time period to commercialization, if any, and would increase the cost of development and harm our competitive position in the marketplace.

Our clinical trials may fail to adequately demonstrate that our product candidates are well tolerated and provide sufficient clinical benefits for patients, which could prevent or delay regulatory approval and commercialization.*

Before obtaining regulatory approvals for the commercial sale of a product candidate, we must demonstrate through lengthy, complex, and expensive preclinical testing and clinical trials that a product candidate is both safe and effective for use in each target indication. Clinical trials often fail to demonstrate safety and efficacy of the product candidate studied for the target indication. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization. We are seeking to develop treatments for MPS IIIB and congenital adrenal hyperplasia ("CAH"). We intend to seek accelerated approval of TA-ERT for MPS IIIB based on existing clinical data. As a condition of seeking such approval of a BLA from the FDA, we will initiate a confirmatory Phase 3 trial, which must be initiated prior to potential accelerated approval of TA-ERT. We intend to submit the BLA for TA-ERT for the treatment of MPS IIIB in the fourth quarter of 2026, and if successful and FDA approval is received, potentially commercially launch in mid-2027. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of TA-ERT and our other current product candidates in other indications.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation and our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products that are more effective or less costly than TA-ERT and our other current product candidates. We believe the key competitive factors that will affect the development and commercial success of our product candidates are, among other things:

- the efficacy, safety and tolerability profile of our product candidates relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the convenience of dosing;
- the price of our product candidates, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- effectiveness of promotional support and high-touch patient initiatives;
- our ability to manufacture commercial quantities of our product candidates if they receive regulatory approval;
- our ability to negotiate preferential formulary status for our product candidates; and
- intellectual property protection.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than products that we may develop. Our competitors' drugs may be more effectively marketed and sold than any drug we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. We believe the key competitive factors affecting the success of our product candidates are likely to be efficacy, safety, and convenience.

Preclinical and clinical drug development involves a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of TA-ERT and our other current and future product candidates.*

Before obtaining marketing approval from regulatory authorities for the sale of any of our product candidates, we or our collaborators must conduct extensive trials to demonstrate the safety and efficacy of the product candidates in humans. Preclinical and clinical testing is expensive and difficult to design and implement, can take many years to complete, and its outcome is inherently uncertain. A failure of one or more preclinical or clinical trials can occur at any stage of testing. The results of preclinical studies and early clinical trials of TA-ERT and preclinical studies of SPR202 may not be predictive of the results of later-stage clinical trials, and interim results of a trial do not necessarily predict final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. For example, we plan to use doses in our clinical trials for TA-ERT that may not be safe or efficacious doses. As such, our hypotheses of efficacy may not show the desired clinical results. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials. Moreover, preclinical and clinical data is often susceptible to varying interpretations and analyses. For example, the Tildacerfont as Antidepressant Medication and Relief in Depression ("TAMARIND") Phase 2 study of tildacerfont in major depressive disorder ("MDD") was discontinued in the first quarter of 2026 following a serious adverse event in which a patient experienced a significant elevation of liver enzymes. The prior sponsor of TA-ERT, Allievex Corporation ("Allievex"), discontinued clinical development due to financial constraints.

Further, if patients drop out of our clinical trials, miss scheduled doses or follow-up visits, or otherwise fail to follow clinical trial protocols, the integrity of data from our clinical trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to initiate or continue our clinical trials for TA-ERT and our other current and future product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA and comparable foreign regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population especially in the case of an orphan indication, the proximity of patients to clinical sites, competition with other organizations or our own clinical trials for clinical trial sites or patients, the eligibility and exclusion criteria for the clinical trial, the design of the clinical trial, competing clinical trials, patient engagement, 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 that may be approved for the indications we are investigating.

In particular, one indication for which we are evaluating TA-ERT is a rare neurodegenerative pediatric disorder with limited patient populations from which to draw participants in clinical trials. We are and will be required to identify and enroll a sufficient number of patients with the disorder under investigation for our clinical trials of TA-ERT. Potential patients may not be adequately diagnosed or identified with the disorders which we are targeting or may not meet the entry criteria for our clinical trials. Additionally, other pharmaceutical companies with more resources and greater experience in drug development and commercialization are targeting these same disorders and are recruiting clinical trial patients from these patient populations, which may delay or make it more difficult to fully enroll our clinical trials. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

Any delays in the commencement or completion, or termination or suspension, of our clinical trials could result in increased costs to us, delay or limit our ability to generate revenue, and adversely affect our commercial prospects.*

Before we can initiate clinical trials for our current product candidates or any future product candidates, we must submit the results of preclinical studies to the FDA, or comparable foreign regulatory authorities, along with other information, including information about chemistry, manufacturing and controls, and our proposed clinical trial protocol, as part of an investigational new drug application or similar regulatory filing under which we must receive authorization to proceed with clinical development.

Before obtaining marketing approval from regulatory authorities for the sale of our current product candidates or any future product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our current product candidates and any future product candidates in humans. Clinical testing is expensive, time-consuming, and uncertain as to outcome. In addition, we may rely in part on preclinical, clinical and quality data generated by clinical research organizations ("CROs") and other third parties for regulatory submissions for our current product candidates and any future product candidates. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, do not make regulatory submissions in a timely manner, in each case pursuant to our

agreements with them, our development programs may be significantly delayed, and we may need to conduct additional clinical trials or collect additional data independently. In either case, our development costs would increase.

We do not know whether our current or any future clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities' failure to accept our proposed manufacturing processes and suppliers and/or requirement to provide additional information regarding our manufacturing processes before providing marketing authorization;
- obtaining regulatory authorizations to commence a clinical trial or reaching a consensus with regulatory authorities on clinical trial design or implementation;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining approval from one or more institutional review boards ("IRBs") or positive opinions from Ethics Committees ("ECs");
- IRBs or ECs refusing to approve or issuing a negative opinion, suspending, varying or terminating the clinical trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval or positive opinion of the clinical trial;
- changes to clinical trial protocols and related operationalization of such changes at clinical trial sites;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- acceptance by the FDA and EMA of the clinical trial design of our planned and ongoing clinical trials of TA-ERT and our other current product candidates;
- sites not timely activating, delaying screening activities, or deviating from clinical trial protocols;
- manufacturing sufficient quantities of TA-ERT or our other current and future product candidates or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment for the indications for which we are developing TA-ERT and our other current and future product candidates, or participating in competing clinical trials;
- lack of subject engagement in the clinical trials or subjects dropping out of a clinical trial;
- lack of adequate funding to continue the clinical trial, such as that experienced by Allievex in relation to the continued development of TA-ERT;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events ("SAEs") in clinical trials of the same class of agents conducted by other companies;
- a facility manufacturing our product candidates or any of its components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practice ("cGMP"), regulations or other applicable requirements, or infections or cross-contaminations of our product candidates in the manufacturing process;
- any changes to our manufacturing process, suppliers or formulation that may be necessary or desired;
- third-party vendors not performing manufacturing and distribution services in a timely manner or to sufficient quality standards;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practice ("GCP"), or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor,

and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; or

- the impacts of contagious disease outbreaks on our ongoing and planned clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ECs of the institutions in which such trials are being conducted or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we have amended, and may need to further amend, clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to competent authorities, IRBs or ECs for reexamination, which may impact the costs, timing, or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, which we have done for TA-ERT and may do for any future product candidates, 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 relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve and have served as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA or comparable foreign regulatory authority 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 or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of TA-ERT or our other current and future product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of TA-ERT or our other current and future product candidates, the commercial prospect of TA-ERT or our other current and future product candidates will be harmed, and our ability to generate product revenue will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of TA-ERT or our other current and future product candidates. Further, delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize, if approved, TA-ERT and our other current product candidates, and our competitors may be able to bring products to market before we do, and the commercial viability of TA-ERT and our other current product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

TA-ERT and our other current and future product candidates will be subject to extensive regulation and compliance obligations, which are costly and time-consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize TA-ERT and our other current and future product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing, and distribution of our product candidates subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market TA-ERT or any other current or future product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity, and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA has substantial discretion in the drug approval process, including the ability to delay, limit, or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. Neither we nor any future collaborator is permitted to market TA-ERT or any other current or future product candidates in the United States until we receive approval of an NDA or BLA from the FDA. Similar requirements and risks are applicable in foreign markets. We have not previously submitted an NDA or BLA to the FDA, or similar drug approval filings to comparable foreign authorities.

Prior to obtaining approval to commercialize a product candidate in the United States or in foreign markets, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from non-clinical studies and clinical trials can be interpreted in different ways. Even if we believe the non-clinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for TA-ERT and any other current and future product candidates either prior to or post-approval, or may object to elements of our clinical development program.

TA-ERT and our other current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by people using drugs similar to TA-ERT and our other current and future 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;
- the FDA or comparable foreign regulatory authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for any of its 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;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials may not be sufficient to satisfy the FDA or comparable foreign regulatory authorities to support the submission of an NDA, BLA or other comparable submissions in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere, requiring, in the case of adult patients with classic CAH, additional clinical trials beyond our ongoing Phase 2b clinical trial prior to any such approval;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; 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.

Any of the above events could prevent us from achieving market approval of TA-ERT or our other current and future product candidates and could substantially increase the costs of commercializing TA-ERT or our other current and future product candidates. The demand for TA-ERT and our other current or any future product candidates could also be negatively impacted by any adverse effects of a competitor's product or treatment.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market TA-ERT and our other current and future product candidates, which would significantly harm our business, financial condition, results of operations, and prospects.

Even if we eventually complete clinical trials and receive approval of an NDA, BLA or foreign marketing application for TA-ERT and our other current and future product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or the implementation of a risk evaluation and mitigation strategy ("REMS") or comparable foreign strategies which may be required to ensure safe use of the drug after approval. The FDA or the comparable foreign regulatory authority also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or comparable foreign regulatory authority may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

Interim, topline, 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.

From time to time, we may publicly disclose interim, topline, or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline 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. Preliminary or top-line data may include, for example, data regarding a small percentage of the patients enrolled in a clinical trial, and such preliminary data should not be viewed as an indication, belief or guarantee that other patients enrolled in such clinical trial will achieve similar results or that the preliminary results from such patients will be maintained. As a result, such data should be viewed with caution until the final data are available. Adverse differences between preliminary, interim, or topline data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability, or commercialization of the particular product candidate or product and our company in general. 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 the 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, product candidate, or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain regulatory approval for, and commercialize, our product candidates and any future product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

If the market opportunities for TA-ERT and our other current and future product candidates are smaller than we believe they are, our future revenue, if any, may be adversely affected, and our business may suffer.

If the size of the market opportunities in each of our target indications for our product candidates and any future product candidates is smaller than we anticipate, we may not be able to achieve profitability and growth. We focus our clinical development on treatments for neurological disorders. For example, we believe that TA-ERT has the potential to bring therapeutic benefit to patients suffering from MPS IIIB. Given the relatively small number of patients who have MPS IIIB, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these disorders. In addition, our estimates of the patient populations for our target indications have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these disorders. The number of patients may turn out to be lower than expected. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. For example, due to the lack of available treatment options, newborn screening programs have not been widely adopted for the detection of MPS IIIB. As a result, patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. In addition, the potentially addressable patient population for MPS IIIB may be limited or may not be amenable to treatment with TA-ERT, if approved. Further, even if we obtain significant adoption and market penetration for TA-ERT in MPS IIIB, we may never achieve profitability despite obtaining such significant market share, as other pharmaceutical companies with more resources and greater experience in drug development and commercialization are targeting this same disorder.

Obtaining and maintaining regulatory approval for a product candidate in one jurisdiction does not mean that we will be successful in obtaining regulatory approval for that product candidate in other jurisdictions.

Obtaining and maintaining regulatory approval for a product candidate in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, including a number of countries in the EU, a product candidate

must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our product candidates is also subject to approval.

As with the FDA, obtaining approval of a Marketing Authorization Application ("MAA") from the European Commission, following the related opinion of the Committee for Medicinal Products for Human Use, is a similarly lengthy and expensive process and the EMA has its own procedures for assessing product candidates. Regulatory authorities in jurisdictions outside of the United States and the EU also have requirements for approval for product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of TA-ERT in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of TA-ERT will be harmed, which would adversely affect our business, prospects, financial condition, and results of operations.

We currently have no marketing and sales organization and have yet to commercialize a product. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell TA-ERT and our other current and future product candidates, we may not be able to generate any product revenues.

We currently do not have a commercial organization for the marketing, sales, and distribution of pharmaceutical products. To commercialize our product candidates and any future product candidates, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We intend to build a highly specialized commercial organization to support the commercialization of TA-ERT, if approved, in the United States.

The establishment and development of our own sales force or the establishment of a contract sales force to market our product candidates and any future product candidates will be expensive and time-consuming and could delay any commercial launch. Moreover, we may not be able to successfully develop this capability. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train, and retain marketing and sales personnel. We also face competition in our search for third parties to assist us with the sales and marketing efforts. To the extent we rely on third parties to commercialize our product candidates, if approved, we may have little or no control over the marketing and sales efforts of such third parties and our revenues from product sales may be lower than if we had commercialized TA-ERT and any other current and future product candidates ourselves. In the event we are unable to develop our own marketing and sales force or collaborate with a third-party marketing and sales organization, we would not be able to commercialize, if approved, TA-ERT and any other current and future product candidates.

Unfavorable U.S. and global economic and geopolitical conditions could adversely affect our business, financial condition, results of operations and prospects.

Our results of operations could be adversely affected by general conditions in the U.S. and global economies, the U.S. and global financial markets and adverse geopolitical and macroeconomic developments. U.S. and global economic and business activities have been, and may continue to be, disrupted and volatile due to many factors, including global trade disputes, labor shortages, declines in consumer confidence, inflation and monetary supply shifts, recession risks, geopolitical uncertainty, potential disruptions from the ongoing wars in Ukraine and the Middle East and related sanctions, disruptions in supply chain continuity, reduced access to liquidity in Europe and globally, declines in economic growth, and uncertainty about economic stability, among others. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, access to our liquidity within the U.S. banking system, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our manufacturers and our suppliers operate.

A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have increased to levels not previously seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve and equivalent foreign entities have raised, and may again raise, interest rates in response to concerns about inflation, which, coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Risks of a prolonged global economic downturn are particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

In addition, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative

expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

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 United States and the other 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 announced imposition of substantial 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, including legal challenges to such tariffs, have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects. The Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States, pose a national security risk and should be subject to additional tariffs.

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, and our principal suppliers of critical raw materials are located in multiple countries. The active pharmaceutical ingredients ("APIs") for our product candidates are manufactured in South Korea and China, and our product candidates are manufactured in South Korea, United States, and China. We also rely on specialized laboratory equipment, supplies, materials, and precursor compounds, 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.

Notwithstanding legal challenges related to tariffs, we expect that current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. 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 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, including as a result of uncertainty surrounding related legal challenges, 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, as well as of related legal challenges, 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, financial condition, results of operations 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.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract, retain, manage and motivate highly qualified managerial, scientific, and medical personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements in a timely manner could potentially harm our business, prospects, financial condition or results of operations.

We conduct our operations in South San Francisco, California. This region serves as the headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific, and development teams may terminate their employment with us on short notice. Although we have employment agreements and/or offer letters with our key employees, these arrangements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

Many of the other biotechnology and pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics are more appealing to high quality candidates than what we can offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can discover, develop and commercialize product candidates will be limited.

Use of TA-ERT and our other current and future product candidates could be associated with side effects, adverse events or other properties that could delay or prevent regulatory approval or result in significant negative consequences following marketing approval, if any.*

As is the case with biopharmaceuticals generally, it is likely that there may be side effects and adverse events associated with the use of TA-ERT and our other current and future product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by TA-ERT and our other current and future product candidates could cause us or regulatory authorities to interrupt, delay, terminate or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. For example, in the first quarter of 2026, the TAMARIND Phase 2 clinical trial of tildacerfont in MDD was discontinued following a serious adverse event in which a patient experienced a significant elevation of liver enzymes. In addition, although in clinical trials TA-ERT has demonstrated an adequate safety profile in a serious and fatal disease for which no treatment is currently available, the most frequent treatment-emergent adverse events (TEAE) by preferred term (reported in ≥40% of participants) was vomiting (22 [100%]), followed by pyrexia (20 [90.9%]), upper respiratory tract infection (17 [77.3%]), pleocytosis (11 [50.0%]), COVID-19 infection (10 [45.5%]), and diarrhea (9 [40.9%]). Four (18%) patients discontinued treatment, although three (14%) discontinuations were due to hydrocephalus, a known complication of MPS IIIB. Adverse events related to the intracerebroventricular ("ICV") device were consistent with other therapies administered by the ICV route.

If drug-related SAEs are observed, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval for TA-ERT and our other current and future product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

Furthermore, if TA-ERT and our other current and future product candidates receive marketing approval, and we or others later identify undesirable side effects caused by such product candidate, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace;
- regulatory authorities may withdraw approvals or suspend or change their approvals of such product or place restrictions on the way it is prescribed;

- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties;
- we could be sued and held liable for harm caused to patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of TA-ERT and our other current and future product candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

If we receive regulatory approval for TA-ERT and our other current and future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product.

Any regulatory approvals that we receive may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including post-market studies or clinical trials, and surveillance to monitor safety and effectiveness. The FDA may also require us to adopt a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals, or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Comparable foreign regulatory authorities may impose similar requirements in their markets.

In addition, if the FDA or a comparable foreign regulatory authority approves a product candidate, the manufacturing, quality control, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export, and recordkeeping for the approved product will be subject to extensive and ongoing regulatory requirements. The FDA and comparable foreign regulatory authorities also require submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements and GCP for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

The occurrence of any event or penalty described above may inhibit our ability to commercialize, if approved, TA-ERT and our other current and future product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission, the Department of Justice ("DOJ"), the Office of Inspector General of the U.S. Department of Health and Human Services ("HHS"), state attorneys general, members of the U.S. Congress, and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries, and investigations, and civil and criminal sanctions by the FDA, DOJ, or comparable foreign authorities. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties.

The policies of the FDA and other regulatory authorities, including foreign regulatory authorities, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval for TA-ERT and our other current and future product candidates. For example, 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 the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative 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, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition, and results of operations.

Changes in funding for the FDA and other government agencies, or comparable foreign regulatory authorities could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the authorities 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 or comparable foreign regulatory authorities may also slow the time necessary for new drugs to be reviewed and/or approved, which would adversely affect our business. For example, over the last several years, including during the government shutdown that began on October 1, 2025, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Even if we obtain regulatory approval for TA-ERT and our other current and future product candidates, they may not gain market acceptance among physicians, patients, healthcare payors and others in the medical community.

TA-ERT and our other current and future product candidates may not be commercially successful. The commercial success of TA-ERT or our other current and future product candidates, if approved, will depend significantly on the broad adoption and use of such product by physicians and patients for approved indications. The degree of market acceptance of TA-ERT or our other current and future products, if approved, will depend on a number of factors, including:

- the clinical indications for which such product candidate is approved;
- physicians and patients considering the product as a safe and effective treatment;
- the potential and perceived advantages of the product over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;

- the timing of market introduction of the product as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts and those of any collaboration or distribution partner on whom we rely for sales in foreign jurisdictions.

If TA-ERT or any other current or future product candidate is approved but fails to achieve market acceptance among physicians, patients, healthcare payors or others in the medical community, we will not be able to generate significant revenues, which would have a material adverse effect on our business, prospects, financial condition, and results of operations. Our commercial success also depends on coverage and adequate reimbursement by third-party payors, including government payors, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our product candidates. In addition, even if TA-ERT and any other current or future product candidate gain acceptance, the markets for the treatment of patients with our target indications may not be as significant as we estimate.

If TA-ERT and any other current or future product candidate is approved for marketing, and we are found to have improperly promoted off-label uses, or if physicians prescribe or use TA-ERT and any other current or future product candidates off-label, we may become subject to prohibitions on the sale or marketing of TA-ERT and any other current or future product candidates, significant fines, penalties, sanctions, or product liability claims, and our image and reputation within the industry and marketplace could be harmed.

The FDA, DOJ, and comparable foreign authorities strictly regulate the marketing and promotional claims that are made about pharmaceutical products following approval. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or comparable foreign authorities as reflected in the product's approved labeling and Summary of Product Characteristics. However, if we receive marketing approval for TA-ERT and any other current or future product candidates, physicians can prescribe such product to their patients in a manner that is inconsistent with the approved label based on the physician's independent medical judgement. If we are found to have promoted such off-label uses, we may receive warning letters from the FDA and comparable foreign authorities, incur penalties, and become subject to significant liability, which would materially harm our business. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA and other governmental authorities, including comparable foreign authorities, have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed in order to resolve enforcement actions. If we are deemed by the FDA, DOJ, or other governmental authorities, or comparable foreign regulatory authorities, to have engaged in the promotion of TA-ERT or any other current or future product candidate for off-label use, we could be subject to certain prohibitions or other restrictions on the sale or marketing and other operations or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry.

Coverage and reimbursement may be limited or unavailable in certain market segments for TA-ERT and our other current or future product candidates, which could make it difficult for us to sell TA-ERT and our other current or future product candidates profitably.

Successful sales of TA-ERT and any other current or future product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Coverage and adequate reimbursement from U.S. governmental healthcare programs, such as Medicare and Medicaid, or comparable foreign healthcare programs, and commercial payors is critical to new product acceptance, and we may not obtain such coverage or adequate reimbursement. Moreover, we focus our clinical development on treatments for serious disorders, some of which have relatively small patient populations. As a result, we must rely on obtaining appropriate coverage and reimbursement for these populations.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and the amount of reimbursement they will provide. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to obtain coverage and adequate reimbursement. If we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use TA-ERT or any other current or future product candidate unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. Additionally, the reimbursement rates and coverage amounts may be affected by the approved label for TA-ERT or any other current or future product candidate. If coverage and reimbursement of our future products are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In addition, the market for TA-ERT and any other current or future product candidates will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access through formulary controls or otherwise to a branded drug when a less costly generic equivalent or other alternative is available.

In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of TA-ERT and any other current or future product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Further, coverage policies and third-party reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

We intend to seek approval to market TA-ERT and our other current product candidates in the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for TA-ERT and our other current product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval for a drug candidate. In addition, market acceptance and sales of a product will depend significantly on the availability of coverage and adequate reimbursement from third-party payors for a product and may be affected by existing and future health care reform measures.

In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. For example, the Inflation Reduction Act of 2022 ("IRA") among other things, (1) requires HHS to negotiate the price of certain single-source biologics that have been on the market for at least 11 years covered under Medicare as part of the Medicare Drug Price Negotiation Program (the "Medicare Drug Price Negotiation Program"), and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation on an annual basis. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis.

Current and future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize TA-ERT and any other current or future product candidates and may affect the prices we may set.*

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively the "Affordable Care Act"), was enacted in the United States. There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. For example, on August 16, 2022, the IRA was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges and amendments in the future. It is unclear how any such challenges and the healthcare reform measures of the second Trump administration will impact the Affordable Care Act and our business.

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

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services ("CMS") and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct to consumer platform ("TrumpRx"), U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directives to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on certain imported pharmaceutical products; and (4) as part of the Make America Healthy Again ("MAHA") Commission's recent Strategy Report, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager, or PBM, payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, the U.S. Supreme Court's *Loper Bright Enterprises v. Raimondo* decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

In addition, certain foreign activities related to drugs, biologics, and research, especially with regard to China, have come under increased scrutiny in the United States. Chinese contract manufacturing organizations may become subject to legislation, trade restrictions, sanctions, tariffs and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities. For example, on December 10, 2025, the National Defense Authorization Act for Fiscal Year 2026 ("NDAA") passed overwhelmingly in the U.S. House of Representatives (the "House") and includes the BIOSECURE Act which, in its current form, would prohibit the U.S. government from procuring biotechnology equipment or services from "biotechnology companies of concern," and would prohibit U.S. government contracts, loans and grants to any entity that uses biotechnology equipment or services from a designated "biotechnology company of concern." "Biotechnology companies of concern" include companies identified on the U.S. Department of Defense's "Chinese military companies operating in the United States" list (the 1260H List) and also authorizes the U.S. government to identify additional entities for inclusion as "biotechnology companies of concern. The U.S. Senate has since passed the NDAA and on December 18, 2025, President Trump signed the NDAA into law. Under the BIOSECURE Act, we may be restricted in our ability to work with certain Chinese biotechnology manufacturing companies to the extent we would contract with, or otherwise receive funding from, the U.S. government. In addition, if we, our suppliers, or our customers were to be designated under the BIOSECURE Act, this could potentially cause harm to our business, financial condition, results of operations and prospects.

Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. The

Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022, began to apply on January 12, 2025 through a phased implementation. The Regulation initially applies to new active substances for oncology and advanced therapy medicinal products. It will be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Select high-risk medical devices will also come into scope in 2026. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation permits EU Member States to use common HTA tools, methodologies, and procedures across the EU to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

In addition, on December 11, 2025, the European Commission, the Parliament and the European Council reached a political agreement on a comprehensive overhaul of EU pharmaceutical legislation (the "Pharma Package"). The reform has been under negotiation since the European Commission submitted its proposal in April 2023. This package—comprised of a new directive and regulation to replace existing legislation—aims to modernize the EU framework. The political agreement is still subject to formal approval by the European Parliament and Council. If approved in the form proposed, the Pharma Package will, among other changes, reduce the baseline market protection period by one year, with limited opportunities for extensions, capped at a maximum of eleven years. The reform will also significantly reshape the incentives regime for orphan medicinal products, by introducing "breakthrough" orphan medicinal products – those addressing diseases with no available medicinal treatment – which will benefit from 11 years of market exclusivity. A decrease in market exclusivity opportunities for our product candidates in the EU could impact the commercial prospects of our product candidates.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates internationally.

In order to market and sell our product candidates in other jurisdictions, we must obtain separate marketing approvals for those jurisdictions and comply with their numerous and varying regulatory requirements. We may not obtain foreign regulatory approvals on a timely basis, or at all. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, product reimbursement approvals must be secured before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Our failure to obtain approval of our product candidates by foreign regulatory authorities may negatively impact the commercial prospects of such product candidates and our business prospects could decline. Also, if regulatory approval for our product candidates is granted, it may be later withdrawn. If we fail to comply with the regulatory requirements in international jurisdictions and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential for our product candidates will be harmed and our business may be adversely affected.

Even if we obtain the necessary regulatory approvals, a variety of risks associated with marketing TA-ERT and any other current or future product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval for TA-ERT and any other current or future product candidates internationally. Even if we obtain such approvals, we will nevertheless be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries, including differing reimbursement, pricing and insurance regimes;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling internationally;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977 ("FCPA") or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities internationally; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

If we fail to develop and commercialize additional product candidates, we may be unable to grow our business.

We intend to seek to in-license or acquire development and commercial-stage product candidates in disorders that have the potential to complement our existing portfolio. Our current product candidates are generally in-licensed from or derived from partnerships with other pharmaceutical companies. If we decide to pursue the development and commercialization of any additional product candidates, we may be required to invest significant resources to acquire or in-license the rights to such product candidates or to conduct drug discovery activities and we may be unable to in-license the rights on reasonable terms if at all. We do not currently have the necessary drug discovery personnel or expertise adequate to discover and develop an additional product candidate on our own. Any other product candidates will require additional, time-consuming development efforts, and significant financial resources, prior to commercial sale, including preclinical studies, extensive clinical trials, and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and/or effective for approval by regulatory authorities. In addition, we may not be able to acquire, discover, or develop any additional product candidates, and any additional product candidates we may develop may not be approved, manufactured, or produced economically, successfully commercialized or widely accepted in the marketplace, or be more effective than other commercially available alternatives. Research programs to identify new product candidates require substantial technical, financial, and human resources whether or not we ultimately identify any candidates. If we are unable to develop or commercialize any other product candidates, our business, financial condition, results of operations and prospects will suffer.

We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. We intend to establish commercial partnerships outside of the United States in selected foreign markets. Any of these relationships may require us to incur non-recurring and other charges, increase our near-and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. Following a strategic transaction or license, we may not achieve the revenues or cash flows that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business, financial condition, results of operations and prospects.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.*

As of March 31, 2026, we had 14 employees, all of whom are full-time. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional development, managerial,

operational, financial, sales, marketing, and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory review process for our product candidates and any future product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. To date, we have used the services of outside vendors to perform tasks including clinical trial management, manufacturing, statistics and analysis, regulatory affairs, formulation development, and other drug development functions. Our growth strategy may also entail expanding our group of contractors or consultants to implement these tasks going forward. Because we rely on numerous consultants, effectively outsourcing many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval for our product candidates and any future product candidates or otherwise advance our business. We may not be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our indebtedness to Avenue may limit our flexibility in operating our business and adversely affect our financial health and competitive position, and our obligations to Avenue are secured by substantially all of our assets, including our intellectual property assets. If we default on these obligations, Avenue could foreclose on our assets, which could materially adversely affect our business, financial condition, results of operations and prospects.*

On January 7, 2026, we entered into the Avenue Loan Agreement. For a description of our Loan Agreement, see Note 6, “Debt — Avenue Loan”, to the financial statements included elsewhere in this Quarterly Report.

The Avenue Loan Agreement contains customary representations, warranties and covenants, including covenants by the company limiting, amongst other things, additional indebtedness, liens, guaranties, mergers and consolidations, substantial asset sales, investments and loans, certain corporate changes, transactions with affiliates and fundamental changes. These covenants may limit our ability to engage in certain transactions that may be in our long-term best interest, including entering into a change in control transaction. While we have not previously breached and are currently in compliance with the covenants contained in the Loan Agreement, we may breach these covenants in the future. Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, the Agent may choose to declare an event of default and require that we immediately repay all amounts outstanding under the Loan Agreement, terminate any commitment to extend further credit and foreclose on the collateral.

The Avenue Loan Agreement also provides for events of default customary for term loans of this type, including but not limited to non-payment, breaches or defaults in the performance of covenants, insolvency, bankruptcy and the occurrence of a material adverse effect on the company. After the occurrence of an event of default, the Agent may (i) accelerate payment of all obligations, impose an increased rate of interest, and terminate the Lender’s commitments under the Avenue Loan Agreement and (ii) exercise any other right or remedy provided by contract or applicable law, including a foreclosure on our assets. The occurrence of any of these events could have a material adverse effect on our business, financial condition, results of operations and prospects. If we default on any of our obligations under the Avenue Loan Agreement, the Lender could foreclose on its security interest and liquidate some or all of the collateral, including our intellectual property assets, which would harm our business, financial condition, results of operations and prospects, and could require us to reduce or cease operations.

In order to service this indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory, and other factors beyond our control. Our business may not be able to generate sufficient cash flow from operations, and future borrowings or other financings may not be available to us in an amount sufficient to enable us to service our indebtedness and to fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures

or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry, and in the economy generally. This could place us at a competitive disadvantage compared to our competitors that have less indebtedness.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations, and those of our CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce TA-ERT and our other current product candidates. Our ability to obtain clinical supplies of TA-ERT and our other current or future product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters is located in California near major earthquake faults and fire zones. The ultimate impact on us, our suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

Our employees, independent contractors, principal investigators, CROs, consultants, strategic partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that employees, independent contractors, principal investigators, CROs, consultants, and vendors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the rules of the FDA and other similar foreign regulatory bodies, including those rules that require the reporting of true, complete, and accurate information to the FDA and other similar foreign regulatory bodies; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or (iv) laws that require the true, complete, and accurate reporting of our financial information or data. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing, and education programs. In particular, the promotion, sales, and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed 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, structuring and commission(s), certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

If we obtain regulatory approval for TA-ERT and our other current product candidates and begin commercializing those products in the United States and in Europe, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal or comparable foreign healthcare programs, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

Our relationships with customers, healthcare providers and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other comparable foreign healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners, or vendors violate these laws, we could face substantial penalties.*

Our relationships with customers, healthcare providers, and third-party payors may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing, and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations designed 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, and other business arrangements. We may also be subject to federal, state and foreign laws governing the privacy and security of identifiable patient information. The U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully, offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchasing, leasing, ordering or arranging for the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has

been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that may be alleged to be intended to induce prescribing, purchases or recommendations, include any payments of more than fair market value, and may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

- federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal government programs that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government, including federal healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act and the civil monetary penalties statute;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal civil and criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, which impose requirements on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors; and
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (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.

We may also be subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope. For example, we may be subject to the following: state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, or that apply regardless of payor; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing; state and local laws requiring certain regulatory licenses to manufacture or distribute our products commercially and/or the registration of pharmaceutical sales and medical representatives; and state and foreign laws, such as the EU's General Data Protection Regulation ("EU GDPR") governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Additionally, we may be subject to federal consumer protection and unfair competition laws, and equivalent foreign laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, or our arrangements with physicians, could be subject to challenge under one or more of such laws. It is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we

may be subject to investigations, enforcement actions and/or significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal or comparable foreign healthcare programs, contractual damages, public reprimands, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of TA-ERT or our other current product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If our information technology systems or data, or those of third parties with whom we work, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties with whom we work collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) proprietary, confidential, and sensitive data, including personal data (such as health-related data including in the context of clinical trials), intellectual property, and trade secrets (collectively, sensitive data).

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties with whom we work. 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), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors 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 with whom we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to physical or electronic break-ins, social engineering attempts (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing and spam emails), malicious code (such as computer viruses and worms), malware (including as a result of advanced persistent threat intrusions), ransomware attacks, natural disasters, terrorism, war, server malfunctions, telecommunication and electrical failure, denial of service attacks (such as credential stuffing attacks), credential harvesting, personnel misconduct or error, supply-chain attacks, software bugs, attacks enhanced or facilitated by AI and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Remote work increases risks to our information technology systems and data, as personnel utilize network connections, computers, and devices outside the control of us or the third parties with whom we work, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our relationship with the third parties with whom we work could introduce additional cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third parties to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, third-party

research institution collaborators and other third parties to conduct clinical trials, data center facilities, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

We have in the past and may continue to expend significant resources (including financial) and modify our business activities (including our clinical trial activities) to try to protect against security incidents and, as applicable, to detect, investigate, mitigate, contain and remediate security incidents. Additionally, certain data privacy and security obligations have required us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

While we have implemented security measures designed to protect against and recover from security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate and remediate vulnerabilities, in our information systems (such as our hardware and/or software, including that of third parties with whom we work). There exists risk that we have in the past and may in the future, however, fail to detect, mitigate and remediate all such vulnerabilities including on a timely basis. Further, there exists risk that we have in the past and may in the future experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats have in the past and may in the future cause a security incident that resulted in or results in unauthorized, unlawful, or accidental acquisition, modification, destruction, alteration, encryption, access to, use or disclosure of, corruption of, or loss of sensitive data or our information technology systems, or those of the third parties with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts will continue in the future. A security incident has and could disrupt our ability (and that of third parties with whom we work) to provide our services.

In the event of a security incident, applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, such as consumers, partners, collaborators, government authorities, and the media or to take other actions, such as providing credit monitoring and identifying theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

Security incidents (or perceived security incidents), may result in material adverse consequences, such as significant liabilities, regulatory and enforcement actions (including investigations, fines, penalties, audits and inspections), reputational damage, additional reporting requirements and/or oversight, restrictions on processing sensitive data (including personal data), litigation, indemnification obligations, negative publicity, monetary fund diversions, interruptions in our operations (including availability of data), diversion of management attention, financial loss, and other harms. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in any regulatory approval or clearance efforts and significantly increase our costs to recover or reproduce the data, and subsequently commercialize the product. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy.

Furthermore, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Additionally, we cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules; contractual obligations; industry standards; policies; and other obligations, in each case related to data privacy or security. Our (or the third parties with whom we work) actual or perceived failure to comply with such obligations could lead to regulatory investigations and actions (which could include civil or criminal penalties); private litigation (including class-action claims) and mass arbitration demands; disruptions to our business operations; adverse publicity; and other adverse business consequences.*

We and the third parties with whom we work process personal and sensitive data and are subject to numerous data privacy and security obligations, such as laws and regulations, rules, industry standards, policies, contractual requirements and other obligations, relating to data privacy or security, including data we collect about trial participants in connection with clinical trials.

In the United States, numerous federal, state, and local laws and regulations, including, as applicable, state data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and other similar laws (e.g., wiretapping laws), govern the processing of personal data and apply to our operations and the operations of the third parties with whom we work. In addition, we obtain health information from third parties (including research institutions from which we obtain clinical trial data) that may be subject to privacy and security requirements under HIPAA, as amended by HITECH. If we violate HIPAA, we may be subject to significant administrative and civil penalties. Additionally, depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, ("CCPA"), applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses (that are subject to the CCPA) to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for statutory fines and allows private litigants affected by certain data breaches to recover significant statutory damages.

Numerous 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. We expect more states to pass similar laws in the future. The CCPA and other U.S. state comprehensive privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work.

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

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security, including our processing of personal data. For example, our processing of personal data is or may become subject in certain circumstances to the EU GDPR and the United Kingdom's GDPR ("UK GDPR") (collectively, "GDPR"). The GDPR imposes stringent standards of data privacy and security concerning personal data and imposes potentially significant sanctions for non-compliance. For example, under the GDPR, companies may face temporary or definitive bans on processing of personal data and other corrective actions; fines of up to 20 million Euros under the EU GDPR; 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or 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.

In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States and other countries outside Europe. 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 the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent 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 and other countries in compliance with law, as applicable, such as the European Commission's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allow for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework and/or Extension), these mechanisms are subject to legal challenges, and there is no assurance that we can always satisfy or rely on these mechanisms 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 (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with certain collaborators, partners, vendors

and other third parties with whom we work, 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 of personal data to recipients outside the EEA for allegedly violating the EU GDPR's cross-border data transfer limitations. Regulators in the United States and other jurisdictions are also increasingly scrutinizing certain data transfers (including to the extent related to personal, de-identified, or anonymized data) and have and may further impose data transfer requirements or prohibitions on cross-border data transfers which impacts the ability to engage in certain data transactions.

Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to engage in transactions or agreements with certain third parties in the future.

In addition to data privacy and security laws, we are bound by other contractual obligations related to data privacy and security, such as industry standards adopted by industry groups, and our efforts to comply with such obligations may not be successful. For example, trial participants about whom we or the third parties with whom we work to obtain information, as well as the third parties with whom we work who share this information with us, have in the past and may in the future contractually limit our ability to use and disclose the information. We also publish privacy policies and other statements regarding data privacy and security. Regulators are increasingly scrutinizing these types of policies and statements, and if these policies or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and individuals' data privacy and security expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Compliance with data privacy and security obligations have in the past and could require us to take on more onerous requirements in our contracts, engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or the third parties with whom we work ability to operate in certain jurisdictions. Applicable data protection laws can be subject to differing applications and interpretations which may be inconsistent or conflict among jurisdictions.

Non-compliance (or perceived non-compliance) with applicable data privacy and security obligations, could result in significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal 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.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of TA-ERT and any other current or future product candidates.

We face an inherent risk of product liability as a result of the clinical testing of TA-ERT and any other current or future product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if TA-ERT or any other current or future product candidates causes or is perceived to cause injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of TA-ERT and our other current product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for TA-ERT and any other current or future product candidates;

- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulatory authorities;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing, or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize TA-ERT and any other current or future product candidates; or
- a decline in the price of our common stock.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of any approved product, we may be unable to obtain such increased coverage on acceptable terms, or at all. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

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, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the FCPA, 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, clinical research organizations, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products internationally once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, clinical research organizations, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.*

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2025, after reducing net operating losses ("NOLs") and tax credits for amounts not expected to be utilized, we had federal NOL carryforwards of approximately $163.1 million and state NOL carryforwards of approximately $150.0 million. The federal NOL carryforwards arising in taxable years beginning prior to 2018 will begin to expire in 2036 and state NOL carryforwards will begin to expire in 2036, unless previously utilized. We also have federal and state tax credit carryforwards totaling $34.2 million and $2.8 million, respectively. The federal tax credit carryforwards will begin to expire in 2036, unless previously utilized. The state tax credits will not expire.

Under the Tax Cuts and Jobs Act of 2017 ("Tax Act"), as modified by the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), federal NOL carryforwards generated in tax years beginning after December 31, 2017 may be carried forward indefinitely but may only be used to offset 80% of our taxable income annually. Similar rules may apply under state tax laws. Such

limitations could result in the expiration of our carryforwards before they can be utilized and, if we are profitable, our future cash flows could be adversely affected due to our increased taxable income or tax liability. Our NOLs and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities and may become subject to annual limitations under Section 382 and 383 of the Internal Revenue Code of 1986, as amended. Under Section 382, certain cumulative changes in the ownership interest of significant stockholders over a rolling three-year period in excess of 50 percentage points (by value), could result in an ownership change that may limit our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities. An ownership change analysis covering periods through December 31, 2025 concluded that an ownership change occurred in May 2016, August 2020, and October 2025. As a result of the ownership changes, we derecognized NOL-related deferred tax assets down to the amount expected to be realized. Our ability to use our remaining NOL carryforwards may be further limited if we experience a Section 382 ownership change as a result of future changes in our stock ownership. As of March 31, 2026, we recorded a full valuation allowance on our net deferred tax assets.

In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California has enacted legislation that, with certain exceptions, suspends the ability to use California net operating losses to offset California income and limits the ability to use California business tax credits to offset California taxes, for taxable years beginning on or after January 1, 2024 and before January 1, 2027.

Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For instance, OBBBA makes permanent key elements of the Tax Act, including 100% bonus depreciation and the business interest expense limitation, as well as makes other significant changes to the U.S. tax laws. We are currently evaluating the impact, if any, of the OBBBA on our business and financial condition. Further, the Tax Act, the CARES Act and the Inflation Reduction Act of 2022 enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities may affect us, and certain aspects of the changes could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, the Inflation Reduction Act, OBBBA or any other newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, and the deductibility of expenses under the Tax Act, the CARES Act, the Inflation Reduction Act, OBBBA or future reform legislation could have a material impact on the value of our net deferred tax assets, could result in significant one-time charges, and could increase our future tax expense.

Risks Related to Ownership of Our Common Stock

If we are unable to maintain compliance with all applicable requirements of the Nasdaq Capital Market ("Nasdaq"), our common stock could be subject to delisting which would adversely affect the market liquidity of our common stock and the market price of our common stock could decrease.

On April 26, 2024, we received a letter from Nasdaq Listing Qualifications, notifying us that, for the previous 30 consecutive business day period prior to the date of the letter, the closing bid price for our common stock was below $1.00 (the "Minimum Bid Price Requirement").

On April 22, 2025, we received a written notification from Nasdaq that as a result of our ongoing failure to comply with the Minimum Bid Price Requirement, the trading in our company's stock was suspended at the open of trading on April 29, 2025. We appealed Nasdaq's determination to its Hearings Panel and on June 9, 2025, we received a letter from the Hearings Panel stating that our appeal was accepted. On July 23, 2025, we filed an Amendment to our Amended and Restated Certificate of Incorporation to effect a one-for-seventy-five (1:75) reverse stock split of our outstanding common stock. Our common stock began trading on the OTCQB on a split-adjusted basis on August 7, 2025 under the ticker symbol "SPRBD". Our common stock resumed trading on the Nasdaq Capital Market on September 15, 2025.

There can be no assurance that we will remain in compliance with the Minimum Bid Price Requirement. A delisting of our common stock could negatively impact us by, among other things, reducing the liquidity and market price of our common stock; reducing the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to raise equity financing; decreasing the amount of news and analyst coverage of us; resulting in a determination that the common stock is a "penny stock" which would require brokers trading in the common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of common stock; limiting our ability to issue additional securities or obtain additional financing in the future; and impairing our ability to provide equity incentives to our employees. In addition, delisting from Nasdaq may negatively impact our reputation and, consequently, our business.

The trading price of our common stock has been, and may continue to be volatile, and you could lose all or part of your investment.*

The trading price of our common stock has been, and is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. These factors include:

- the commencement, enrollment or results of our ongoing and planned clinical trials of TA-ERT, or any future clinical trials we may conduct of TA-ERT and any other current or future product candidates, or changes in the development status of TA-ERT and any other current or future product candidates;
- acceptance by the FDA and EMA of the clinical trial design of our planned and ongoing clinical trials of TA-ERT;
- any delay in our regulatory filings for TA-ERT and any other current or future product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials as a result of outbreaks of contagious diseases, patient engagement, protocol amendments or otherwise;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval for TA-ERT and any other current or future product candidates;
- changes in laws or regulations applicable to TA-ERT and any other current or future product candidates, including but not limited to clinical trial requirements for approvals;
- the failure to obtain coverage and adequate reimbursement of TA-ERT and any other current or future product candidates, if approved;
- changes in the structure of healthcare payment systems;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved drug product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize TA-ERT and any other current or future product candidates;
- unanticipated serious safety concerns related to the use of TA-ERT and any other current or future product candidates;
- introduction of new products or services offered by us or our competitors, or the release or publication of clinical trial results from competing product candidates;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth, if any, of the markets for MPS IIIB, major depressive disorder, and other disorders that we may target;
- actual or anticipated variations in quarterly or annual operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- fluctuations in the market valuation of companies perceived by investors to be comparable to us;
- overall performance of the equity markets;
- issuances of debt or equity securities;

- sales of our common stock by us, our insiders or our other stockholders in the future;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- geopolitical and macroeconomic conditions, including global trade disputes and the wars in Ukraine and the Middle East and related sanctions; and
- other events or factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report, many of which are beyond our control.

In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and negative impact on the market price of our common stock.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which could harm our business, financial condition, results of operations and prospects.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.*

We have never declared or paid any cash dividend 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 for the foreseeable future. In addition, pursuant to the Avenue Loan Agreement, we are prohibited from paying cash dividends without the prior written consent of Avenue, and future debt instruments may materially restrict our ability to pay dividends on our common stock. Any return to stockholders would therefore be limited to the appreciation, if any, of their stock.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.

Our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding capital stock, beneficially own shares representing a significant percentage of our common stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

We are a smaller reporting company and the reduced reporting requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a "smaller reporting company" as defined in the Exchange Act which allows us to take advantage of exemptions, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002

("Sarbanes-Oxley Act"), and reduced disclosure obligations regarding executive compensation. We will be able to take advantage of these scaled disclosures for so long as our voting and non-voting 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 voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. Investors may find our common stock less attractive because we may 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.

As a result of being a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting, and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.*

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. We must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in this Quarterly Report, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to our IPO, we had never been required to test our internal controls within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

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, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

We have incurred and will continue to incur significant 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.

As a public company, we have incurred and will continue to incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act") was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Smaller reporting companies are exempted from certain of these requirements, but we may be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. 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.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.*

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March 31, 2026, there were 1,372,278 shares of our common stock outstanding.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, Rule 144 and Rule 701 under the Securities Act of 1933, as amended ("Securities Act"). If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

In February 2023, we entered into a securities purchase agreement with several institutional and accredited investors, including holders of more than 5% of our total common stock outstanding on the date of the securities purchase agreement, pursuant to which we issued and sold 214,873 shares of common stock, pre-funded warrants to purchase 10,666 shares of common stock, and warrants to purchase 169,147 shares of common stock. All of the pre-funded warrants have been exercised. Additionally, in October 2025, we entered into a securities purchase agreement with certain institutional investors, pursuant to which we agreed to sell and issue 502,181 shares of common stock and pre-funded warrants to purchase up to 233,144 shares of common stock in a private placement transaction. Pursuant to the securities purchase agreements, we have registered for resale such securities. In December 2025, three holders of pre-funded warrants to purchase shares of common stock exercised those warrants to purchase 233,144 shares of common stock. On January 7, 2026, we also entered into the Avenue Loan Agreement, pursuant to which we issued a warrant to purchase $3.2 million in shares of common stock at a price of $50.00 per share. Lender may also elect to convert up to $4.0 million of the principal amount outstanding under the Avenue Loan Agreement into shares of our common stock at a price of $60.00 per share. If these additional shares of common stock, and the shares of common stock issued or issuable pursuant to such pre-funded warrants and warrants, are resold, or if it is perceived that they will be resold, in the public market, the trading price of our common stock could decline.

Further, certain holders of shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to registration statements, warrants, the Loan Agreement, any future loan agreements, and our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.*

We expect that we will need significant additional capital in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities, and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time, including through the registration statement on Form S-3, declared effective in November 2025, covering the sale of up to $300.0 million of our securities (the "Shelf Registration"). For example, in March 2026, we entered into an Open Market Sales Agreement℠ (the "Sales Agreement") with Jefferies LLC ("Jefferies"), pursuant to which we may elect to issue and sell, from time to time, shares of common stock having an aggregate offering price of up to $75.0 million under the Shelf Registration through Jefferies acting as the sales agent and/or principal. As of March 31, 2026, we have not issued any shares of common stock pursuant to the Sales Agreement. Additionally, on April 22, 2026, we closed our previously announced underwritten public offering of 1,150,000 shares of our common stock and pre-funded warrants to purchase up to 50,000 shares of our common stock. In addition, we granted the underwriters a 30-day option to purchase up to 180,000 additional shares of common stock, which was exercised in full. The gross proceeds to us from the offering, before deducting underwriting discounts and commissions and estimated offering expenses payable by us, were approximately $69.0 million. As described in the section titled "Risk Factors—Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall" above, we have in the past entered into transactions where we issued and sold common stock, pre-funded warrants and common warrants to purchase shares of our common stock, and we may enter into other or similar transactions in the future. If we sell additional shares of common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to our 2020 Equity Incentive Plan ("2020 Plan") and 2026 Inducement Plan ("Inducement Plan"), our management is authorized to grant stock options and other stock awards to our employees, directors and consultants. Additionally, the number of shares of our common stock reserved for issuance under our 2020 Plan will automatically increase on January 1 of each year continuing through and including January 1, 2030, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. In addition, pursuant to our 2020 Employee Stock Purchase Plan, the number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year continuing through January 1, 2030, by the lesser of (i) 1% of the total number of shares of our

common stock outstanding on the last day of the calendar month before the date of the automatic increase, and (ii) 5,883 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware (and any appellate court therefrom) is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action for breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers, or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (in each case as may be amended from time to time); (v) any claim or cause of action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. These provisions would not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act and the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in

multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation and our amended and restated bylaws further provide that, to the fullest extent permitted by law, the federal district courts of the United States of America is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation and our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may not be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find either exclusive forum provision contained in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could seriously harm our business.

Risks Related to Our Reliance on Third Parties

We depend on intellectual property licensed from others, the termination of which could result in the loss of significant rights, which would harm our business.*

We are dependent on technology, patents, know-how, and proprietary materials, both our own and licensed from others. For example, we entered into a license agreement with BioMarin Pharmaceutical Inc. in October 2019 pursuant to which we obtained a limited exclusivity, royalty bearing, and sublicensable license to certain technology, patent rights, know-how, and proprietary materials relating to certain enzyme replacement therapy products. We entered into a collaboration and license agreement with HBM Alpha Therapeutics, Inc ("HBM") in January 2025 pursuant to which we obtained a limited exclusivity, royalty bearing, and sublicensable license to certain technology, patent rights, manufacturing rights, know-how, and proprietary materials relating to certain compounds developed by HBM (the "HBM License Agreement").

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below under "Risks Related to Our Intellectual Property." If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

We rely on third parties to conduct our 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 TA-ERT and our other current and future product candidates.

We currently rely on, and intend to continue relying on, third-party CROs in connection with our current and planned clinical trials for TA-ERT and our other current product candidates. We control or will control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with applicable protocol, legal, regulatory, and scientific standards, and our reliance on our CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these CROs fail to comply with applicable GCP regulations, 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 before approving our marketing applications. Upon inspection, such regulatory authorities may determine that our clinical trials do not comply with the GCP regulations. In addition, our clinical trials must be conducted with drug product produced under cGMP regulations and will require a large number of test subjects. Our failure or any failure by our CROs to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of our CROs violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Our CROs are not our employees and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and non-clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, suspended, varied, delayed, or terminated and we may not be

able to complete development of, obtain regulatory approval for or successfully commercialize TA-ERT and our other current and any future product candidates. As a result, our financial results and the commercial prospects for TA-ERT and our other current and any future product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Although we carefully manage our relationships with our CROs, we may encounter challenges or delays in the future and these delays or challenges may have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, quarantines, shelter-in-place, and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to infectious diseases could impact personnel at our CROs, which could disrupt our clinical timelines, which could have a material adverse impact on our business, financial condition, results of operations and prospects.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies and we intend to rely on third parties to produce commercial supplies of TA-ERT and our other current and future product candidates, if approved, and these third parties may fail to obtain and maintain regulatory approval for their facilities, fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.

We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture TA-ERT and our other current and future product candidates on a clinical or commercial scale. Instead, we rely on contract manufacturers for such production. In particular, we currently rely on a single-source manufacturer for drug product, and a single-source manufacturer for drug substance.

We currently have a long-term agreement with a manufacturer to produce raw materials, active pharmaceutical ingredients ("APIs"), and the finished product of TA-ERT. Our reliance on third-party suppliers and manufacturers, including single-source suppliers, could harm our ability to develop TA-ERT and our other current and future product candidates or to commercialize any product candidates that are approved. Further, any delay in identifying and qualifying a manufacturer for commercial production could delay the potential commercialization of TA-ERT and our other current and future product candidates, and, in the event that we do not have sufficient product to complete our clinical trials, it could delay such trials.

The facilities used by our contract manufacturers to manufacture TA-ERT and our other current and future product candidates must be approved by the applicable regulatory authorities, including the FDA or comparable foreign regulatory authorities, pursuant to inspections that will be conducted after an NDA, BLA or comparable foreign regulatory marketing application is submitted. We currently do not control the manufacturing process of TA-ERT and our other current product candidates and are completely dependent on our contract manufacturing partners for compliance with the FDA's and comparable foreign regulatory authorities' cGMP requirements for manufacture of both the active drug substances and finished drug product. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's and comparable foreign regulatory authorities' strict regulatory requirements, they will not be able to secure or maintain FDA or comparable foreign regulatory approval for the manufacturing facilities. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authority does not approve these facilities for the manufacture of TA-ERT and our other current and future product candidates or if it withdraws any such approval in the future, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture for us, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all, which would significantly impact our ability to develop, obtain regulatory approval for, or market TA-ERT and our other current and future product candidates.

In addition, the manufacture of pharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. Furthermore, if contaminants are discovered in our supply of TA-ERT and our other current and future product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any stability or other issues relating to the manufacture of TA-ERT and our other current product candidates may occur in the future. In addition, quarantines, shelter-in-place, and similar government orders, or the perception that such orders, shutdowns, or other restrictions on the conduct of business operations could occur, related to infectious diseases could impact personnel at our third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our product candidates. Additionally, our manufacturers may experience manufacturing difficulties

due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

If we or 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 and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state, and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical, radioactive 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, radioactive 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 radioactive 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.

Social media platforms and AI-based platforms present new risks and challenges to our business.

As social media continues to expand, it also presents us with new risks and challenges. Social media is increasingly being used to communicate information about us, our programs and the diseases our product candidates are being developed to treat. Social media practices in the biopharmaceutical industry are evolving, creating uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media platforms to comment on the effectiveness of, or adverse experiences with, a product or a product candidate, which could result in reporting obligations or other consequences. Further, the accidental or intentional disclosure of non-public information by our workforce or others through media channels could lead to information loss. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us, our products, or our product candidates on any social media platform. The nature of social media prevents us from having real-time control over postings about us on social media. We may not be able to reverse damage to our reputation from negative publicity or adverse information posted on social media platforms or similar mediums. If any of these events were to occur or we otherwise fail to comply with application regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business including quick and irreversible damage to our reputation, brand image and goodwill. Additionally, AI-based platforms are increasingly being used in the biopharmaceutical industry. The use of AI platforms by people, including our vendors, suppliers and contractors, with access to our proprietary and confidential information, including trade secrets, may continue to increase and may lead to the release of such information, which may negatively impact our company, including our ability to realize the benefit of our intellectual property.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for TA-ERT and our other current and future product candidates, and other proprietary technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize TA-ERT and our other current and future product candidates and other proprietary technologies, if approved, may be adversely affected.

Our commercial success will depend in part on our ability to obtain and maintain a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to TA-ERT and our other current and future product candidates, and other proprietary technologies we develop. If we are unable to obtain or maintain patent protection with respect to TA-ERT and our other current and future product candidates, and other proprietary technologies we may develop, our business, financial condition, results of operations, and prospects could be materially harmed.

The patent position of biotechnology and pharmaceutical companies is highly uncertain and involves complex legal, scientific, and factual questions and has been the subject of frequent litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our patent applications may not result in patents being issued which protect our product candidates and uses thereof, any future product candidates, and other proprietary technologies we may develop or which effectively prevent others from commercializing competitive technologies and products. Further, no consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be

obtained or enforced in the patents that have been issued or may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents or applications we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting TA-ERT and our other current and future product candidates and other proprietary technologies and their uses by obtaining, defending and enforcing patents. These risks and uncertainties include the following:

- the United States Patent and Trademark Office ("USPTO") and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or may otherwise not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use and sell our potential product candidates and may limit, interfere with, or eliminate our ability to obtain patents related to our product candidates;
- other parties may have or may seek to design around our claims or develop technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications and patents, either by claiming the same composition of matter, methods or formulations or by claiming subject matter that could dominate our patent position;
- any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or product candidates that we may develop;
- because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates, any future product candidates, and other proprietary technologies and their uses;
- an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications for any application with an effective filing date before March 16, 2013; as such, subject matter covered in patents or patent applications that we or our licensors have filed before March 16, 2013 may be challenged and invalidated under an interference proceeding;
- 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; and
- 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 in those countries.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, or maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection for such output. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, 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 be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. Additionally, recent reforms and changes at government agencies of the United States and those of non-U.S. jurisdictions could increase the delays, uncertainties and costs surrounding the prosecution of our patent applications, and

the maintenance, enforcement, or defense of our issued patents. For example, the ability of the USPTO and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain personnel and fill key leadership appointments, among various factors. Termination of employees or delays in replacing or hiring for positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our patent applications, and our ability to timely and adequately maintain, enforce, or defend our issued patents.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use TA-ERT and our other current and future product candidates, and other proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example:

- others may be able to make compounds that are similar to TA-ERT and our other current and future product candidates but that are not covered by the claims of our patents;
- others may be able to make and use TA-ERT and our other current and future product candidates in countries where valid enforceable patents are not obtained;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- we may not develop additional proprietary technologies that are patentable;
- our competitors might conduct research and development activities in countries where we do not have patent rights or where patent protection is weak and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our products;
- we cannot ensure that we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own or license expire;
- others may obtain patents that cover the use or manufacture of TA-ERT or our other current product candidates; or
- the patents of others may have an adverse effect on our business.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

We cannot be certain that the claims in our issued patents and pending patent applications covering our current product candidates, including TA-ERT and our other current and future product candidates will be considered patentable by the USPTO, courts in the United States, or by patent offices or courts in foreign countries. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property internationally.

The strength of patents in the biotechnology and pharmaceutical fields involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current product candidates and any future product candidates in the United States or in foreign countries. Even if such patents do successfully issue, third parties may challenge the ownership, validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to our patents could deprive us of exclusive rights necessary for the successful commercialization of our current product candidates and any future product candidates. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for our current product candidates or any future product candidates or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold with respect to our current product candidates or any future product candidates is threatened, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our current product candidates or any future product candidates.

For U.S. patent applications in which claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our participation in an interference proceeding may fail and, even if successful, may result in substantial costs and distract our management and other employees.

For U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act ("America Invents Act") was signed into law. The America Invents Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is developing regulations and procedures to govern the administration of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and in particular, the "first to file" provisions, were enacted on March 16, 2013. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. It remains unclear what impact the America Invents Act will have on the operation of our business. As such, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, such as patent term adjustments, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we or our licensors obtain patents covering our product candidates, when the terms of all patents covering a product expire, our business may become subject to competition from competitive products, including generic products. Given the amount of time required for the development, testing, and regulatory review and approval of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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 marketing approval of our product candidates, or any future product candidate we may develop, one or more of patents issuing from our U.S. patent applications may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 ("Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term ("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 ("SPC"). If we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our product candidates and any future product candidates under patent protection would be reduced. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Additionally, administrative changes at the USPTO or other applicable patent authorities, such as reduced hiring and/or funding, may result in delays in issuance of a patent or in accrual of patent term extension, thereby reducing the amount of patent term extension that could otherwise be received. Administrative changes (e.g., at the FDA or USPTO) may also lead to delays in review and analysis of regulatory submissions or requests for patent term extension, which could result in a patent term extension not being timely granted (e.g., before the expiration of the patent) and there may be no patent eligible for extension. Moreover, the applicable time period or the scope of patent protection afforded could be less than we project or request. In addition, to the extent we wish to pursue patent term extension based on a patent that we may license from a third party in the future, we may need the cooperation of that third party. If we are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we project or 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 we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, such as the HBM License Agreement, or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.*

We are a party to license agreements under which we are granted intellectual property rights that are important to our business and our product candidates. If we fail to comply with our obligations under the license agreements, or we are subject to a bankruptcy, the license agreements may be terminated, in which event we would not be able to develop, commercialize or market our product candidates.

In January 2025, we entered into the HBM License Agreement with HBM. Pursuant to the HBM License Agreement, we obtained an exclusive license to a specified product candidate developed by HBM in all countries outside of mainland China, Taiwan, Hong Kong, and Macau, for upfront consideration of $5.0 million and the issuance to HBM of a pre-funded warrant equal to 4.99% of our outstanding common stock as of the date of issuance of such warrant. Furthermore, we are obligated to pay HBM up to an aggregate of $390.0 million upon the achievement of certain development, regulatory, and sales milestones. In addition, we are required to pay to HBM certain mid to high-single digit tiered royalties on aggregate annual net sales of licensed products during the applicable royalty term, subject to certain customary reductions.

Licensing of intellectual property rights is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including:

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

Further, our current licensors or any future licensor may not always act in our best interest. If disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, our business, results of operations, financial condition, and prospects may be adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer adverse consequences.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we, our current licensors, or any future licensor fail to adequately protect this intellectual property, our ability to commercialize our product candidates and any future product could be impeded.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to foreign patent agencies. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations 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, our competitors might be able to enter the market with similar or identical products or technology earlier than should otherwise have been the case, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Our patent rights may be affected by developments or uncertainty in U.S. or foreign patent statutes, patent case law, USPTO rules and regulations or the rules and regulations of foreign patent offices. Obtaining and enforcing patents in the biotechnology and pharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States may, at any time, enact changes to U.S. patent law and regulations, including by legislation, by regulatory rule-making, or by judicial precedent, that adversely affect the scope of patent protection available and weaken the rights of patent owners to obtain patents, enforce patent infringement and obtain

injunctions and/or damages. For example, the scope of patentable subject matter under 35 U.S.C. 101 has evolved significantly over the past several years as the Court of Appeals for the Federal Circuit and the U.S. Supreme Court issued various opinions, and the USPTO modified its guidance for practitioners on multiple occasions. Other countries may likewise enact changes to their patent laws in ways that adversely diminish the scope of patent protection and weaken the rights of patent owners to obtain patents, enforce patent infringement, and obtain injunctions and/or damages.

Further, the United States and other governments may, at any time, enact changes to law and regulation that create new avenues for challenging the validity of issued patents. For example, the America Invents Act created new administrative post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings that allow third parties to challenge the validity of issued patents. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. We cannot predict how decisions by the U.S. courts, the U.S. Congress or the USPTO may impact the value of our patent rights. For example, the U.S. Supreme Court held in *Amgen v. Sanofi* (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. As such, our patent rights with functional claims may be vulnerable to third party challenges seeking to invalidate these claims for lacking enablement or adequate support in the specification. In addition, the Federal Circuit recently issued a decision, *In re Cellect, LLC* (2023) involving the interaction of patent term adjustment ("PTA"), terminal disclaimers, and obvious-type double patenting which may affect the patent term of any issued patents that rely on any PTA. The trend of these decisions along with resulting changes in patentability requirements being implemented by the USPTO could make it increasingly difficult for us to obtain and maintain patents on our products and could jeopardize patent term adjustment or otherwise reduce patent term, reduce the scope of, or invalidate or render unenforceable our patent rights. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the 2013 case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. For example, the IRA passed by the U.S. Congress authorizes the Secretary of the Department of HHS to negotiate prices directly with participating manufacturers for selected medicines covered by Medicare even if these medicines are protected by an existing patent. For small molecule medicines, the process begins seven years after initial approval by the FDA. While we do not believe that the IRA or its effects will impact our ability to obtain patents in the near future, we cannot be certain that it will not affect our patent strategy in the long term.

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 our product candidates, any future product candidates, and other proprietary technologies we develop in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our 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 have patent protection, but enforcement of such patent protection is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The requirements for patentability may differ in certain countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval for a drug and its patent status. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors.

In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly,

our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology or pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. For example, as of June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court (the "UPC"). 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 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. European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the UPC. The UPC and Unitary Patent are significant changes in European patent practice. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our 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. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC. As a single court system can invalidate a European patent, we, where applicable, may opt out of the UPC and as such, each European patent would need to be challenged in each individual country. We may decide to opt out future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the opt-out formalities and requirements under the UPC, our 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 European patents, and allow for the possibility of a competitor to obtain pan-European injunctions. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates due to increased competition and, resultantly, on our financial condition, prospects and results of operations.

Geo-political actions in the United States and in foreign countries (such as, the Russia and Ukraine war and conflicts in the Middle East; retaliatory measures by foreign countries in response to actions by the United States, in particular, tariffs) could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. Many foreign countries could threaten to impose retaliatory measures that may adversely impact our intellectual property rights in those countries. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. As another example, on March 14, 2025, Brazil enacted Law No. 15.122/2025 (known as the "Economic Reciprocity Law"), which provides a framework that allows for the suspension of obligations related to foreign entity's intellectual property rights. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

We may be subject to claims that former employees (including former employees of our licensors), collaborators or other third parties have an interest in our patents rights, trade secrets, 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. For example, we may have inventorship disputes 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 and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending 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 have a material adverse effect on 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 and other employees.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have intellectual property rights, through licenses from third parties including Lilly, related to our product candidates. Because our program may require the use of additional proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may

require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license, on reasonable terms, proprietary rights related to any compositions, formulations, methods of use, processes or other intellectual property rights from third parties that we identify as being necessary for our product candidates. Even if we are able to obtain a license to such proprietary rights, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Where we obtain licenses from, grant licenses to, or collaborate with third parties, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, covering technology that we license to or from third parties in certain countries or regions. Such activities, if controlled by us, may require the input of such third parties. Such activities, if controlled by such third parties, may require the input of us. However, in either case, such third parties may not cooperate with us even where such third parties are obligated to do so. We may not align on strategies for prosecuting the relevant patent applications or maintaining the relevant patents. For example, such third-party may not cooperate with us and may decide to prosecute the patent application in a manner that is inconsistent with the best interests of our business, or fails to comply with applicable laws and regulations. The validity and enforceability of such patents or any patents that may issue from such patent applications may be affected.

We may also require the cooperation of our licensors, licensees, and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and patent applications may not be prosecuted, maintained, and/or enforced in a manner consistent with the best interests of our business, or in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such patent applications. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical or similar to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

The licensing and acquisition of third-party proprietary rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party proprietary rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we may collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate an exclusive license to any of the institution's proprietary rights in technology resulting from the collaboration. Regardless of such option to negotiate a license, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer, on an exclusive basis, their proprietary rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. 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 on commercially reasonable terms, our ability to commercialize our products, and our business, financial condition, and prospects for growth, could suffer.

Third-party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts.*

Our success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including *inter partes* review, interference and reexamination proceedings before the USPTO, or oppositions and other comparable proceedings in foreign jurisdictions. The America Invents Act introduced new procedures including *inter partes* review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future and the outcome of

such challenges. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our product candidates may give rise to claims of infringement of the patent rights of others.

The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. We cannot assure you that any of our current or future product candidates will not infringe existing or future patents. We may not be aware of patents that have already issued that a third party might assert are infringed by one of our current or future product candidates.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third-party patent applications which may later result in issued patents that our product candidates, any future product candidates, and other proprietary technologies may infringe, or which such third parties claim are infringed by the use of our technologies. Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates or future product candidates. Defense of these claims, regardless of their merit, could involve substantial expenses and could be a substantial diversion of management and other employee resources from our business. If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties.

We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. We cannot be certain that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of 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, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- 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;
- pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates, and any future product candidates or the use of our technologies, our product candidates, and any future product candidates;
- identification of third-party patent rights that may be relevant to our technology 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;
- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Furthermore, 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 and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. Further, we may incorrectly determine that our technologies, products, or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or internationally that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or product candidates.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and future approved products or impair our competitive position. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or

manufacture of our product candidates. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications and may be entitled to priority over our applications in such jurisdictions.

Any claims of patent infringement asserted by third parties would be time-consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing our product candidates or any future product candidates until the asserted patent expires or is finally held invalid, unenforceable, or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be willfully infringing; and/or
- require us to enter into royalty or license agreements, which may not be available on commercially reasonable terms, or at all.

Although no third party has asserted a claim of patent infringement against us as of the date of this Quarterly Report, others may hold proprietary rights that could prevent our product candidates from being marketed. For example, we are aware of issued patents that claim a method of treatment based upon a general mode of action. While we believe that these patents are difficult to enforce and that we would have valid defenses to these claims of patent infringement, we cannot be certain that we would prevail in any dispute, and we cannot be certain how an adverse determination would affect our business.

It is possible that a third party may assert a claim of patent infringement directed at any of our product candidates. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our products, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Even if we were able to obtain a license, the rights may be nonexclusive, which may give our competitors access to the same intellectual property.

Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates, treatment indications, or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Additionally, we may be subject to claims of patent infringement during those proceedings, and delays caused by the federal agencies may increase the time period that we are subject to such claims. For example, administrative changes, including reduced personnel and budgets experienced by the Patent and Trial Appeal Board, could further delay our ability to timely challenge any such patents. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses, and could distract 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 and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such 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 conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent proceedings could compromise our ability to compete in the marketplace. If we do not prevail in the patent proceedings the third parties may assert a claim of patent infringement directed at our product candidates.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees or consultants have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates and other proprietary technologies. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. 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 or personnel or sustain damage, which could adversely affect our business. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.*

Our patents or pending patent applications, or the patents or pending patent applications that we license, may be challenged in the courts or administrative bodies in the United States and other foreign jurisdictions. Such proceedings to challenges in enforceability or validity could result in the revocation of, cancellation of or amendment to our owned and in-licensed patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our licensing partners and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

Third parties including competitors may infringe, misappropriate or otherwise violate our patents, patents that may issue to us in the future, or the patents of our licensors that are licensed to us. To counter infringement or unauthorized use, we may need to or choose to file infringement claims, which can be expensive and time-consuming. We may not be able to prevent, alone or with our licensors, infringement, misappropriation, or other violation of our intellectual property, particularly in countries where the laws may not protect those rights as fully as in the United States.

If we choose to go to court to stop another party from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that such patents are invalid, unenforceable, or should not be enforced against that third party for any number of reasons. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements for patentability, including, but not limited to, lack of novelty, obviousness, lack of written description, indefiniteness, or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution, i.e., committed inequitable conduct.

Third parties may also raise similar claims before the USPTO, even outside the context of litigation or infringement. Such mechanisms could include re-examination, post-grant review, inter partes review, derivation proceedings, and equivalent proceedings

in foreign jurisdictions (e.g., opposition proceedings). For example, we were a party to an opposition proceeding with the European Patent Office with respect to EP Patent No. 3,784,233, a Revocation Proceeding with respect to EP Patent No. 3,784,233 (the "'233 Patent"), and a Unified Patent Court (UPC) Revocation Proceeding with respect to EP Patent No. 3,784,233. Oral proceedings took place on November 25, 2025, and on December 16, 2025, the Opposition Division issued a Decision of the Opposition Division stating the '233 Patent is revoked. The Decision of the Opposition Division may be appealed by filing a notice of appeal and grounds of appeal with the EPO's Boards of Appeal, due within a non-extendable period of two months and four months respectively from the date of the written decision. We may be subject to new or additional third-party pre-issuance submission of prior art to the USPTO or become involved in other post-grant review procedures, derivations, reexaminations, or *inter partes review* proceedings, in the United States or oppositions or similar proceedings in foreign jurisdictions, challenging our patent rights. The legal threshold for initiating such proceedings may be low, so that even proceedings with a low probability of success might be initiated. 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 products, or limit the duration of the patent protection of our technology and products.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development or manufacturing partnerships that would help us bring any future product candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract 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 and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. 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 conduct such litigation or proceedings adequately. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. 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 this type of litigation. Intellectual property litigation or administrative proceedings are very costly and time-consuming and could interfere with our ability to sell and market our products. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. 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.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality

agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors, and inventions agreements with employees, consultants, and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer, or third party with authorized access. Our security measures may not prevent an employee, consultant or customer 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. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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 future trademarks or trade names may be unable to be obtained, challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. 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 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 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. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Moreover, any name we have proposed to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed

product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it 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. Similar requirements exist in Europe. 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. 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. 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.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements, including the HBM License Agreement, 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 products 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;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates and any future 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 causes the delay or termination of the research, development, or commercialization of our current or future products or that results 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 current or future products;
- collaborators may own or co-own intellectual property covering our products 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;
- we may not be able to obtain intellectual property rights in technologies or products resulting from the collaboration; under certain situations, the collaborators may provide us with an option to negotiate a license to such developed technologies or products, however, we may not be able to negotiate such license; 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Securities

Pursuant to the Avenue Loan Agreement, we issued the Avenue Warrant to Avenue to purchase up to 64,000 shares of our common stock at an exercise price of $50.00 per share. We also granted a related conversion option to Avenue pursuant to which the holder may convert up to $4.0 million of the outstanding principal into shares of our common stock at a conversion price of $60.00, subject to the terms and conditions set forth in the applicable agreement. The Avenue Warrant and the associated conversion option were issued in a private placement transaction and were not registered under the Securities Act, in reliance on the exemption from registration provided by Section 4(a)(2).

Working Capital Restrictions and Limitations Upon the Payment of Dividends

Pursuant to the Avenue Loan Agreement, we are prohibited from paying cash dividends without the prior written consent of Avenue.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

During the three months ended March 31, 2026, no director or Section 16 officer of the Company adopted, modified or terminated any "Rule 10b5-1 trading arrangement" or any "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date
1.1	Open Market Sales Agreement[SM], dated March 9, 2026, by and between Spruce Biosciences, Inc. and Jefferies LLC	8-K	001-39594	1.1	March 9, 2026
1.2	Underwriting Agreement, dated April 20, 2026, by and among the Company, Leerink Partners LLC, Guggenheim Securities, LLC and Oppenheimer & Co. Inc.	8-K	001-39594	1.1	April 22, 2026
3.1	Amended and Restated Certificate of Incorporation	8-K	001-39594	3.1	October 14, 2020
3.2	Certificate of Amendment of the Amended and Restated Certificate of Incorporation	8-K	001-39594	3.1	July 24, 2025
3.3	Amended and Restated Bylaws	8-K	001-39594	3.2	October 14, 2020
4.1	Form of 2026 Warrant to Purchase Common Stock	10-K	001-39594	4.9	March 9, 2026
4.2	Form of 2026 Pre-Funded Warrant	8-K	001-39594	4.1	April 22, 2026
10.1	Loan and Security Agreement, dated January 7, 2026, by and between the registrant, Avenue Capital Management II, L.P. and Avenue Venture Opportunities Fund II, L.P.	8-K	001-39594	10.1	January 8, 2026
10.2	Supplement to the Loan and Security Agreement, dated January 7, 2026, by and between the registrant, Avenue Capital Management II, L.P. and Avenue Venture Opportunities Fund II, L.P.	8-K	001-39594	10.2	January 8, 2026
10.3	Offer Letter, by and between Spruce Biosciences, Inc. and Corwin Dale Hooks, dated February 18, 2026	8-K	001-39594	10.1	March 9, 2026
10.4	Form of Restricted Stock Unit Grant Notice and Award Agreement for Inducement Grant Outside of the Spruce Biosciences, Inc. 2020 Equity Incentive Plan	8-K	001-39594	10.2	March 9, 2026
10.5	Termination Agreement with Kaken Pharmaceutical Co. Ltd., dated March 16, 2026			Filed herewith	
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 amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			Filed herewith	
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 amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			Filed herewith	
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			Filed herewith	
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			Filed herewith	
101.INS	Inline XBRL Instance Document			Filed herewith	
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Document			Filed herewith	
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)			Filed herewith	

The information in Exhibits 32.1 and 32.2 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (including this Quarterly Report on Form 10-Q), unless the Registrant specifically incorporates the foregoing information into those documents by reference.

* Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted by means of marking such portions with asterisks because the registrant has determined that the information is the type that the registrant customarily and actually treats as private or confidential and is not material.

SIGNATURES

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

SPRUCE BIOSCIENCES, INC.

Date: May 13, 2026

By: */s/ Javier Szwarcberg M.D., MPH*
Javier Szwarcberg, M.D., MPH
Chief Executive Officer
(Principal Executive Officer)

Date: May 13, 2026

By: */s/ Samir Gharib*
Samir Gharib
President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.5

Termination Agreement

This Termination Agreement (the "Termination Agreement") is entered into as of March 31, 2026 (the "Termination Date") by and between SPRUCE BIOSCIENCES, INC., a Delaware corporation having its principal place of business at 611 Gateway Boulevard, Suite 740, South San Francisco, CA 94080, USA ("Spruce") and KAKEN PHARMACEUTICAL CO., LTD., a corporation organized under the laws of Japan and having its principal place of business at 28-8, Honkomagome 2-chome, Bunkyo-ku, Tokyo 113-8650, Japan ("Kaken"). Spruce and Kaken are each a "Party" and collectively the "Parties".

RECITALS

WHEREAS, the Parties entered into that certain Collaboration and License Agreement dated as of January 5, 2023 (the "Collaboration Agreement") and that Clinical Supply Agreement dated as of August 9, 2024 ("CSA"); and

WHEREAS, the Parties wish to terminate the Collaboration Agreement and CSA by mutual agreement and to set forth the terms and conditions of such termination.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the Parties agree as follows:

1 Termination of Agreements; Effective Date

1.1 The Collaboration Agreement and CSA are hereby terminated by mutual agreement, effective as of the Termination Date. From and after the Termination Date, the Collaboration Agreement and CSA shall each be of no further force or effect except as otherwise expressly set forth in each respective agreement.

1.2 Without limiting the foregoing, following the Termination Date, each Party shall properly maintain and store all information and data in connection with the Development (including nonclinical and clinical data) for the required period in accordance with applicable Law.

2 Mutual Releases

2.1 Release by Spruce. Except as to such rights or claims as may be created by this Termination Agreement and the provisions of the Collaboration Agreement that survive termination as set forth in this Termination Agreement, Spruce for itself and for its assigns, attorneys, insurers, beneficiaries, employees, officers, directors, shareholders, legal and equitable owners, members, predecessors in interest, successors in interest, representatives, and any and all other persons, trusts, firms, exchanges, corporations, joint ventures, limited liability companies, partnerships or subsidiaries with whom any of the foregoing have been, are now or may hereafter be affiliated (collectively, the "Spruce Releasing Parties"), hereby generally and specifically release and forever discharge Kaken and its assigns, attorneys, insurers, beneficiaries, employees, officers, directors, shareholders, legal and equitable owners, members, predecessors in interest, successors in interest, representatives, property manager, and any and all other persons, trusts, firms, exchanges, corporations, joint ventures, limited liability companies, partnerships or subsidiaries with whom any of the foregoing have been, are now or may hereafter be affiliated from any and all present, past, or future claims, demands, debts, losses, obligations, warranties, costs, expenses, rights of action, and causes of action of every kind and nature whatsoever, whether based on contract, tort, statutory, or other legal or equitable theory of recovery, known or unknown, suspected or unsuspected, existing, or claimed to exist, which the Spruce Releasing Parties had or may hereafter accrue or which may be acquired, from the beginning of time to the Termination Date arising out of the Collaboration Agreement or the CSA.

2.2 Release by Kaken. Except as to such rights or claims as may be created by this Termination Agreement and the provisions of the Collaboration Agreement that survive termination as set forth in this Termination Agreement, Kaken for itself and for its assigns, attorneys, insurers, beneficiaries, employees, officers, directors, shareholders, legal and equitable owners, members, predecessors in interest, successors in interest, representatives, and any and all other persons, trusts, firms, exchanges, corporations, joint ventures, limited liability companies, partnerships or subsidiaries with whom any of the foregoing have been, are now or may hereafter be affiliated (collectively, the

"Kaken Releasing Parties"), hereby generally and specifically release and forever discharge Spruce and its assigns, attorneys, insurers, beneficiaries, employees, officers, directors, shareholders, legal and equitable owners, members, predecessors in interest, successors in interest, representatives, property manager, and any and all other persons, trusts, firms, exchanges, corporations, joint ventures, limited liability companies, partnerships or subsidiaries with whom any of the foregoing have been, are now or may hereafter be affiliated from any and all present, past, or future claims, demands, debts, losses, obligations, warranties, costs, expenses, rights of action, and causes of action of every kind and nature whatsoever, whether based on contract, tort, statutory, or other legal or equitable theory of recovery, known or unknown, suspected or unsuspected, existing, or claimed to exist, which the Kaken Releasing Parties had or may hereafter accrue or which may be acquired, from the beginning of time to the Termination Date arising out of the Collaboration Agreement or the CSA.

2.3 Unknown Claims Waiver. The Parties acknowledge the risk that, subsequent to the execution of this Termination Agreement, they may discover, incur, or suffer damages based upon claims which were unknown or unanticipated at the time this Termination Agreement was executed. The Parties acknowledge that they are assuming the risk of such unknown and unanticipated claims and agree that this Termination Agreement applies to such unknown and unanticipated claims.

2.4 Later Discovery. Each Party is aware that it may hereafter discover claims or facts in addition to or different from those it now knows or believes to be true with respect to the matters related herein. Nevertheless, it is the intention of the Parties to fully, finally and forever settle and release all such matters, and all claims relative thereto, which do now exist, may exist, or heretofore have existed between them. In furtherance of such intention, the release given herein shall be and remain in effect as full and complete mutual releases of all such matters, notwithstanding the discovery or existence of any additional or different claims or facts relative thereto.

2.5 No Admission. This Termination Agreement is not, and shall not be represented or construed by any Party as an admission of liability, breach or wrongdoing on the part of the other Party to this Termination Agreement or any liability whatsoever for any claims under the Collaboration Agreement or the CSA.

3 Public Announcement of Termination

Notwithstanding anything to the contrary in this Termination Agreement, the Parties agree that, either Party shall have the right to issue a public press release or make other public disclosures specifically announcing the termination of the Agreement, except as required to comply with applicable Laws, including those related to disclosures to the Securities and Exchange Commission. The Party proposing such disclosure shall (i) provide the other Party with the proposed text of the disclosure at least three (3) Business Days prior to the proposed public release for review and comment, and (ii) reasonably consider and incorporate any specific, material comments provided by the other Party within such three (3) Business Day period. If the Parties cannot agree on the final text within such three (3) Business Day period, either Party may proceed with a disclosure that is a fair and accurate statement of the termination, provided that such disclosure does not include the other Party's Confidential Information or commercially sensitive terms (including, without limitation, financial terms, detailed transition arrangements, or proprietary technical information).

4 Governing Law; Dispute Resolution

This Termination Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to conflict of laws rules.

5 Signatures

IN WITNESS WHEREOF, the Parties have executed this Termination Agreement as of the Termination Date. The Parties agree that this Termination Agreement may be executed by electronic signature (including but not limited to DocuSign or other reliable electronic signature platforms), and that such electronic signatures shall be deemed to have the same legal effect, validity and enforceability as original handwritten signatures. Delivery of an executed counterpart of this

Termination Agreement by electronic means (e.g., PDF or other electronic transmission of a signed document) shall be sufficient to bind the delivering Party.

SPRUCE BIOSCIENCES, INC.

By: /s/ Samir Gharib_____
Name: Samir Gharib
Title: President and Chief Financial Officer
Date: _____

KAKEN PHARMACEUTICAL CO., LTD.

By: /s/ Mitsuru Watanuki_____
Name: Mitsuru Watanuki
Title: Executive Director, Member of the Board, and Head of R&D Division
Date: _____

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, Javier Szwarcberg, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Spruce Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: May 13, 2026

By: */s/ Javier Szwarcberg, M.D., MPH*

Javier Szwarcberg, M.D., MPH
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, Samir Gharib, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Spruce Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: May 13, 2026

By: */s/ Samir Gharib*
Samir Gharib
President and 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 Spruce Biosciences, Inc. (the "Company") on Form 10-Q for the period ended March 31, 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 Section 15(d) of the Securities Exchange Act of 1934, as amended; 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: May 13, 2026

By: */s/ Javier Szwarcberg, M.D., MPH*
Javier Szwarcberg, M.D., MPH
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 Spruce Biosciences, Inc. (the "Company") on Form 10-Q for the period ended March 31, 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 Section 15(d) of the Securities Exchange Act of 1934, as amended; 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: May 13, 2026

By: */s/ Samir Gharib*

Samir Gharib
President and Chief Financial Officer
(Principal Financial and Accounting Officer)