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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 September 30, 2026

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39594

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	The Nasdaq Stock Market LLC

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

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

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

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

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

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

As of November 5, 2026, the registrant had 2,874,013 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 do not currently have sufficient working capital to fund our planned operations for the next twelve months and substantial doubt exists as to our ability to continue as a going concern.
- 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.
- 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 nonclinical 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.
- 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.
- Nonclinical 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 or future product candidates, which could make it difficult for us to sell TA-ERT and our other current or future product candidates profitably.
- If we fail to develop and commercialize additional product candidates, we may be unable to grow our business.
- 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.
- The separation of our CRHX-101 (formerly known as SPR202) program into Adrenyx and the planned distribution of Adrenyx shares to our stockholders may not be completed on the anticipated timeline or at all, may not achieve the intended benefits, and could disrupt our business and divert management attention.
- 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 nonclinical 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 and other proprietary technologies, if approved, may be adversely affected.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 87,691	$ 48,906
Prepaid expenses	2,406	353
Other current assets	203	2,853
Total current assets	90,300	52,112
Right-of-use assets	450	666
Other assets	1,198	243
Total assets	$ 91,948	$ 53,021
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,732	$ 943
Accrued expenses and other current liabilities	11,978	9,143
Debt, current portion	4,000	—
Total current liabilities	18,710	10,086
Lease liabilities, net of current portion	155	419
Debt, net of current portion	3,822	—
Warrant liability	2,966	—
Total liabilities	25,653	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 September 30, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 2,874,013 and 1,372,043 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	408,030	331,750
Accumulated deficit	(341,735)	(289,234)
Total stockholders' equity	66,295	42,516
Total liabilities and stockholders' equity	$ 91,948	$ 53,021

See accompanying notes to the condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 18,133	$ 5,011	$ 37,871	$ 15,418
General and administrative	5,848	3,218	14,609	9,995
Total operating expenses	23,981	8,229	52,480	25,413
Loss from operations	(23,981)	(8,229)	(52,480)	(25,413)
Interest expense	(1,201)	(19)	(2,972)	(84)
Interest and other income, net	819	138	2,070	660
Change in fair value of warrant and conversion option liabilities	357	(102)	881	517
Net loss and comprehensive loss	(24,006)	(8,212)	(52,501)	(24,320)
Net loss per share, basic and diluted	$ (8.51)	$ (14.58)	$ (23.71)	$ (41.25)
Weighted-average shares of common stock outstanding, basic and diluted	2,821,316	563,066	2,214,382	589,520

See accompanying notes to the condensed consolidated financial statements.

SPRUCE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED 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 July 1, 2026	2,752,810	$ —	$ 401,459	$ (317,729)	$ 83,730
Issuance of common stock under the August 2026 Private Placement, net of offering costs of $31	121,203	—	5,469	—	5,469
Stock-based compensation	—	—	1,102	—	1,102
Net loss	—	—	—	(24,006)	(24,006)
Balance as of September 30, 2026	2,874,013	$ —	$ 408,030	$ (341,735)	$ 66,295

	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 under the August 2026 Private Placement, net of offering costs of $31	121,203	—	5,469	—	5,469
Issuance of common stock and warrants under the April 2026 Public Offering, net of offering costs of $4,562	1,380,000	—	64,438	—	64,438
Issuance of common stock related to employee stock purchase plan	532	—	2	—	2
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	—	—	2,662	—	2,662
Net loss	—	—	—	(52,501)	(52,501)
Balance as of September 30, 2026	2,874,013	$ —	$ 408,030	$ (341,735)	$ 66,295

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of July 1, 2025	563,042	$ —	$ 279,556	$ (266,376)	$ 13,180
Issuance of common stock related to employee stock purchase plan	449	—	3	—	3
Stock-based compensation	—	—	415	—	415
Net loss	—	—	—	(8,212)	(8,212)
Balance as of September 30, 2025	563,491	$ —	$ 279,974	$ (274,588)	$ 5,386

	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
Issuance of common stock related to employee stock purchase plan	449	—	3	—	3
Stock-based compensation	—	—	882	—	882
Net loss	—	—	—	(24,320)	(24,320)
Balance as of September 30, 2025	563,491	$ —	$ 279,974	$ (274,588)	$ 5,386

See accompanying notes to the condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities		
Net loss	$ (52,501)	$ (24,320)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,662	882
Depreciation and amortization	1,621	16
Non-cash lease expense	216	199
Change in fair value of warrant and conversion option liabilities	(881)	(517)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	397	1,606
Other assets	(486)	—
Accounts payable	1,789	91
Accrued expenses and other current liabilities	2,835	(4,310)
Other liabilities	(264)	(518)
Net cash used in operating activities	(44,612)	(26,871)
Cash flows from investing activities		
Purchases of property and equipment	(145)	—
Net cash used in investing activities	(145)	—
Cash flows from financing activities		
Proceeds from issuance of common stock and warrants, gross	70,360	—
Proceeds from debt, gross	14,200	—
Proceeds from issuance of common stock related to employee stock purchase plan	2	3
Repayment of debt	—	(1,216)
Payment of debt and equity offering costs including deferred costs	(1,010)	—
Tax withholding payments on restricted stock units	(10)	—
Net cash provided by (used in) financing activities	83,542	(1,213)
Net increase (decrease) in cash, cash equivalents, and restricted cash	38,785	(28,084)
Cash, cash equivalents, and restricted cash at beginning of period	48,942	38,788
Cash, cash equivalents, and restricted cash at end of period	$ 87,727	$ 10,704
Reconciliation of cash, cash equivalents, and restricted cash		
Cash and cash equivalents	$ 87,691	$ 10,669
Restricted cash, long-term (included in other assets)	36	35
Total cash, cash equivalents, and restricted cash	$ 87,727	$ 10,704
Supplemental cash flow data:		
Cash paid for interest on term loan	$ 1,092	$ 65
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	$ —

See accompanying notes to the condensed consolidated financial statements.

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

1. Organization and Principal Activities

Description of Business

Spruce Biosciences, Inc. ("Spruce" and together with its consolidated subsidiary, 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. Spruce was incorporated in the state of Delaware in April 2016 and its wholly-owned consolidated subsidiary, Adrenyx Biosciences, Inc. ("Adrenyx") was incorporated in the state of Delaware in August 2026. Adrenyx was formed in connection with the Company's separation of its CRHX-101 (formerly known as SPR202) program, as further described in Note 13.

August 2026 Private Placement

On August 7, 2026, the Company entered into a Stock Purchase Agreement with the National MPS Society and the Cure Sanfilippo Foundation (the "Purchasers"), pursuant to which the Company sold and issued to the Purchasers 121,203 shares of common stock in a private placement transaction. The purchase price was $45.38 per share of common stock. The total net proceeds to the Company, after deducting offering expenses payable by the Company, were $5.5 million. The proceeds will be used to partially fund the Company's planned open-label, single-arm expanded access program to provide TA-ERT for the treatment of MPS IIIB in children.

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 net proceeds to the Company from the offering, after deducting underwriting discounts and commissions and offering expenses payable by the Company, were $64.4 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 September 30, 2026, the Company has not issued any shares of common stock under the Sales Agreement.

Reverse Stock Split

Effective April 29, 2025, trading of the Company's common stock on the Nasdaq Capital Market was suspended 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 effective time of the Reverse Stock Split, 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 nine months ended September 30, 2026, the Company incurred a net loss of $52.5 million and used $44.6 million of cash in operations. As of September 30, 2026, the Company had an accumulated deficit of $341.7 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. Without alternative financing or proceeds from other strategic alternatives, the Company believes that based on its current operating plan, its cash and cash equivalents of $87.7 million as of September 30, 2026 will be insufficient to fund its planned operations and debt obligations for at least 12 months following the issuance date of these condensed consolidated financial statements. Accordingly, there is substantial doubt about the Company's ability to continue as a going concern for at least 12 months following the issuance date of these condensed consolidated financial statements. In addition, the Avenue Loan Agreement contains a subjective acceleration clause. If Avenue were to declare an event of default, including on the basis of a material adverse effect, the outstanding obligations under the Avenue Loans could become immediately due and payable.

The Company's ability to continue as a going concern will require the Company to raise additional capital to fund the Company's operations and there can be no assurance that additional financing will be available to the Company or that such financing, if available, will be available on terms acceptable to the Company. In order to meet these additional cash requirements, the Company may seek to sell one or more priority review vouchers, if received, out-license rights to develop and commercialize its investigational product candidates, sell additional equity or issue debt, convertible debt or other securities that may result in dilution to its stockholders. If the Company raises additional funds through the issuance of debt or convertible debt securities, these securities could have rights senior to those of its shares of common stock and could contain covenants that restrict its operations. Additional debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting the Company's ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. The Company's failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on its business, results of operations, financial condition and prospects.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

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 consolidated financial statements include the accounts of Spruce and its wholly-owned subsidiary, Adrenyx. All intercompany balances and transactions have been eliminated in consolidation.

The condensed consolidated balance sheet as of September 30, 2026, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2026 and 2025, the condensed consolidated statement of stockholders' equity for the three and nine months ended September 30, 2026 and 2025, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2026 and 2025 are unaudited. The interim condensed consolidated 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 consolidated balance sheet as of December 31, 2025 is derived from the Company's audited financial statements. The results of operations for the three and nine months ended September 30, 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 consolidated 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").

Prior year amounts relating to the change in fair value of warrant liability that were previously included in Interest and other income, net on the condensed consolidated statement of operations and comprehensive loss for the three and nine months ended September 30, 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, U.S. federal government shutdowns and the risk of future lapses in appropriations 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 consolidated 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 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 consolidated statements of operations and comprehensive loss. The measure of segment assets is reported on the condensed consolidated balance sheet as total assets.

Significant Accounting Policies

There have been no significant changes to the significant accounting policies during the nine months ended September 30, 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.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements* ("ASU 2025-11"), which intends to improve the navigability of the guidance in ASC 270 and clarify the applicability of the interim reporting guidance, the types of interim reporting, and the form and content of interim financial statements. ASU 2025-11 is effective for annual periods beginning after December 15, 2027, and interim periods within those annual periods, with early adoption permitted. The Company expects that the adoption of ASU 2025-11 will not have a material impact on its financial statements and related disclosures.

In December 2025, the FASB issued Accounting Standards Update 2025-12, *Codification Improvements* ("ASU 2025-12"), which provides narrow-scope amendments to clarify, correct errors, and improve the consistency of various topics within the Accounting Standards Codification. The update addresses several technical issues, including refining diluted earnings per share calculations during loss periods. ASU 2025-12 is effective for annual periods beginning after December 15, 2026, and interim periods within those annual periods, with early adoption permitted. 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):

	September 30, 2026			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Cash equivalents:				
Money market funds	$ 86,872	$ 86,872	$ —	$ —
Total	$ 86,872	$ 86,872	$ —	$ —
Financial liabilities:				
Warrant liability	$ 2,966	$ —	$ 2,966	$ —
Total	$ 2,966	$ —	$ 2,966	$ —

	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

As of September 30, 2026, the Company estimated the fair value of the Avenue Loans (see Note 6) to be $12.0 million, based on Level 3 inputs, compared to a carrying value of $7.8 million. Although the Avenue Loans bear interest at a variable rate based in part on the prime rate, the 12.25% interest rate floor applied as of September 30, 2026.

Warrant and Conversion Option Liabilities

As of September 30, 2026, the Company classified its warrant liability as a Level 2 instrument as it was valued using the Black-Scholes option-pricing model using observable inputs. 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):

	September 30, 2026	December 31, 2025
Accrued research and development expenses	$ 7,923	$ 3,496
Accrued general and administrative expenses	1,364	3,556
Accrued compensation and benefits	2,346	1,774
Lease liabilities, current portion	345	317
Total accrued expenses and other current liabilities	$ 11,978	$ 9,143

Accrued research and development expenses were primarily related to manufacturing and 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 September 30, 2026, the stated interest rate of the Avenue Loans was 12.25%. As of September 30, 2026, no amounts had been drawn under Tranche 2, and the original availability period for Tranche 2 expired on September 30, 2026. In November 2026, the Company amended the Avenue Loan Agreement to, among other things, increase and extend the availability of Tranche 2 and amend the terms of Tranche 3 (see Note 13).

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. Because no portion of Tranche 2 was funded as of September 30, 2026, the 6-month extension of the interest-only period under the original terms of the Avenue Loan Agreement was not available as of that date. Pursuant to the amendment described in Note 13, the interest-only period was extended through March 31, 2027, and, unless the interest-only period is further extended, monthly principal payments will commence in April 2027.

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 September 30, 2026, the Company was in compliance with all covenants under the Avenue Loan Agreement.

The Avenue Loan Agreement includes a subjective acceleration clause under which the Agent may declare an event of default upon the occurrence of circumstances that could reasonably be expected to have a material adverse effect, as defined in the agreement. As of the issuance date of these condensed consolidated financial statements, Avenue has not declared an event of default, and the Company has determined that acceleration under this provision is not probable. Accordingly, the Avenue Loans continue to be classified based on their scheduled repayment terms. If Avenue were to determine that a material adverse effect has occurred, all outstanding obligations could become immediately due and payable.

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 September 30, 2026, the carrying value of the Avenue Loans was $7.8 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 $8.8 million, which are being amortized using the effective interest method over the life of the Avenue Loans.

For the three and nine months ended September 30, 2026, interest expense on the Avenue Loans was $1.2 million and $3.0 million, respectively, consisting of contractual interest of $0.5 million and $1.4 million and amortization of debt discount and issuance costs of $0.7 million and $1.6 million.

As of September 30, 2026, future payments of principal and interest of the Avenue Loans are as follows (in thousands):

Year ending December 31,		
2026 (remaining 3 months)	$	470
2027		7,020
2028		6,778
2029		5,207
Total	$	19,475
Less: interest		(2,875)
Debt, gross	$	16,600
Less: unamortized debt discount and costs		(8,778)
Less: debt, current portion		(4,000)
Debt, net of current portion	$	3,822

Avenue Warrant

On March 9, 2026, 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. 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. In November 2026, the Company amended the Avenue Warrant to increase the number of shares of the Company's common stock issuable pursuant to the Avenue Warrant by 5,000 shares. The Avenue Warrant will expire on March 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 was not 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 using a Monte Carlo simulation model, with changes in fair value recognized on the condensed consolidated statements of operations and comprehensive loss.

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 consolidated statements of operations and comprehensive loss.

Following the April 2026 Public Offering (see Note 1), the valuation method for the Avenue Warrant was changed from the Monte Carlo simulation model to the Black-Scholes option-pricing model. The Monte Carlo simulation model previously incorporated uncertainty regarding the exercise price and number of shares issuable under a financing-related reset provision. Upon completion of the April 2026 Public Offering, that contingency was resolved, establishing an exercise price of $50.00 per share and 64,000 shares issuable upon exercise. Given the resolution of this contingency and the Company's assessment that the remaining contingent settlement provisions did not materially affect fair value, the Company determined that the Black-Scholes option-pricing model appropriately reflected the Avenue Warrant's remaining terms and market participant assumptions.

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 using a Monte Carlo simulation model, with changes in fair value recognized on the condensed consolidated statements of operations and comprehensive loss.

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 were measured using a Monte Carlo simulation model at the grant and issue dates and the Avenue Warrant was measured using the Black-Scholes option-pricing model at September 30, 2026 with the following inputs as of the periods noted:

	Avenue Warrant		Avenue Conversion Option	
	Grant Date 1/7/2026	Quarter End 9/30/2026	Grant Date 1/7/2026	Issue Date 3/9/2026
Warrant exercise price / Conversion price max	$ 89.21	$ 50.00	$ 4,000,000	$ 4,000,000
Expected term (in years)	5.1	4.5	3.5	3.3
Expected stock price volatility	178.8%	184.2%	178.8%	179.3%
Risk-free interest rate	3.7%	5.1%	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	(853)	(28)	(881)
Reclass to additional paid-in capital	—	(3,719)	(3,719)
Fair value as of September 30, 2026	$ 2,966	$ —	$ 2,966

As of September 30, 2026, 64,000 shares of common stock remain issuable under the Avenue Warrant at an exercise price of $50.00 and the Avenue Conversion Option, under which up to 66,667 shares of common stock are issuable, has not been exercised. Subsequently in November 2026, the shares of common stock issuable under the Avenue Warrant increased by 5,000 shares (see Note 13).

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 September 30, 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 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 September 30, 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 an exclusive (outside of mainland China, Taiwan, Hong Kong and Macau), royalty-bearing and sublicensable license to certain technology, patent rights, manufacturing rights, know-how, and proprietary materials relating to CRHX-101, an anti-corticotropin-releasing hormone monoclonal antibody ("CRHX-101").

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 nine months ended September 30, 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.

In connection with the Separation and planned Distribution described in Note 13, the Company assigned the HBM License Agreement to Adrenyx.

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 September 30, 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.

The Company enters into contracts in the normal course of business with third-party contract manufacturing organizations and CROs for clinical trials, nonclinical studies, drug substance and product manufacturing and other services for operating purposes. These contracts are generally cancelable by the Company 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 the Company's service providers, up to the date of cancellation. As of September 30, 2026, total noncancelable obligations under these arrangements were $22.1 million.

9. Capital Structure

Common Stock

As of September 30, 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 September 30, 2026, no dividends were declared.

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

	September 30, 2026	December 31, 2025
Common stock warrants, issued and outstanding	233,147	169,147
Stock options, issued and outstanding	49,174	42,421
Restricted stock units, issued and outstanding	147,584	47,200
Shares available for future issuance under 2020 Equity Incentive Plan	37,380	19,715
Shares available for future issuance under 2020 Employee Stock Purchase Plan	17,882	12,531
Shares available for future issuance under 2026 Inducement Plan	40,400	—
Shares issuable upon conversion of the Avenue Conversion Option	66,667	—
Total shares reserved	592,234	291,014

10. Stock-Based Compensation Expense

The following table summarizes the components of stock-based compensation expense recognized in the Company's condensed consolidated statements of operations and comprehensive loss during the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 344	$ 44	$ 733	$ (254)
General and administrative	758	371	1,929	1,136
Total stock-based compensation expense	$ 1,102	$ 415	$ 2,662	$ 882

Restricted Stock Units ("RSUs")

During the nine months ended September 30, 2026, the Company granted 103,550 RSUs with a weighted-average grant date fair value of $67.12 per unit, of which 36,900 RSUs are subject to performance-based vesting conditions related to the satisfaction of a regulatory milestone. As of September 30, 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (24,006)	$ (8,212)	$ (52,501)	$ (24,320)
Denominator:				
Weighted-average shares of common stock outstanding	2,821,316	563,066	2,214,382	589,520
Net loss per share, basic and diluted	$ (8.51)	$ (14.58)	$ (23.71)	$ (41.25)

Weighted-average shares of common stock outstanding during the periods presented include any outstanding pre-funded warrants. 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:

	September 30,	
	2026	2025
Shares subject to outstanding common stock warrants	233,147	169,147
Shares subject to outstanding common stock options	49,174	40,034
Shares subject to outstanding RSUs	147,584	25,512
Estimated shares issuable under the 2020 Employee Stock Purchase Plan	2,086	1,388
Shares issuable upon conversion of the Avenue Conversion Option	66,667	—
Total	498,658	236,081

12. Related Party Transactions

Effective December 20, 2024, Kirk Ways, M.D., a member of the board of directors, began serving as the Company's interim Chief Medical Officer pursuant to a consulting agreement and served in such role until July 27, 2026, when Adrian Quartel, M.D., FFPM, was appointed as the Company's Chief Medical Officer. Following such appointment, Dr. Ways continued to provide consulting services to the Company. During the nine months ended September 30, 2026 and 2025, the Company recognized compensation expense of $0.9 million and $0.3 million, respectively, related to services provided by Dr. Ways, which is included in research and development expenses on the condensed consolidated statement of operations and comprehensive loss. As of September 30, 2026, the Company accrued compensation expense of $0.1 million related to such services, which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheet.

13. Subsequent Events

The Company has evaluated subsequent events through the date on which these condensed consolidated financial statements were issued.

Separation and Distribution

On November 6, 2026, the Company's board of directors approved a plan to separate and contribute the Company's CRHX-101 program into Adrenyx (the "Separation"). Also on November 6, 2026, the Company and Adrenyx entered into a series of agreements, including a separation and distribution agreement (the "Separation Agreement") and a transition services agreement (the "Transition Services Agreement"). Pursuant to the Separation Agreement, among other things, the Company contributed to Adrenyx certain assets and liabilities relating to the CRHX-101 program as part of the Separation, including assignment of the HBM License Agreement. The Separation Agreement sets forth the conditions to, and the procedures for effecting, the distribution of all of the outstanding shares of Adrenyx common stock to the Company's stockholders on a pro rata basis (the "Distribution"), subject to approval by the Company's board of directors.

The Company will provide certain services to Adrenyx for a period of up to 12 months following the Distribution, subject to extension, compensated by Adrenyx as provided in the Transition Services Agreement.

Approval by the Company's stockholders is not required as a condition to the consummation of the Distribution and there can be no assurance that the Distribution will be completed on the anticipated timeline, on the anticipated terms or at all.

Adrenyx's Secured Convertible Notes

On November 6, 2026, Adrenyx entered into a secured convertible note purchase agreement (the "Note Purchase Agreement") with a leading institutional biotechnology investor, pursuant to which Adrenyx may issue secured convertible promissory notes in an aggregate principal amount of up to $10.0 million, of which $5.0 million in aggregate principal amount was issued at the initial closing (the "Initial Adrenyx Notes"). The Initial Adrenyx Notes bear cash interest at 6% per annum, mature on the twelve-month anniversary of the initial closing and are automatically convertible into Conversion Securities (as defined in the Note Purchase Agreement, and which may include shares of Adrenyx's common stock or other securities) upon the closing of a qualified equity financing raising aggregate gross proceeds of $37.5 million to investors, at a conversion price equal to 90% of the per-unit price issued to investors in such financing, or certain other financings of Adrenyx. Subject to certain terms and conditions set forth in the Note

Purchase Agreement, including consent of such investor, Adrenyx may issue up to an additional $5.0 million of secured convertible promissory notes under the Note Purchase Agreement on the same terms as the Initial Adrenyx Notes (collectively, the "Adrenyx Notes"). Adrenyx is required to use the proceeds of the Adrenyx Notes to develop and commercialize the CRHX-101 program and for its other general corporate purposes, and the Company is not permitted to use any such proceeds to fund its own operations. The Adrenyx Notes are secured by substantially all assets of Adrenyx. The Adrenyx Notes are not secured by any assets of the Company or guaranteed by the Company. The Note Purchase Agreement contains customary negative covenants, including restrictions on the incurrence of additional indebtedness, the granting of additional liens, the payment of dividends and the consummation of certain transactions, in each case without the prior written consent of the holders of a majority-in-interest of the aggregate principal amount of the Adrenyx Notes. The Note Purchase Agreement also includes certain customary events of default, including payment defaults, breach of covenants and certain insolvency events of Adrenyx. Upon the occurrence of an event of default, the holders of the Adrenyx Notes may accelerate the outstanding amounts thereunder and the collateral agent may enforce its rights against the collateral.

Amendment to Avenue Loan Agreement

On November 6, 2026, the Company entered into an amendment to the Avenue Loan Agreement (the "Avenue Amendment"), which, among other things, (i) increased the amount available under Tranche 2 to up to $15.0 million, which may be drawn in a minimum amount of $5.0 million and in increments of $2.5 million between January 1, 2027 and March 31, 2027, subject to the satisfaction of certain conditions and to earlier expiration in certain circumstances; (ii) amended Tranche 3 to be available between July 1, 2027 and December 31, 2027, made Tranche 3 discretionary and subject to the approval of the Lender's investment committee at the time of any draw, and provided that the amount of Tranche 3 will be reduced by the amount of any Tranche 2 borrowings in excess of $10.0 million, such that the aggregate commitment amount under Tranche 1, Tranche 2 and Tranche 3 remains unchanged; and (iii) extended the interest-only period through March 31, 2027 and provided that the interest-only period may be further extended through October 31, 2027 (an interest-only period of 21 months, compared to 18 months under the original terms of the Avenue Loan Agreement) and, thereafter, through October 31, 2028 (an interest-only period of 33 months), in each case subject to the satisfaction of certain conditions. In connection with the Avenue Amendment, which also included Avenue's consent to the Separation, including the release of Avenue's lien on the assets contributed to Adrenyx, the Company amended the Avenue Warrant to increase the number of shares of common stock issuable thereunder by 5,000 shares, with no change to the exercise price of $50.00 per share. Also in connection with the Avenue Amendment, Adrenyx issued a warrant to Avenue for 69,000 shares of Adrenyx common stock (the "Adrenyx Avenue Warrant") at an exercise price of the lower of $17.53 or the lowest effective price per share of any equity offering of Adrenyx's common stock after the warrant's issuance and prior to June 30, 2027.

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 consolidated 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. and its consolidated subsidiary.

Forward-Looking Statements

In addition to historical financial information, this Quarterly Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are based upon current expectations and 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.

Forward-looking statements include, but are not limited to, statements regarding: the timing of our planned biologics license application ("BLA") submission for TA-ERT and the potential for, and timing of, U.S. Food and Drug Administration ("FDA") acceptance, priority review and accelerated approval; the initiation, design, enrollment and timing of our planned TrAnsform confirmatory study and expanded access program; our manufacturing and supply plans; the anticipated commercial launch of TA-ERT, if approved; our potential receipt and sales of one or more priority review vouchers; the Separation of Adrenyx and the planned Distribution and its anticipated timing and benefits; the availability of additional funding under the Avenue Loan Agreement, as amended; our expected cash needs, funding requirements and ability to continue as a going concern; and the effects of tariffs and macroeconomic conditions on our business. Forward-looking statements speak only as of the date of this Quarterly Report. Except as required by law, we undertake no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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 late-stage biopharmaceutical company focused on developing and commercializing novel therapies for neurological disorders with significant unmet medical need. We focus on 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 incorporated in April 2016. In November 2026, we entered into a separation and distribution agreement (the "Separation Agreement") to separate our CRHX-101 (formerly SPR202) program into Adrenyx Biosciences, Inc. ("Adrenyx"), our wholly-owned subsidiary, and to distribute all outstanding shares of Adrenyx to our stockholders. See "Separation of Adrenyx and Planned Distribution" below.

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 nonclinical 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 mucopolysaccharidosis type IIIB ("MPS IIIB"), or Sanfilippo Syndrome Type B. In October 2025, TA-ERT received breakthrough therapy designation from the FDA for the treatment of Sanfilippo Syndrome Type B. TA-ERT has also received Rare Pediatric Disease Designation and Fast Track Designation from the FDA and Orphan Drug Designation in the United States and the European Union ("EU"). We anticipate submitting a BLA seeking accelerated approval of TA-ERT for the treatment of Sanfilippo Syndrome Type B in December 2026. In the second quarter of 2026, we completed two pre-BLA meetings with the FDA, in which the FDA generally agreed with our proposed approach to the overall content and format of the BLA and indicated that our analytical comparability strategies following the transfer of TA-ERT manufacturing to a global biologics contract manufacturer appeared reasonable to support the BLA. We completed the first drug product process performance qualification ("PPQ") batch in July 2026 and expect to complete the second PPQ batch in December 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 nine months ended September 30, 2026 and 2025, we incurred net losses of $52.5 million and $24.3 million, respectively, and used $44.6 million and $26.9 million of cash in operations, respectively. As of September 30, 2026, we had an accumulated deficit of $341.7 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.

As of September 30, 2026, we had cash and cash equivalents of $87.7 million. Since inception through September 30, 2026, we have raised aggregate gross proceeds of $432.6 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, $109.1 million from private placement financings (including the August 2026 private placement), $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.

Without alternative financing or proceeds from other strategic alternatives, we believe that based on our current operating plan, our cash and cash equivalents of $87.7 million as of September 30, 2026 will be insufficient to fund our planned operations and debt obligations for at least 12 months following the issuance date of these condensed consolidated 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 our planned TrAnsform confirmatory study (a randomized, single-blind, parallel-group, controlled, multicenter study of TA-ERT evaluating the safety, tolerability and efficacy of intracerebroventricular ("ICV")-administered TA-ERT compared to standard of care in children 1 to 5 years of age with severe (non-attenuated) MPS IIIB, which the FDA has indicated must be initiated during its review of our BLA as a condition of potential accelerated approval) and expanded access program (under an intermediate-size population expanded access protocol). The TrAnsform confirmatory study, which is on track to initiate in December 2026, is expected to enroll approximately 14 participants. The expanded access program initiated in November 2026, and is expected to enroll approximately 10 participants;
- expand manufacturing capacity to accommodate anticipated global demand of TA-ERT, if approved, for the treatment of MPS IIIB;
- implement operational, financial, and management information systems;
- hire additional personnel; and
- obtain, maintain, expand, and protect our intellectual property portfolio.

In November 2025, the 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 September 30, 2026, we have not issued any shares of common stock under the Sales Agreement.

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 net proceeds to us from the offering, after deducting underwriting discounts and commissions and offering expenses payable by us, were $64.4 million.

On August 7, 2026, we entered into a Stock Purchase Agreement with the National MPS Society and the Cure Sanfilippo Foundation (the "Purchasers"), pursuant to which we sold and issued to the Purchasers 121,203 shares of common stock in a private

placement transaction. The purchase price was $45.38 per share of common stock. The net proceeds to us, after deducting offering expenses payable by us, were $5.5 million. The proceeds will be used to partially fund our planned open-label, single-arm expanded access program to provide TA-ERT for the treatment of MPS IIIB in children.

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, U.S. federal government shutdowns and the risk of future lapses in appropriations, 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.

Separation of Adrenyx and Planned Distribution

On November 6, 2026, our board of directors approved a plan to separate our CRHX-101 program into Adrenyx (the "Separation") and we and Adrenyx entered into a separation and distribution agreement. We currently intend to distribute all of the outstanding shares of Adrenyx common stock to our stockholders on a pro rata basis (the "Distribution"), in a transaction that is intended to result in two independent public companies, although our board of directors has not yet approved the Distribution or set a record date for the Distribution. This transaction is intended to enable Adrenyx to pursue distinct strategic priorities, establish independent capital structures and offer investors separate investment opportunities.

Also on November 6, 2026, Adrenyx entered into a secured convertible note purchase agreement with a leading institutional biotechnology investor, pursuant to which Adrenyx may issue secured convertible promissory notes in an aggregate principal amount of up to $10.0 million, of which $5.0 million in aggregate principal amount was issued at the initial closing and which are secured by substantially all assets of Adrenyx. Adrenyx is required to use the proceeds of these notes to develop and commercialize the CRHX-101 program and for its other general corporate purposes. The Company is not permitted to use any such proceeds to fund its own operations, and these notes are neither secured by any assets of the Company nor guaranteed by the Company. The notes are automatically convertible into Conversion Securities upon the closing of a qualified equity financing raising aggregate gross proceeds of $37.5 million, at a conversion price equal to 90% of the per-unit price issued to investors in such financing, or certain other financings of Adrenyx.

In connection with the Separation, we will provide certain services to Adrenyx for a period of up to 12 months following the Distribution, subject to extension, compensated by Adrenyx as provided in the transition services agreement. The Distribution is expected to be completed in the first half of 2027, with a private placement of Adrenyx equity securities expected to be completed in connection with the Distribution, subject to the satisfaction or waiver of certain conditions. See Note 13 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

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 September 30, 2026, the outstanding principal was $15.0 million under Tranche 1. No amounts had been drawn under Tranche 2 as of September 30, 2026, and the original availability period for Tranche 2 expired on September 30, 2026.

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. Because no portion of Tranche 2 was funded as of September 30, 2026, the 6-month extension of the interest-only period under the original terms of the Avenue Loan Agreement was not available as of that date. Pursuant to the Avenue Amendment described below, the interest-only period was extended through March 31, 2027, and, unless the interest-only period is further extended, monthly principal payments will commence in April 2027.

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 us 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 us. 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 Avenue Loan Agreement includes a subjective acceleration clause under which the Agent may declare an event of default upon the occurrence of circumstances that could reasonably be expected to have a material adverse effect, as defined in the agreement. As of the issuance date of these condensed consolidated financial statements, Avenue has not declared an event of default, and we have determined that acceleration under this provision is not probable. Accordingly, the Avenue Loans continue to be classified based on their scheduled repayment terms. If Avenue were to determine that a material adverse effect has occurred, all outstanding obligations could become immediately due and payable.

Amendment to Avenue Loan Agreement

On November 6, 2026, we entered into an amendment to the Avenue Loan Agreement (the "Avenue Amendment"), which, among other things, (i) increased the amount available under Tranche 2 to up to $15.0 million, which may be drawn in a minimum amount of $5.0 million and in increments of $2.5 million between January 1, 2027 and March 31, 2027, subject to the satisfaction of certain conditions and to earlier expiration in certain circumstances; (ii) amended Tranche 3 to be available between July 1, 2027 and December 31, 2027, made Tranche 3 discretionary and subject to the approval of the Lender's investment committee at the time of any draw, and provided that the amount of Tranche 3 will be reduced by the amount of any Tranche 2 borrowings in excess of $10.0 million, such that the aggregate commitment amount under Tranche 1, Tranche 2 and Tranche 3 remains unchanged; and (iii) extended the interest-only period through March 31, 2027 and provided that the interest-only period may be further extended through October 31, 2027 (an interest-only period of 21 months, compared to 18 months under the original terms of the Avenue Loan Agreement) and, thereafter, through October 31, 2028 (an interest-only period of 33 months), in each case subject to the satisfaction of certain conditions. In connection with the Avenue Amendment, which also included Avenue's consent to the Separation, including the release of Avenue's lien on the assets contributed to Adrenyx, we amended that certain warrant to purchase up to $3.2 million worth of shares of the Company's common stock issued to Avenue on March 9, 2026 (the "Avenue Warrant") to increase the number of shares of common stock issuable thereunder by 5,000 shares, with no change to the exercise price of $50.00 per share. Also in connection with the Avenue Amendment, Adrenyx issued a warrant to Avenue for 69,000 shares of Adrenyx common stock (the

"Adrenyx Avenue Warrant") at an exercise price of the lower of $17.53 or the lowest effective price per share of any equity offering of Adrenyx's common stock after the warrant's issuance and prior to June 30, 2027.

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;
  - nonclinical studies—expenses associated with nonclinical 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 nonclinical 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 and Nine Months Ended September 30, 2026 and 2025

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
Operating expenses:						
Research and development	$ 18,133	$ 5,011	$ 13,122	$ 37,871	$ 15,418	$ 22,453
General and administrative	5,848	3,218	2,630	14,609	9,995	4,614
Total operating expenses	23,981	8,229	15,752	52,480	25,413	27,067
Loss from operations	(23,981)	(8,229)	(15,752)	(52,480)	(25,413)	(27,067)
Interest expense	(1,201)	(19)	(1,182)	(2,972)	(84)	(2,888)
Interest and other income, net	819	138	681	2,070	660	1,410
Change in fair value of warrant and conversion option liabilities	357	(102)	459	881	517	364
Net loss	$ (24,006)	$ (8,212)	$ (15,794)	$ (52,501)	$ (24,320)	$ (28,181)

Research and Development Expenses

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
External expenses:						
Clinical development	$ 5,544	$ 1,661	$ 3,883	$ 13,676	$ 8,992	$ 4,684
Manufacturing	10,257	2,678	7,579	18,631	2,576	16,055
Other research and development	416	101	315	1,044	514	530
Internal expenses:						
Personnel	1,868	527	1,341	4,370	3,121	1,249
Facilities and other	48	44	4	150	215	(65)
Total research and development expenses	$ 18,133	$ 5,011	$ 13,122	$ 37,871	$ 15,418	$ 22,453

Research and development expenses increased by $13.1 million during the three months ended September 30, 2026 compared to the three months ended September 30, 2025. The increase in clinical development expenses of $3.9 million was primarily related to increased expenses for TA-ERT of $4.4 million, offset by the discontinuation of the tildacerfont CAH development program of $0.5 million. The increase in manufacturing expenses of $7.6 million was primarily related to TA-ERT. There was also an increase in personnel related costs of $1.3 million, of which $0.3 million was related to an increase in stock-based compensation expense.

Research and development expenses increased by $22.5 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. The increase in clinical development expenses of $4.7 million was primarily related to increased expenses for TA-ERT of $14.0 million, offset by lower one-time product acquisition related costs of $5.7 million for CRHX-101 and the discontinuation of the tildacerfont CAH development program of $3.5 million. The increase in manufacturing expenses of $16.1 million was primarily related to TA-ERT. There was also an increase in personnel related costs of $1.2 million, of which $1.0 million was related to an increase in stock-based compensation expense.

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 December 2026 and potential FDA approval.

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

General and Administrative Expenses

General and administrative expenses increased by $2.6 million during the three months ended September 30, 2026 compared to the three months ended September 30, 2025 primarily due to an increase in personnel related costs of $1.4 million, of which $0.4

million was related to an increase in stock-based compensation expense, and an increase in professional fees of $1.1 million, of which $0.8 million was related to the planned separation of the CRHX-101 program.

General and administrative expenses increased by $4.6 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025 primarily due to an increase in personnel related costs of $2.4 million, of which $0.8 million was related to an increase in stock-based compensation expense, and an increase in professional fees of $1.9 million, of which $0.8 million was related to the planned separation of the CRHX-101 program.

Interest Expense

Interest expense increased by $1.2 million during the three months ended September 30, 2026 compared to the three months ended September 30, 2025 and increased by $2.9 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025 due to an increase in our debt and its related interest rate and an increase in the related amortization of debt discount and issuance costs.

Interest and Other Income, Net

Interest and other income, net increased by $0.7 million during the three months ended September 30, 2026 compared to the three months ended September 30, 2025 and increased by $1.4 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025 primarily due to higher money market fund balances.

Change in Fair Value of Warrant and Conversion Option Liabilities

Change in fair value of warrant and conversion option liabilities increased by $0.5 million during the three months ended September 30, 2026 compared to the three months ended September 30, 2025 and increased by $0.4 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. In the prior periods, the change in fair value was for pre-funded warrants issued to HBM Alpha Therapeutics, Inc. In the current periods, 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 September 30, 2026 and December 31, 2025, we had an accumulated deficit of $341.7 million and $289.2 million, respectively. As of September 30, 2026 and December 31, 2025, we had cash and cash equivalents of $87.7 million and $48.9 million, respectively.

Since inception through September 30, 2026, we have raised aggregate gross proceeds of $432.6 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, $109.1 million from private placement financings (including the August 2026 private placement), $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.

On August 7, 2026, we entered into a Stock Purchase Agreement with the National MPS Society and the Cure Sanfilippo Foundation, pursuant to which we agreed to sell and issue 121,203 shares of our common stock in a private placement transaction. The purchase price per share was $45.38 per share. The net proceeds to us, after deducting offering expenses payable by us, were $5.5 million. The proceeds will be used to partially fund our expanded access program, which was initiated in November 2026.

Without alternative financing or proceeds from other strategic alternatives, we believe that based on our current operating plan, our cash and cash equivalents of $87.7 million as of September 30, 2026 will be insufficient to fund our planned operations and debt obligations for at least 12 months following the issuance date of these condensed consolidated financial statements included elsewhere in this Quarterly Report. These conditions raise substantial doubt about our ability to continue as a going concern.

Until we can generate sufficient revenue, if ever, to fund our operations, we will need to finance future cash needs through sales of one or more priority review vouchers, 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 Capital Market, the existing trading market for our common stock. As of September 30, 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 sales of one or more priority review vouchers, 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 September 30, 2026, future payments of principal and interest on the Avenue Loans, which matures in July 2029, were $19.5 million. For a description of the terms of the Avenue Loans, including the Avenue Amendment, see the sections titled “Material Agreements — Loan Agreement with Avenue” and “Material Agreements — Amendment to Avenue Loan Agreement” above.

As of September 30, 2026, the total undiscounted lease payments for our non-cancelable operating lease for office space, which terminates in February 2028 unless renewed, was $0.5 million.

We enter into contracts in the normal course of business with third-party contract manufacturing organizations and CROs for clinical trials, nonclinical 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. As of September 30, 2026, total noncancelable obligations under these arrangements were $22.1 million.

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 September 30, 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 consolidated 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):

	Nine Months Ended September 30,		
	2026	2025	Change
Net cash used in operating activities	$ (44,612)	$ (26,871)	$ (17,741)
Net cash used in investing activities	(145)	—	$ (145)
Net cash provided by (used in) financing activities	83,542	(1,213)	84,755
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 38,785	$ (28,084)	$ 66,869

Operating Activities

Net cash used in operating activities increased by $17.7 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025 primarily due to increased manufacturing and clinical development activities for TA-ERT offset by the 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 consolidated financial statements “License Agreements” presented elsewhere in this Quarterly Report.

Investing Activities

For the nine months ended September 30, 2026, net cash used in investing activities was related to purchase of property and equipment.

Financing Activities

For the nine months ended September 30, 2026, net cash provided by financing activities was $83.5 million, consisting primarily of net proceeds from the April 2026 Public Offering of $64.4 million, net proceeds from the August 2026 Private Placement of $5.5 million and net proceeds from the Avenue Loans of $14.0 million.

For the nine months ended September 30, 2025, net cash used in financing activities was $1.2 million, consisting of principal payments on debt of $1.2 million.

Critical Accounting Estimates

Our condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these condensed consolidated 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 nine months ended September 30, 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 September 30, 2026 consisted of $87.7 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 Avenue Loans bear interest at a variable rate based on the prime rate, subject to a floor of 12.25%, which applied as of September 30, 2026.

As of September 30, 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 inflation, tariffs and other geopolitical and macroeconomic factors may increase our costs, as of September 30, 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, has 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 September 30, 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 consolidated 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 do not currently have sufficient working capital to fund our planned operations for the next twelve months and substantial doubt exists as to our ability to continue as a going concern.*

For the nine months ended September 30, 2026, we had incurred a net loss of $52.5 million and used $44.6 million of cash in operations. As of September 30, 2026, we had an accumulated deficit of $341.7 million and cash and cash equivalents of $87.7 million. We expect to continue to generate operating losses and have significant cash outflows from operating activities for at least the next few years. Until we can generate sufficient revenue, if ever, to fund our operations, we will need to finance future cash needs through sales of one or more priority review vouchers, 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. Without alternative financing or proceeds from other strategic alternatives, we believe, based on our current operating plan, that our cash and cash equivalents as of September 30, 2026 will be insufficient to fund our operations and debt obligations for at least twelve months following the issuance date of our unaudited financial statements included elsewhere in this Quarterly Report. These conditions raise substantial doubt about our ability to continue as a going concern.

The perception of our ability to continue as a going concern may make it more difficult for us to obtain financing for the continuation of our operations and could result in the loss of confidence by investors and employees. If we are not able to obtain the necessary additional financing on a timely or commercially reasonable basis, we will be forced to delay or scale down some or all of our development activities (or perhaps even cease the operation of our business). If we are unable to continue as a going concern, our stockholders may lose some or all of their investment in the Company.

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 September 30, 2026, we had cash and cash equivalents of $87.7 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 completed a private placement for total net proceeds of $46.6 million. On January 7, 2026, we entered into the Avenue Loan Agreement, which provided for term loans (the "Avenue Loans") in an aggregate principal amount of up to $50.0 million, of which $15.0 million was funded under Tranche 1. No amounts were drawn under Tranche 2 prior to the expiration of its original availability period on September 30, 2026. In November 2026, we amended the Avenue Loan Agreement to, among other things, increase Tranche 2 to up to $15.0 million, available between January 1, 2027 and March 31, 2027, and make Tranche 3 available between July 1, 2027 and December 31, 2027 at the discretion of the Lender. Our ability to draw Tranche 2 is subject to the satisfaction of certain conditions, which we may not satisfy, and any funding of

Tranche 3 or the Discretionary Tranche 4 is subject to the Lender's approval. 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 net proceeds to us from the offering were $64.4 million. Additionally, in August 2026 we completed a private placement for net proceeds of $5.5 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 sales of one or more priority review vouchers, if received, 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 incorporated in 2016, 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 nonclinical 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 nine months ended September 30, 2026 and 2025, we reported net losses of $52.5 million and $24.3 million, respectively. As of September 30, 2026, we had an accumulated deficit of $341.7 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 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 nonclinical 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. In March 2024, in a Type C meeting between the FDA and Allievex, the prior

sponsor of TA-ERT, the FDA indicated that it considered cerebrospinal fluid heparan sulfate non-reducing end ("CSF HS-NRE") to be a biomarker reasonably likely to predict clinical benefit and could serve as a basis for accelerated approval. The FDA also indicated that the completed clinical and nonclinical studies of TA-ERT appeared sufficient to support a BLA submission and provided guidance around key design elements of a confirmatory trial (placebo-controlled 5-year study in 14 patients), which, under the FDA's more recent guidance to us, we must initiate during the FDA's review of our BLA as a condition of potential accelerated approval. Our current design for this study, which we refer to as TrAnsform, is a randomized, single-blind, parallel-group, controlled, multicenter study evaluating the safety, tolerability and efficacy of intracerebroventricular ("ICV")-administered TA-ERT compared to standard of care in children 1 to 5 years of age with severe (non-attenuated) MPS IIIB, with cognition as the primary objective.

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 indicated 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 surrogate endpoint to support an accelerated approval. Following the January 2026 CMC meeting, the FDA considered our plan to address drug product ("DP") process performance qualification ("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.

In the second quarter of 2026, we completed two pre-BLA meetings with the FDA. In these meetings, the FDA generally agreed with our proposed approach to the overall content and format of the BLA, including the structure of the integrated summaries of efficacy and safety, and indicated that our drug substance and drug product analytical comparability strategies following the transfer of TA-ERT manufacturing to a global biologics contract manufacturer appeared reasonable to support the BLA. The FDA also requested that we initiate our TrAnsform confirmatory study during the FDA's review of the BLA. We completed the first PPQ batch in July 2026, and data from this batch will be included in the BLA; we expect to complete the second PPQ batch in December 2026 and to provide data from that batch prior to the mid-cycle of the FDA's review. However, feedback from the FDA in pre-BLA meetings is not binding, and during its review of our BLA the FDA may disagree with our approach, including with respect to analytical comparability, the adequacy of our PPQ data, the use of our integrated clinical and natural history data, or the design of our confirmatory study. If we are unable to complete the second PPQ batch on our anticipated timeline, or if its results are not satisfactory, the FDA's review of our BLA could be delayed or the FDA could issue a Complete Response Letter.

Based, in part, on these discussions, we intend to submit the BLA for TA-ERT for the treatment of MPS IIIB in December 2026, and if successful and FDA approval is received, potentially commercially launch in 2027. However, even if we submit the BLA as planned, we may receive a Refusal to File letter or if the BLA is filed by FDA be unsuccessful in providing sufficient evidence of CSF HS-NRE to predict clinical benefit in support of an accelerated approval, and after reviewing our BLA submission, the FDA may ultimately issue a Complete Response Letter. 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 proposed surrogate endpoint, 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 surrogate endpoint, 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.

Even if we obtain accelerated approval, under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA may use expedited procedures to withdraw approval if, among other things, our confirmatory trial fails to verify the predicted clinical benefit of TA-ERT, we fail to conduct the confirmatory trial with due diligence, or other evidence demonstrates that TA-ERT is not shown to be safe or effective under its conditions of use. Enrolling and completing a randomized, controlled confirmatory trial in a small pediatric population with a rapidly progressing, fatal disease may be particularly challenging, including because caregivers may be unwilling to enroll children in a trial in which they may be randomized to standard of care, particularly once TA-ERT is commercially available. In addition, although in March 2026 the FDA granted accelerated approval to another therapy for a neuronopathic mucopolysaccharidosis based on reductions in CSF heparan sulfate, the FDA's decisions with respect to other product candidates are not necessarily predictive of the outcome of its review of our BLA, and the FDA's approach to surrogate endpoints in rare neurodegenerative diseases continues to evolve.

We may not receive a rare pediatric disease priority review voucher for TA-ERT, and, even if we do, we may not be able to sell it on favorable terms, on a timely basis or at all.*

TA-ERT has received Rare Pediatric Disease Designation from the FDA. In February 2026, the Mikaela Naylon Give Kids a Chance Act, enacted as part of the Consolidated Appropriations Act, 2026, reauthorized the FDA's rare pediatric disease priority review voucher program for drugs and biologics designated as such through September 30, 2029, subject to the conditions of the statute. A voucher is awarded only upon approval of a qualifying application that meets the statutory requirements, and the FDA may determine that our BLA does not qualify. Our current funding plans contemplate the potential sale of one or more priority review vouchers. If we do not receive a voucher, or if we are unable to sell a voucher we receive at an attractive price or on a timely basis, including as a result of changes in the supply of or demand for vouchers, our liquidity and ability to fund our operations, including the commercial launch of TA-ERT and repayment of the Avenue Loans, could be materially adversely affected. In addition, the program may be modified or allowed to lapse in the future.

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 nonclinical 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, through Adrenyx, 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 accelerated approval of a BLA from the FDA, we will initiate a confirmatory Phase 3 trial, which the FDA has requested that we initiate during its review of our BLA. We intend to submit the BLA for TA-ERT for the treatment of MPS IIIB in December 2026, and if successful and FDA approval is received, potentially commercially launch in 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.

Nonclinical 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. Nonclinical 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 nonclinical or clinical trials can occur at any stage of testing. The results of nonclinical studies and early clinical trials of TA-ERT and nonclinical studies of CRHX-101, an anti-corticotropin-releasing hormone monoclonal antibody ("CRHX-101") 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 nonclinical studies and initial clinical trials. For example, the doses of TA-ERT we have selected for our clinical trials may not prove to be safe or efficacious. 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, nonclinical 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 nonclinical 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 nonclinical, 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 are 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 a new drug application ("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 nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical 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 nonclinical 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 nonclinical 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;
- 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 nonclinical 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.*

Although we have begun to build our commercial leadership team, including the appointment in 2026 of vice presidents of marketing, market access and commercial operations, we have not yet established a sales force or the other commercial infrastructure needed 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 remained elevated relative to historical levels, 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 raised interest rates significantly in recent years and, although rates have since been reduced, may raise interest rates again 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. 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. In February 2026, the U.S. Supreme Court held that the International Emergency Economic Powers Act does not authorize the imposition of tariffs, and the administration has since imposed or announced tariffs under other statutory authorities. In April 2025, the Bureau of Industry and Security of the U.S. Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 to determine whether imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, pose a national security risk. Based on this investigation, on April 2, 2026, the President issued a proclamation imposing a tariff of up to 100% on certain imported patented pharmaceuticals and associated pharmaceutical ingredients, which became effective for most importers, including us, on September 29, 2026. The proclamation provides for reduced rates or exemptions in certain circumstances, including reduced rates for products from certain jurisdictions that have current or forthcoming trade and security framework agreements with the United States, such as the EU, Japan and South Korea, and a 0% rate for certain orphan drugs that satisfy specified conditions. There can be no assurance that TA-ERT or the materials we import will qualify for any reduced rate or exemption, or that the scope, rates or exemptions under the proclamation will not change.

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, the 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 and restricted stock units that vest over time. The value to employees of equity awards 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, in clinical trials of TA-ERT, which is being developed for a serious and fatal disease for which there is currently no FDA-approved therapy, the most frequent treatment-emergent adverse events (“TEAEs”) by preferred term (reported in ≥40% of participants) were 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, three (14%) of which were due to hydrocephalus, a known complication of MPS IIIB. Adverse events related to the ICV device were also observed. In addition, TA-ERT is administered through a surgically implanted ICV access device supplied by third parties. Device-related complications (such as infection, malfunction or the need for revision surgery), the availability of compatible devices, or FDA requirements regarding device compatibility and labeling could delay or limit approval of TA-ERT or adversely affect its commercial uptake.

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 the FDA or comparable foreign regulatory authorities taking actions to, 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 provide 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. In addition, in 2025, HHS implemented significant workforce reductions, including at the FDA, and the FDA has experienced substantial turnover in senior leadership and review staff, which could affect the FDA's ability to meet review goal dates, conduct pre-license inspections and respond to sponsor communications in a timely manner.

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, the U.S. government has shut down several times, including a 43-day lapse in appropriations from October 1, 2025 through November 12, 2025, and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. Current federal appropriations for many agencies, including the FDA, are provided under a continuing resolution that expires on December 11, 2026, and a lapse in appropriations thereafter could occur during the FDA's review of our planned BLA for TA-ERT. 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 drugs and biologics covered under Medicare that have been on the market for at least seven years (in the case of drugs) or 11 years (in the case of biologics) 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. HHS selected 10 products for 2026 and 15 products for each of 2027 and 2028, and may select up to 20 products per year beginning in 2029. Although the IRA, as amended by the "One Big Beautiful Bill Act" ("OBBBA"), excludes from negotiation certain drugs and biologics that are designated for, and approved only for, one or more rare diseases or conditions, and delays negotiation eligibility for such products until they no longer qualify for the exclusion, TA-ERT may not qualify for or maintain this exclusion, including if it is approved for additional indications, and the exclusion may be modified in the future. 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, which expired at the end of 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 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 did not extend the ACA enhanced advance premium tax credits, which expired 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 certain 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. As part of these initiatives, the administration is implementing or considering various CMS Center for Medicare and Medicaid Innovation models, under which manufacturers may owe rebates for certain prescription drugs under Medicaid or Medicare if the price of a drug included in an applicable model exceeds an international benchmark calculated based on prices available in certain reference countries. These

include the finalized Global Benchmark for Efficient Drug Pricing Model ("GLOBE") Model for certain Medicare Part B drugs; and the proposed Guarding United States Medicare Against Rising Drug Costs ("GUARD") Model for certain Medicare Part D drugs. 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, in December 2025, the BIOSECURE Act was enacted as part of the National Defense Authorization Act for Fiscal Year 2026, which President Trump signed into law on December 18, 2025. The BIOSECURE Act prohibits U.S. federal agencies from entering into or renewing any contract, loan, or grant with any entity that uses biotechnology equipment or services produced or provided by a "biotechnology company of concern" to perform that contract. The BIOSECURE Act also prohibits U.S. government loan and grant recipients from using federal loan or grant money to enter into contracts with entities that use equipment from "biotechnology companies of concern" in the performance of any federal prime contract or subcontract. The Office of Management and Budget (OMB) of the U.S. Government will issue a list of "biotechnology companies of concern," which will include certain companies that are identified on the U.S. Department of Defense's annual List of Chinese Military Companies, also known as the 1260H List, other entities which the U.S. Government has deemed as such pursuant to a separate designation process, and certain subsidiary, parent, and successor entities of the foregoing. The BIOSECURE Act includes a safe harbor provision providing that the restrictions do not apply to equipment or services that were formerly but are no longer provided by a "biotechnology company of concern." The BIOSECURE Act also includes a grandfathering provision providing that the prohibitions shall not apply for a five-year period to biotechnology equipment or services produced or provided under a contract or agreement entered into before the applicable effective date. 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 nonclinical (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.

On December 11, 2025, the Parliament and the 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. The Pharma Package, comprised of a new directive and regulation to replace existing legislation, aims to modernize the EU framework. The Council formally adopted its first-reading position on the Pharma Package on September 28, 2026. The legislation is still subject to formal approval by the European Parliament, following which it will be published in the Official Journal of the European Union and enter into force. The Pharma Package encompasses a broad range of measures, including changes to regulatory data and market protection periods, including an eight-year regulatory data protection period and a one-year market

protection period, with opportunities for additional periods of market protection subject to specified conditions and a maximum combined regulatory protection period of eleven years; changes to the orphan medicinal product framework, including a reduction in the standard period of orphan market exclusivity from ten to nine years, an eleven-year period of orphan market exclusivity for certain "breakthrough" orphan medicinal products, and changes to the incentives available for additional orphan indications; and an expansion of the "Bolar" exemption to permit certain activities relating to generic and biosimilar medicines while relevant intellectual property rights remain in force, including submissions for procurement tenders. A decrease in market exclusivity opportunities for our product candidates in the EU, combined with the expanded Bolar exemption, could open them to generic or biosimilar competition earlier than under the current regime, potentially impacting reimbursement status and the commercial prospects of our product candidates. 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, separate pricing and reimbursement approvals may be required before a product can be commercially launched or reimbursed in that jurisdiction. 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 nonclinical 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 September 30, 2026, we had 25 employees, all of whom are full-time. As our development and commercialization plans and strategies develop, 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, which was amended in November 2026 by the Avenue Amendment (as defined below). For a description of the Avenue Loan Agreement and the Avenue Amendment, see Note 6, "Debt — Avenue Loan," and Note 13, "Subsequent Events—Amendment to Avenue Loan Agreement," financial statements included elsewhere in this Quarterly Report.

The Avenue Loan Agreement contains customary representations, warranties and covenants, including covenants by us 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. 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 Avenue 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 Avenue 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.

In addition, no amounts were drawn under Tranche 2 prior to the expiration of its original availability period on September 30, 2026. In November 2026, we entered into an amendment to the Avenue Loan Agreement (the "Avenue Amendment") pursuant to which, among other things, Tranche 2 was increased to up to $15.0 million and made available between January 1, 2027 and March 31, 2027, and Tranche 3 was made available between July 1, 2027 and December 31, 2027 at the discretion of the Lender. The Avenue Amendment also extended the interest-only period under the Avenue Loans through March 31, 2027. Our ability to draw Tranche 2, and to further extend the interest-only period through October 31, 2027 and thereafter through October 31, 2028, is subject to the satisfaction of certain conditions, some of which are outside of our control, and Tranche 2 may expire before the end of its availability period in certain circumstances. If we do not satisfy these conditions, we will not be able to borrow under Tranche 2, and we will be required to begin making monthly principal payments in April 2027. The Lender may decline to fund Tranche 3 or the Discretionary Tranche 4 in its sole discretion. In addition, the Avenue Loan Agreement restricts our ability to transfer assets, including intellectual property, and to make investments in subsidiaries, and the Separation of Adrenyx required Avenue's consent, including for the release of Avenue's lien on the assets contributed to Adrenyx.

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 identity 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', personnel's, 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 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.

U.S. 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 ownership changes occurred in May 2016, August 2020, and October 2025. As a result of the prior ownership changes, we derecognized NOL-related deferred tax assets down to the amount expected to be realized. We have not completed an analysis for the 2026 tax year. Thus,

our ability to use our remaining NOL carryforwards may be further limited if we experience a Section 382 ownership change as a result of changes in our stock ownership in the current year or in the future. In addition, the planned Distribution is intended to be a taxable transaction for U.S. federal income tax purposes, and our ability to offset any gain we recognize in connection with the Distribution with our NOL carryforwards and other tax attributes could be subject to the limitations described above, which could result in a cash tax liability. As of September 30, 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, the OBBBA makes permanent key elements of the Tax Cuts and Jobs Act of 2017 (the "Tax Act"), including 100% bonus depreciation, the immediate expensing of domestic research and experimental expenditures and a more favorable 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 Coronavirus Aid, Relief, and Economic Security 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, the 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, the 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 the Separation of Adrenyx and Planned Distribution

The separation of our CRHX-101 (formerly known as SPR202) program into Adrenyx and the planned distribution of Adrenyx shares to our stockholders may not be completed on the anticipated timeline or at all, may not achieve the intended benefits, and could disrupt our business and divert management attention.*

In November 2026, our board of directors approved a plan to separate our CRHX-101 program (the "Separation") into Adrenyx Biosciences, Inc., our wholly-owned subsidiary. We currently intend to distribute all of the outstanding shares of Adrenyx common stock to our stockholders on a pro rata basis (the "Distribution"), although our board of directors has not yet approved the Distribution or set a record date for the Distribution. The Distribution is subject to a number of conditions, including approval by our board of directors, the effectiveness of a registration statement filed by Adrenyx with the SEC, and the approval for listing of Adrenyx common stock on Nasdaq. Our board of directors may abandon or modify the planned Distribution at any time. We may not satisfy these conditions, and the Distribution may be delayed or may not occur at all.

We have incurred, and expect to continue to incur, significant costs in connection with the Separation and the planned Distribution, including legal, accounting, tax and advisory fees, many of which will be incurred whether or not the Distribution is completed. The Distribution requires significant time and attention from our management and board of directors, which could divert attention from our planned BLA submission for TA-ERT, the FDA's review of our BLA and our preparations for the potential commercial launch of TA-ERT. Certain of our officers and directors are expected to serve as officers or directors of, or consultants to, Adrenyx, and may have actual or apparent conflicts of interest with respect to matters involving both companies, including the negotiation and administration of the agreements governing the Separation and the Distribution. Following the Distribution, we will provide certain transition services to Adrenyx under the transition services agreement we entered into in November 2026, which could further burden our limited personnel and resources.

The Distribution is intended to be a taxable transaction for U.S. federal income tax purposes. We may recognize taxable gain, and our stockholders may be treated as receiving a taxable distribution, in each case based on the fair market value of the Adrenyx shares at the time of the Distribution, which cannot be predicted, and our ability to offset any such gain with our NOLs and other tax attributes may be limited. Following the Distribution, we will no longer own the CRHX-101 program, and the trading price of our common stock may decline to reflect the Distribution. We cannot predict the trading prices of our common stock or Adrenyx common stock following the Distribution, and the combined trading prices may be less than the trading price of our common stock prior to the Distribution. Under the Separation Agreement, liabilities relating to the CRHX-101 program are allocated between the Company and

Adrenyx, and we and Adrenyx have agreed to indemnify one another for certain liabilities arising from the Separation and planned Distribution.

In November 2026 in connection with the Separation, Adrenyx issued secured convertible promissory notes to a leading institutional biotechnology investor, which are secured by substantially all assets of Adrenyx. Prior to the Distribution, Adrenyx's results, including its financing activities, are consolidated in our financial statements and may increase our reported net loss and liabilities, and any conversion of such notes or other Adrenyx financings will dilute our stockholders' indirect interest in Adrenyx.

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. In addition, under Nasdaq rules, if we fail to comply with the Minimum Bid Price Requirement in the future and have effected one or more reverse stock splits over the prior two-year period with a cumulative ratio of 250 shares or more to one, we would not be eligible for a compliance period and Nasdaq would issue a delisting determination. 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;
- the completion of the Separation of Adrenyx and the timing, terms and completion of the planned Distribution, and the trading prices of our common stock and Adrenyx common stock following the planned Distribution;
- our ability to effectively manage our growth;
- the size and growth, if any, of the markets for MPS IIIB 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 our Annual Report on Form 10-K, 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. In addition, the formation of Adrenyx and the Separation and planned Distribution will require us to design and implement additional controls, including over the accounting for and disclosure of the Separation, the Distribution and related transition services, and our finance and accounting team is small, which may make it difficult to meet 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." 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 September 30, 2026, there were 2,874,013 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, on March 9, 2026, a warrant to purchase $3.2 million in shares of common stock at a price of $50.00 per share. In November 2026, in connection with an amendment to the Avenue Loan Agreement, we increased the number of shares issuable under this warrant by 5,000 shares. The

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. In August 2026, we entered into a stock purchase agreement pursuant to which we agreed to sell and issue 121,203 shares of common stock in a private placement transaction. 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 Avenue 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 September 30, 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 net proceeds to us from the offering, after deducting underwriting discounts and commissions and offering expenses payable by us, were $64.4 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 Corporation 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 are 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, in October 2024, pursuant to an asset purchase agreement with the assignee for the benefit of creditors of Allievex, we acquired an exclusive license agreement originally entered into between BioMarin Pharmaceutical Inc. ("BioMarin") and Allievex in October 2019 (the "BioMarin License Agreement"), pursuant to which we hold an exclusive, 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 an exclusive (outside of mainland China, Taiwan, Hong Kong and Macau), royalty-bearing and sublicensable license to certain technology, patent rights, manufacturing rights, know-how, and proprietary materials relating to CRHX-101(the "HBM License Agreement"). We depend on the BioMarin License Agreement for our rights to TA-ERT. In connection with the Separation, we have assigned the HBM License Agreement to Adrenyx.

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 nonclinical and 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 nonclinical 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. In 2026, we completed the transfer of TA-ERT drug substance and drug product manufacturing to a global biologics contract manufacturer. Although the FDA indicated in our pre-BLA meetings that our analytical comparability strategies appeared reasonable to support the BLA, the FDA may conclude during its review that we have not demonstrated comparability between material manufactured by our prior and current manufacturers, which could require additional analytical, nonclinical or clinical data and could delay or prevent approval of TA-ERT.

We currently have a long-term agreement with a manufacturer to produce raw materials, drug substance and drug 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 pre-license or pre-approval inspections that are expected to be conducted during review of a BLA or comparable foreign regulatory marketing application. 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. As the sponsor and prospective BLA holder, we remain responsible for ensuring that TA-ERT is manufactured in compliance with cGMP, which we oversee through quality agreements, audits and batch disposition; deficiencies in that oversight could also result in regulatory action. 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 or biosimilar 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 Act 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 BioMarin License Agreement and 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.

Under the BioMarin License Agreement, we are obligated to pay BioMarin up to $25.5 million upon the achievement of certain milestones 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, as well as tiered royalties ranging from the high-single digits to the low-double digits on annual net sales of licensed MPS IIIB products, subject to certain customary reductions and floors. BioMarin may terminate the BioMarin License Agreement if we challenge the licensed patents, cease all material research and development activity for licensed products for a specified period of time, materially breach the agreement and fail to cure such breach within a specified period, or become subject to bankruptcy or insolvency. Termination of the BioMarin License Agreement would result in the loss of our rights to TA-ERT and would materially harm our business.

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, and for biologics, such as TA-ERT, the process begins 11 years after initial licensure. 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, in April 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, 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 nonclinical 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.

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 Trial and 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 are a party to three post-grant review (PGR) proceedings before the Patent Trial and Appeal Board of the USPTO with respect to U.S. Patent Nos. 12,576,084, 12,569,490, and 12,569,491. 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 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

Unregistered Sales of Equity Securities

On August 7, 2026, we entered into a Stock Purchase Agreement with the National MPS Society and the Cure Sanfilippo Foundation, pursuant to which we agreed to sell and issue 121,203 shares of our common stock at a purchase price of $45.38 per share, for gross proceeds of $5.5 million, in a private placement that closed in August 2026. The shares were offered and sold in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act and Rule 506(b) of Regulation D promulgated thereunder.

Issuer Purchases of Equity Securities

None.

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

Insider Trading Arrangements

During the three months ended September 30, 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.

Amendment to Avenue Loan Agreement

On November 6, 2026, we entered into the Avenue Amendment and amended the Avenue Warrant and Adrenyx issued the Adrenyx Avenue Warrant, as described in Note 13, "Subsequent Events—Amendment to Avenue Loan Agreement," to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report, which description is incorporated herein by reference. The foregoing description is qualified in its entirety by reference to the full text of the Avenue Amendment, the amendment to the Avenue Warrant, and the Adrenyx Avenue Warrant, which are filed as Exhibits 10.1, 4.1 and 4.2 to this Quarterly Report.

Separation and Distribution Agreement

On November 6, 2026, our board of directors approved a plan to separate and contribute our CRHX-101 program into Adrenyx (the "Separation"). We currently intend to distribute all of the outstanding shares of Adrenyx common stock to our stockholders on a pro rata basis (the "Distribution"), in a transaction that is intended to result in two independent public companies, although our board of directors has not yet approved the Distribution or set a record date for the Distribution.

Also on November 6, 2026, we and Adrenyx entered into a series of agreements, including a separation and distribution agreement (the "Separation Agreement") and a transition services agreement (the "Transition Services Agreement"). Pursuant to the Separation Agreement, among other things, we contributed to Adrenyx certain assets and liabilities relating to the CRHX-101 program as part of the Separation, including assignment of the HBM License Agreement. The Separation Agreement sets forth the conditions to, and the procedures for effecting, the Distribution, subject to approval by our board of directors.

We will provide certain services to Adrenyx for a period of up to 12 months following the Distribution, subject to extension, compensated by Adrenyx as provided in the Transition Services Agreement.

The Distribution is expected to be completed in the first half of 2027, with a private placement of Adrenyx equity securities expected to be completed in connection with the Distribution, subject to the satisfaction or waiver of certain conditions, including the effectiveness of a registration statement filed by Adrenyx with the SEC, approval of the listing of Adrenyx common stock on Nasdaq, and our board of directors having declared the Distribution. Approval by our stockholders is not required as a condition to the consummation of the Distribution. The Distribution is intended to be a taxable transaction for U.S. federal income tax purposes. There can be no assurance that the Distribution will be completed on the anticipated timeline, on the anticipated terms or at all.

The foregoing description is qualified in its entirety by reference to the full text of the Separation Agreement and the Transition Services Agreement, which are filed as Exhibits 10.2 and 10.3 to this Quarterly Report.

Adrenyx Convertible Note Financing

On November 6, 2026, Adrenyx, our wholly-owned subsidiary, issued the Adrenyx Notes, as described in Note 13, "Subsequent Events—Adrenyx's Secured Convertible Notes," to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report, which description is incorporated herein by reference. The foregoing description is qualified in its entirety by reference to the full text of the Note Purchase Agreement, which is filed as Exhibit 10.4 to this Quarterly Report.

Item 6. Exhibits

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date
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	First Amendment to Warrant to Purchase Shares of Common Stock			Filed herewith	
4.2	Warrant to Purchase Shares of Common Stock of Adrenyx Biosciences, Inc.			Filed herewith	
10.1*	Consent and First Amendment to Loan Documents, dated November 6, 2026, by and among the Company, Avenue Capital Management II, L.P., as administrative agent and collateral agent, and Avenue Venture Opportunities Fund II, L.P., as lender			Filed herewith	
10.2*	Separation and Distribution Agreement, dated November 6, 2026, by and between the Company and Adrenyx Biosciences, Inc.			Filed herewith	
10.3*	Transition Services Agreement, dated November 6, 2026, by and between the Company and Adrenyx Biosciences, Inc.			Filed herewith	
10.4*	Secured Convertible Note Purchase Agreement, dated November 6, 2026			Filed herewith	
10.5	Offer Letter, by and between Spruce Biosciences, Inc. and Adrian Quartel, effective July 27, 2026	10-Q	001-39594	10.4	August 12, 2026
10.6	Form of Stock Purchase Agreement, dated August 7, 2026 by and among the Company and the Purchasers	10-Q	001-39594	10.5	August 12, 2026
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as 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 – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document			Filed herewith	
101.SCH	Inline XBRL Taxonomy Extension Schema 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: November 9, 2026

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

Date: November 9, 2026

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

Exhibit 4.1

FIRST AMENDMENT TO WARRANT TO PURCHASE SHARES OF COMMON STOCK

THIS FIRST AMENDMENT TO WARRANT TO PURCHASE SHARES OF COMMON STOCK (this "**Warrant Amendment**") is entered into as of November 6, 2026, by and between **AVENUE VENTURE OPPORTUNITIES FUND II, L.P.**, a Delaware limited partnership ("**Holder**"), and **SPRUCE BIOSCIENCES, INC.**, a Delaware corporation (the "**Company**").

RECITALS

A. WHEREAS, the Company issued to Holder that certain Warrant to Purchase Shares of Common Stock dated as of March 9, 2026 (the "**Warrant**");

B. WHEREAS, Company and Holder are parties to those certain Loan Documents dated as of January 7, 2026, including that certain Loan and Security Agreement (as amended from time to time, the "**Agreement**") and Supplement to Loan and Security Agreement (as amended from time to time, the "**Supplement**");

C. WHEREAS, the Company and Holder are entering into that certain Consent and First Amendment to Loan Documents dated as of even date herewith (the "**First Amendment**"); and

D. WHEREAS, it is a condition to the First Amendment that the Company executes and delivers this Warrant Amendment in favor of Holder.

NOW, THEREFORE, the parties agree as follows:

1. The definition of "Applicable Number" as set forth on the first page of the Warrant hereby is amended and restated to read in its entirety as follows:

> "Applicable Number" means the number of shares of Common Stock purchasable hereunder obtained by (a) dividing (A) $3,200,000 by (B) the Exercise Price, plus (b) an additional Five Thousand (5,000) shares of Common Stock of the Company purchasable hereunder; provided that such number may be adjusted in accordance with Section 4.

2. This Warrant Amendment shall be affixed to the Warrant and shall become a part thereof for all purposes.

3. Except as expressly amended by this Warrant Amendment, the Warrant remains unchanged and in full force and effect, and all references in the Warrant to "this Warrant" shall mean the Warrant as amended hereby.

4. Section 14 of the Warrant is incorporated herein by reference, *mutatis mutandis,* as though set forth in full.

5. Section 19 of the Warrant is incorporated herein by reference, *mutatis mutandis,* as though set forth in full.

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1.

IN WITNESS WHEREOF, the undersigned have executed this Warrant Amendment as on the day and year first above written.

COMPANY:

SPRUCE BIOSCIENCES, INC.

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

AGREED AND ACCEPTED:

HOLDER:

AVENUE VENTURE OPPORTUNITIES FUND II, L.P.

By: Avenue Venture Opportunities Partners II, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Authorized Signatory

[*Signature Page to First Amendment to Warrant to Purchase Shares of Common Stock*]

Exhibit 4.2

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE AND DISTRIBUTION THEREOF, AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT") OR ANY STATE SECURITIES LAWS. SUCH SECURITIES MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF (A) SUCH REGISTRATION, (B) AN OPINION OF COUNSEL IN A FORM REASONABLY ACCEPTABLE TO COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED DUE TO AN EXEMPTION THEREFROM UNDER SAID ACT AND ANY APPLICABLE STATE SECURITIES LAWS OR (C) ADRENYX BIOSCIENCES, INC. OTHERWISE SATISFIES ITSELF THAT SUCH TRANSACTION IS COMPLIANT WITH SUCH LAWS.

Date of Issuance: November 6, 2026

WARRANT TO PURCHASE

SHARES OF COMMON STOCK OF

ADRENYX BIOSCIENCES, INC.

(Void after November 30, 2031)

This certifies that AVENUE VENTURE OPPORTUNITIES FUND II, L.P., a Delaware limited partnership, or permitted assigns ("Holder"), for value received, is entitled to purchase from ADRENYX BIOSCIENCES, INC., a Delaware corporation ("Company"), the Applicable Number (hereinafter defined) of fully paid and nonassessable shares of the Company's Common Stock (the "Common Stock"), for cash, at a purchase price per share equal to the Exercise Price (hereinafter defined). Holder may also exercise this Warrant on a cashless or "net issuance" basis as described in Section 1(b) below, and this Warrant shall be deemed to have been exercised in full on such basis on the Expiration Date (hereinafter defined), to the extent not fully exercised prior to such date. This Warrant is issued in connection with that certain Consent and First Amendment to Loan and Security Agreement and Supplement thereto, both dated as of November 6, 2026 (as amended, restated and supplemented from time to time, the "Loan Agreement" and the "Supplement", respectively), between SPRUCE BIOSCIENCES, INC., a Delaware corporation, as borrower, and Holder, as lender ("Lender"). Capitalized terms used herein and not otherwise defined in this Warrant shall have the meaning(s) ascribed to them in the Loan Agreement and the Supplement, unless the context would otherwise require.

In addition to the terms defined elsewhere in this Warrant, the following terms have the meanings indicated below:

"Applicable Number" means 69,000; provided that such number may be adjusted in accordance with Section 4.
"Closing Price" means $17.53.

"Exercise Price" means the lower of the Closing Price or the Next Round Price (as hereinafter defined).

"Next Round Price" means the lowest effective price per share of any bona fide equity offering of the Common Stock after the Date of Issuance and prior to June 30, 2027.

"Person" and "Persons" means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, any other entity and any governmental entity or any department or agency thereof.

"Principal Trading Market" means the principal trading market for the Company's Common Stock on The Nasdaq Stock Market LLC (or any successor thereof).

"Trading Day" means a day when the Principal Trading Market is open for trading in shares of the Common Stock.

"Transfer Agent" means Computershare Trust Company, N.A., the anticipated transfer agent of the Company, with a mailing address of 150 Royall St., Suite 101, Canton, MA 02021, and any successor transfer agent of the Company.

Subject to Section 4.3, this Warrant may be exercised at any time or from time to time following the effectiveness of the Form 10 Registration Statement to be filed by the Company, and up to and including 5:00 p.m. (Pacific time) on November 30, 2031 (the "Expiration Date"), upon surrender to Company at its principal office at 611 Gateway Boulevard, Suite 740, South San Francisco, CA 94080 (or at such other location as Company may advise Holder in writing) of this Warrant properly endorsed with the Form of Subscription attached hereto duly completed and signed and upon payment in cash or by check of the aggregate Exercise Price, or pursuant to Section 1(b) below, for the number of shares for which this Warrant is being exercised determined in accordance with the provisions hereof. The Exercise Price and the number of shares purchasable hereunder are subject to further adjustment as provided in Section 4 of this Warrant.

This Warrant is subject to the following terms and conditions:

1. Exercise; Issuance of Certificates; Payment for Shares.

(a) Unless an election is made pursuant to clause (b) of this Section 1, this Warrant shall be exercisable at the option of Holder, at any time or from time to time, on or before the Expiration Date for all or any portion of the shares of Common Stock (but not for a fraction of a share) which may be purchased hereunder for the Exercise Price multiplied by the number of shares to be purchased. Company agrees that the shares of Common Stock purchased under this Warrant shall be and are deemed to be issued to Holder as the record owner of such shares as of the close of business on the date on which the form of subscription shall have been delivered and payment made for such shares. Except as provided in clause (b) of this Section 1, in case of a purchase of less than all the shares which may be purchased under this Warrant, Company shall cancel this Warrant and execute and deliver a new Warrant or Warrants of like tenor for the balance of the shares purchasable under this Warrant surrendered upon such purchase to Holder within a reasonable time. Company shall cause the shares of Common Stock purchased hereunder to be transmitted by the Transfer Agent to Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the shares of Common Stock purchased pursuant to this Warrant by the Holder or (B) the shares of Common Stock purchased pursuant to this Warrant by the Holder are eligible for resale by the Holder without volume or manner of sale limitations pursuant to Rule 144 (assuming cashless exercise of the Warrants, if then permitted), and otherwise by book-entry form or, if requested by the Holder, a physical delivery of a certificate, registered in Company's share register in the name of the Holder or its designee, for the number of shares of Common Stock to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the form of subscription by the date that is three (3) Trading Days after the delivery to Company of the aggregate Exercise Price to the Company. Each stock certificate so delivered shall be in such denominations of Common Stock as may be requested by Holder and shall be registered in the name of such Holder or such other name as shall be designated by such Holder, subject to the limitations contained in Section 2.

(b) Holder, in lieu of exercising this Warrant by the cash payment of the Exercise Price pursuant to clause (a) of this Section 1, may elect, at any time on or before the Expiration Date, to surrender this Warrant and receive that number of shares of Common Stock computed using the following formula:

$$X = \frac{Y(A - B)}{A}$$

Where: X = the number of shares of Common Stock to be issued to Holder.

Y = the Applicable Number of shares of Common Stock (or such lesser number of shares as Holder may designate in the case of a partial exercise of this Warrant).

A = the closing price per share of the Common Stock on the Principal Trading Market as of the last Trading Day immediately prior to the date of exercise under this Section 1(b).

B = the Exercise Price then in effect.

Election to exercise under this Section 1(b) may be made by delivering a signed form of subscription to Company via electronic mail or facsimile, to be followed by delivery of this Warrant. Notwithstanding anything to the contrary contained in this Warrant, if as of the close of business on the last business day preceding the Expiration Date this Warrant remains unexercised as to all or a portion of the shares of Common Stock purchasable hereunder, then effective at 9:00 a.m. (Pacific time) on the Expiration Date, Holder shall be deemed, automatically, to have elected to exercise this Warrant in full pursuant to the provisions of this Section 1(b), and upon surrender of this Warrant shall be entitled to receive that number of shares of Common Stock computed using the above formula, provided that the application of such formula as of the Expiration Date yields a positive number for "X" (such automatic exercise, the "Expiration Exercise"); provided, however, that no Expiration Exercise shall be effective unless Holder provides written notice to the Company within ten (10) business days after the Expiration Date confirming that the Expiration Exercise has occurred.

(c) The Company shall not effect the exercise of this Warrant, and the Holder shall not have the right to exercise this Warrant, to the extent that after giving effect to such exercise, such Person (together with such Person's affiliates) would beneficially own in excess of 4.99% (the "Maximum Percentage") of the shares of Common Stock outstanding immediately after giving effect to such exercise. For purposes of the foregoing sentence, the aggregate number of shares of Common Stock beneficially owned by such Person and its affiliates shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which the determination of such sentence is being made, but shall exclude shares of Common Stock which would be issuable upon (i) exercise of the remaining, unexercised portion of this Warrant beneficially owned by such Person and its affiliates, and (ii) exercise or conversion of the unexercised or unconverted portion of any other securities of the Company beneficially owned by such Person and its affiliates (including, without limitation, any convertible notes or convertible preferred stock or warrants) subject to a limitation on conversion or exercise analogous to the limitation contained herein. Except as set forth in the preceding sentence, for purposes of this paragraph, beneficial ownership shall be calculated in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended. For purposes of this Warrant, in determining the number of outstanding shares of Common Stock, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (1) the Company's most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q, Current Report on Form 8-K or other public filing with the Securities and Exchange Commission, as the case may be, (2) a more recent public announcement by the Company or (3) any other notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. To the extent that the limitation contained in this Section 1(c) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which a portion of this Warrant is exercisable shall be in the sole discretion of a Holder, in each case subject to such aggregate percentage limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. For any reason at any time, upon the written or oral request of the Holder, the Company shall within a reasonable time (but no later than two (2) business days) confirm to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder and its affiliates since the date as of which such number of outstanding

shares of Common Stock was reported. By written notice to the Company, the Holder may from time to time increase or decrease the Maximum Percentage to any other percentage specified in such notice; provided that (i) any such increase will not be effective until the sixty-first (61st) day after such notice is delivered to the Company, and (ii) any such increase or decrease will apply only to the Holder. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 1(c) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended beneficial ownership limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. Notwithstanding anything anywhere in this Warrant to the contrary, the aggregate number of shares issued pursuant to the exercise of this Warrant shall not exceed the aggregate number of shares of Common Stock which the Holder may exercise pursuant to the terms of this Warrant without breaching the Company's obligations under the rules or regulations of the Principal Trading Market (the number of shares which may be issued without violating such rules and regulations, the "Exchange Cap"), except that such limitation shall not apply in the event that the Company obtains the approval of its stockholders as required by the applicable rules of the Principal Trading Market.

2. Limitation on Transfer.

(a) This Warrant and the Common Stock issued upon exercise of the Warrant shall not be transferable except upon the conditions specified in this Section 2, which conditions are intended to ensure compliance with the provisions of the Securities Act of 1933, as amended (the "Securities Act"). Each holder of this Warrant or the Common Stock issuable hereunder will cause any proposed transferee of the Warrant or such Common Stock to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Section 2. Notwithstanding the foregoing and any other provision of this Section 2 but subject to the last sentence of Section 2(c), Holder may freely transfer all or part of this Warrant or the shares issuable upon exercise of this Warrant (or the securities issuable, directly or indirectly, upon conversion of the shares, if any) at any time to any affiliate of Lender under the Loan Agreement, by giving Company notice of the portion of the Warrant being transferred setting forth the name, address and taxpayer identification number of the transferee and surrendering this Warrant to Company for reissuance to the transferees(s) (and Holder, if applicable).

(b) Each certificate representing (i) this Warrant, (ii) the Common Stock issued pursuant to this Warrant, and (iii) any other securities issued in respect of the Common Stock issued pursuant to this Warrant issued upon any stock split, stock dividend, recapitalization, merger, consolidation or similar event, shall (unless otherwise permitted by the provisions of this Section 2 or unless such securities have been registered under the Securities Act or sold under Rule 144) be stamped or otherwise imprinted with a legend substantially in the following form (in addition to any legend required under applicable state securities laws):

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE AND DISTRIBUTION THEREOF, AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OR ANY STATE SECURITIES LAWS. SUCH SECURITIES MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF (A) SUCH REGISTRATION, (B) AN OPINION OF COUNSEL IN A FORM REASONABLY ACCEPTABLE TO COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED DUE TO AN EXEMPTION THEREFROM UNDER SAID ACT AND ANY APPLICABLE STATE SECURITIES LAWS OR (C) ADRENYX BIOSCIENCES, INC. OTHERWISE SATISFIES ITSELF THAT SUCH TRANSACTION IS COMPLIANT WITH SUCH LAWS.

(c) Holder of this Warrant and each person to whom this Warrant is subsequently transferred represents and warrants to Company and agrees (by acceptance of such transfer) that it will not transfer this Warrant (or securities issuable upon exercise hereof unless a registration statement under the Securities Act was in effect with respect to such securities at the time of issuance thereof) unless (i) there is an effective registration statement under the Securities Act and applicable state securities laws covering any such transaction, (ii) pursuant to Rule 144 under the Securities Act (or any other rule under the Securities Act relating to the disposition of securities), (iii) Company receives an opinion of counsel, reasonably satisfactory to Company, that an exemption from such registration is available or (iv) the Company otherwise satisfies itself that such transaction is exempt from registration. Notwithstanding the foregoing or any other provision of this Section 2, Holder shall not transfer this Warrant (or

securities issuable upon exercise hereof, or securities issuable, directly or indirectly, upon conversion of such securities, if any) to any competitor of Company, as determined in good faith by the Board of Directors of Company (the "Board"), without the prior written consent of Company.

3. Shares to be Fully Paid; Reservation of Shares. Company covenants and agrees that all shares of Common Stock which may be issued upon the exercise of the rights represented by this Warrant will, upon issuance, be duly authorized, validly issued, fully paid and nonassessable and free from all preemptive rights of any stockholder and free of all taxes, liens and charges with respect to the issue thereof. Company further covenants and agrees that during the period within which the rights represented by this Warrant may be exercised, Company will at all times have authorized and reserved, for the purpose of issue or transfer upon exercise of the subscription rights evidenced by this Warrant, a sufficient number of shares of authorized but unissued Common Stock, or other securities and property, when and as required to provide for the exercise of the rights represented by this Warrant. Company will take all such action as may be necessary to assure that such shares of Common Stock may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of any domestic securities exchange upon which the Common Stock may be listed. Company will not take any action which would result in any adjustment of the Exercise Price (as described in Section 4 hereof) (i) if the total number of shares of Common Stock issuable after such action upon exercise of all outstanding warrants, together with all shares of Common Stock then outstanding and all shares of Common Stock then issuable upon exercise of all options and upon the conversion of all convertible securities then outstanding, would exceed the total number of shares of Common Stock then authorized by Company's Certificate of Incorporation, as amended and restated from time to time (the "Charter"), or (ii) if the par value per share of the Common Stock would exceed the Exercise Price.

4. Adjustment of Exercise Price and Number of Shares. The Exercise Price and the number of shares purchasable upon the exercise of this Warrant shall be subject to adjustment from time to time upon the occurrence of certain events described in this Section 4. Upon each adjustment of the Exercise Price, Holder of this Warrant shall thereafter be entitled to purchase, at the Exercise Price resulting from such adjustment, the number of shares obtained by multiplying the Exercise Price in effect immediately prior to such adjustment by the number of shares purchasable pursuant hereto immediately prior to such adjustment, and dividing the product thereof by the Exercise Price resulting from such adjustment.

4.1 Subdivision or Combination of Stock. In case Company shall at any time subdivide its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to such subdivision shall be proportionately reduced, and conversely, in case the outstanding shares of Common Stock of Company shall be combined into a smaller number of shares, the Exercise Price in effect immediately prior to such combination shall be proportionately increased.

4.2 Dividends. If at any time or from time to time the holders of Common Stock (or any shares of stock or other securities at the time receivable upon the exercise of this Warrant) shall have received or become entitled to receive,

(a) Common Stock, or any shares of stock or other securities whether or not such securities are at any time directly or indirectly convertible into or exchangeable for Common Stock, or any rights or options to subscribe for, purchase or otherwise acquire any of the foregoing by way of dividend or other distribution,

(b) any cash paid or payable including as a cash dividend, or

(c) Common Stock or other or additional stock or other securities or property (including cash) by way of spin off, split-up, reclassification, combination of shares or similar corporate rearrangement, (other than shares of Common Stock issued as a stock split, adjustments in respect of which shall be covered by the terms of Section 4.1 above),

then and in each such case, Holder hereof shall, upon the exercise of this Warrant, be entitled to receive, in addition to the number of shares of Common Stock receivable thereupon, and without payment of any additional consideration therefor, the amount of stock and other securities and property (including cash in the cases referred to in clauses (b) and (c) above) which such Holder would hold on the date of such exercise had it been the holder of record of such Common Stock as of the date on which holders of Common Stock received or became entitled to receive such shares and/or all other additional stock and other securities and property.

4.3 Change of Control. In the event of a Change of Control (as hereinafter defined), this Warrant shall be automatically exchanged for a number of shares of Company's securities, such number of shares being equal to the maximum number of shares issuable pursuant to the terms hereof as of immediately prior to such Change of Control (after taking into account all adjustments described herein) had Holder elected to exercise this Warrant immediately prior to the closing of such Change of Control and purchased all such shares pursuant to the cash exercise provision set forth in Section 1(a) hereof (as opposed to the cashless exercise provision set forth in Section 1(b)). Company acknowledges and agrees that Holder shall not be required to make any payment (cash or otherwise) for such shares as further consideration for their issuance pursuant to the terms of the preceding sentence. "Change of Control" shall mean any sale, license, or other disposition of all or substantially all of the assets of Company, any reorganization, consolidation, merger or other transaction involving Company where the holders of Company's securities before the transaction beneficially own less than 50% of the outstanding voting securities of the surviving entity after the transaction; provided that an issuance of equity securities for the primary purpose of raising capital shall not be considered a Change of Control under this Warrant; and, provided further, that the distribution of all of the shares of the Company's Common Stock held by Spruce Biosciences, Inc. to stockholders of Spruce Biosciences, Inc. on a pro rata basis shall not be considered a Change of Control under this Warrant. This Warrant shall terminate upon Holder's receipt of the number of shares of Company's equity securities described in this Section 4.3.

4.4 Reserved.

4.5 Notice of Adjustment. Upon any adjustment of the Exercise Price, and/or any increase or decrease in the number of shares purchasable upon the exercise of this Warrant, Company shall give written notice thereof to Holder pursuant to Section 12. The notice, which may be substantially in the form of Exhibit "A" attached hereto, shall be signed by Company's chief financial officer and shall state the Exercise Price resulting from such adjustment and the increase or decrease, if any, in the number of shares purchasable at such price upon the exercise of this Warrant, setting forth in reasonable detail the method of calculation and the facts upon which such calculation is based.

4.6 Other Notices. If at any time:

(a) Company shall declare any cash dividend upon its Common Stock;

(b) Company shall declare any dividend upon its Common Stock payable in stock or make any special dividend or other distribution to the holders of its Common Stock;

(c) Company shall offer for subscription pro rata to the holders of its Common Stock any additional shares of stock of any class or other rights;

(d) there shall be any capital reorganization or reclassification of the capital stock of Company, or consolidation or merger of Company with, or sale of all or substantially all of its assets to, another entity;

(e) there shall be a voluntary or involuntary dissolution, liquidation or winding-up of Company; or

(f) Company shall take or propose to take any other action, notice of which is actually provided to holders of the Common Stock;

then, in any one or more of said cases, Company shall give Holder, pursuant to Section 12, (i) at least 20 days' prior written notice of the date on which the books of Company shall close or a record shall be taken for such dividend, distribution or subscription rights or for determining rights to vote in respect of any such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding-up, or other action and (ii) in the case of any such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding-up, or other action, at least 20 days' written notice of the date when the same shall take place. Any notice given in accordance with the foregoing clause (i) shall also specify, in the case of any such dividend, distribution or subscription rights, the date on which the holders of Common Stock shall be entitled thereto. Any notice given in accordance with the foregoing clause (ii) shall also specify the date on which the holders of Common Stock shall be entitled to exchange their Common Stock for securities or other property deliverable upon such reorganization, reclassification, consolidation, merger, sale, dissolution, liquidation or winding-up, or other action as the case may be.

4.7 Reserved.

5. Issue Tax. The issuance of certificates for shares of Common Stock upon the exercise of this Warrant shall be made without charge to Holder of this Warrant for any issue tax in respect thereof; provided, however, that Company shall not be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of any certificate in a name other than that of the then Holder of this Warrant being exercised.

6. Closing of Books. Company will at no time close its transfer books against the transfer of this Warrant or of any shares of Common Stock issued or issuable upon the exercise of this Warrant in any manner which interferes with the timely exercise of this Warrant.

7. No Voting Rights; Limitation of Liability. Nothing contained in this Warrant shall be construed as conferring upon Holder hereof the right to vote or to consent as a stockholder in respect of meetings of stockholders for the election of directors of Company or any other matters or any rights whatsoever as a stockholder of Company. No dividends or interest shall be payable in respect of this Warrant or the interest represented hereby or the shares purchasable hereunder until, and only to the extent that, this Warrant shall have been exercised; provided, however, that if any dividends are due or paid at any time on the underlying securities for which this Warrant is exercisable, then upon exercise, the securities issued to Holder shall be deemed to have accrued dividends and be paid identical dividends from the same time as the outstanding shares for which this Warrant is exercisable were first issued (or, if later, the date of this Warrant). No provisions hereof, in the absence of affirmative action by Holder to purchase shares of Common Stock, and no mere enumeration herein of the rights or privileges of Holder hereof, shall give rise to any liability of such Holder for the Exercise Price or as a stockholder of Company, whether such liability is asserted by Company or by its creditors.

8. Amendment of Charter. Unless Holder consents thereto in writing, Company shall not amend its Charter prior to the exercise of this Warrant if the Common Stock would be adversely affected by such amendment in a manner that would be more adverse to Holder with respect to the shares of Common Stock issuable upon the exercise of this Warrant than, and substantially dissimilar to, such amendment's effect on the other holders of the Common Stock.

9. Registration Rights. If the Company has an effective shelf registration statement on Form S-3 (or any successor form) with available capacity for the resale of Registrable Securities (as defined below) and is not subject to any underlying restrictions that would prevent such registration (including, without limitation, any limitations on the aggregate market value of securities that may be sold by or on behalf of the Company pursuant to General Instruction I.B.6 of Form S-3), upon request from a Holder, the Company shall file a prospectus supplement to register for resale the shares of Common Stock issued upon exercise of this Warrant (the "Registrable Securities"). In the event of an underwriter cutback in any offering, Holders of Registrable Securities will be subject to cutback

before any other holders of securities with registration rights granted prior to the date hereof, and thereafter on a pro rata basis with other holders of Registrable Securities, if applicable.

10. Rights and Obligations Survive Exercise of Warrant. The rights and obligations of Company, of Holder of this Warrant and of the holder of shares of Common Stock issued upon exercise of this Warrant, contained in Sections 6, 8, 9 and 18 shall survive the exercise of this Warrant.

11. Modification and Waiver. This Warrant and any provision hereof may be changed, waived, discharged or terminated only by an instrument in writing signed by the party against which enforcement of the same is sought.

12. Notices. Any notice, request or other document required or permitted to be given or delivered to Holder or Company shall be deemed to have been given (i) upon receipt if delivered personally or by courier (ii) upon confirmation of receipt if by telecopy or (iii) three business days after deposit in the US mail, with postage prepaid and certified or registered, to each such Holder at its address as shown on the books of Company or to Company at the address indicated therefor in the opening paragraphs of this Warrant (or at such other location as Company may advise Holder in writing).

13. Survival of Certain Obligations. All of the obligations of Company relating to the Common Stock issuable upon the exercise of this Warrant shall survive the exercise and termination of this Warrant. All of the covenants and agreements of Company shall inure to the benefit of and be binding upon the successors and permitted assigns of Holder. Company will, at the time of the exercise of this Warrant, in whole or in part, upon request of Holder but at Company's expense, acknowledge in writing its continuing obligation to Holder in respect of any rights (including, without limitation, any right to registration of the shares of Common Stock) to which Holder shall continue to be entitled after such exercise in accordance with this Warrant; provided, that the failure of Holder to make any such request shall not affect the continuing obligation of Company to Holder in respect of such rights.

14. Descriptive Headings and Governing Law. The descriptive headings of the several sections and paragraphs of this Warrant are inserted for convenience only and do not constitute a part of this Warrant. This Warrant shall be construed and enforced in accordance with, and the rights of the parties shall be governed by, the laws of the State of California.

15. Lost Warrants or Stock Certificates. Company agrees that upon receipt of evidence reasonably satisfactory to Company of the loss, theft, destruction, or mutilation of any Warrant or stock certificate and, in the case of any such loss, theft or destruction, upon receipt of an indemnity reasonably satisfactory to Company, or in the case of any such mutilation upon surrender and cancellation of such Warrant or stock certificate, Company at its expense will make and deliver a new Warrant or stock certificate, of like tenor, in lieu of the lost, stolen, destroyed or mutilated Warrant or stock certificate.

16. Fractional Shares. No fractional shares shall be issued upon exercise of this Warrant. Company shall, in lieu of issuing any fractional share, pay the holder entitled to such fraction a sum in cash equal to such fraction multiplied by the then effective Exercise Price.

17. Representations of Holder. With respect to this Warrant, Holder represents and warrants to Company as follows:

17.1 Experience. It is experienced in evaluating and investing in companies engaged in businesses similar to that of Company; it understands that investment in this Warrant involves substantial risks; it has made detailed inquiries concerning Company, its business and services, its officers and its personnel; the officers of Company have made available to Holder any and all written information it has requested; the officers of Company have answered to Holder's satisfaction all inquiries made by it; in making this investment it has relied upon information made available to it by Company; and it has such knowledge and experience in financial and business

matters that it is capable of evaluating the merits and risks of investment in Company and it is able to bear the economic risk of that investment.

17.2 Investment. It is acquiring this Warrant for investment for its own account and not with a view to, or for resale in connection with, any distribution thereof. It understands that this Warrant and the shares of Common Stock issuable upon exercise of this Warrant, have not been registered under the Securities Act, nor qualified under applicable state securities laws.

17.3 Rule 144. It acknowledges that this Warrant and the Common Stock issuable upon exercise of this Warrant must be held indefinitely unless they are subsequently registered under the Securities Act or an exemption from such registration is available. It has been advised or is aware of the provisions of Rule 144 promulgated under the Securities Act.

17.4 Access to Data. It has had an opportunity to discuss Company's business, management and financial affairs with Company's management and has had the opportunity to inspect Company's facilities.

17.5 Accredited Investor. It is an "accredited investor" within the meaning of Regulation D promulgated under the Securities Act.

18. Additional Representations and Covenants of Company. Company hereby represents, warrants and agrees as follows:

18.1 Corporate Power. Company has all requisite corporate power and corporate authority to issue this Warrant and to carry out and perform its obligations hereunder.

18.2 Authorization. All corporate action on the part of Company, its directors and stockholders necessary for the authorization, execution, delivery and performance by Company of this Warrant has been taken. This Warrant is a valid and binding obligation of Company, enforceable in accordance with its terms.

18.3 Offering. Subject in part to the truth and accuracy of Holder's representations set forth in Section 17 hereof, the offer, issuance and sale of this Warrant is, and the Common Stock issuable upon exercise of this Warrant will be, exempt from the registration requirements of the Securities Act, and are exempt from the qualification requirements of any applicable state securities laws; and neither Company nor anyone acting on its behalf will take any action hereafter that would cause the loss of such exemptions.

18.4 Listing; Stock Issuance. Company shall secure and maintain the listing of the Common Stock issuable upon exercise of this Warrant and the shares of Common Stock or other securities issuable upon exercise of this Warrant, upon each securities exchange or over-the-counter market upon which securities of the same class or series issued by Company are listed, if any. Upon exercise of this Warrant, Company will use commercially reasonable efforts to cause stock certificates representing the shares of Common Stock purchased pursuant to the exercise to be issued in the names of Holder, its nominees or assignees, as appropriate at the time of such exercise.

18.5 Charter Documents. Company has provided Holder with true and complete copies of Company's Charter, By-Laws, and each Certificate of Designation or other charter document setting, forth any rights, preferences and privileges of Company's capital stock, each as amended and in effect on the date of issuance of this Warrant.

18.6 Reserved.

19. Counterparts; Facsimile; Electronic Signatures. This Warrant may be executed by one or more of the parties hereto in any number of separate counterparts, all of which together shall constitute one and the same instrument. Holder's execution and delivery of Holder's counterpart signature page to this Warrant via facsimile or

electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) shall constitute Holder's effective execution and delivery of this Warrant and agreement to and acceptance of the terms hereof for all purposes.

[*Remainder of this page intentionally left blank; signature page follows*]

IN WITNESS WHEREOF, Company has caused this Warrant to be duly executed by its officer, thereunto duly authorized as of the date of issuance set forth on the first page hereof.

ADRENYX BIOSCIENCES, INC.

By: /s/Samir Gharib
Name: Samir Gharib
Title: Chief Executive Officer

AGREED AND ACCEPTED:

HOLDER:

AVENUE VENTURE OPPORTUNITIES FUND II, L.P.

By: Avenue Venture Opportunities Partners II, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Authorized Signatory

FORM OF SUBSCRIPTION

(To be signed only upon exercise of Warrant)

To: _____

- The undersigned, the holder of the within Warrant, hereby irrevocably elects to exercise the purchase right represented by such Warrant for, and to purchase thereunder, (1) _____ (_____) shares[1] (the "Shares") of Common Stock of _____ and herewith makes payment of _____ Dollars ($_____) therefor, and requests that the certificates for such shares be issued in the name of, and delivered to, _____, whose address is _____.

- The undersigned hereby elects to convert _____ percent (__%) of the value of the Warrant pursuant to the provisions of Section 1(b) of the Warrant.

The undersigned acknowledges that it has reviewed the representations and warranties contained in Section 17 of this Warrant and by its signature below hereby makes such representations and warranties to Company.

Dated _____

Holder: _____

By: _____

Its: _____

(Address)

_____

_____

[1] Insert here the Applicable Number of shares of Common Stock (or, in the case of a partial exercise, the portion thereof as to which the Warrant is being exercised), in either case without making any adjustment for additional Common Stock or any other stock or other securities or property or cash which, pursuant to the adjustment provisions of the Warrant, may be issuable upon exercise.

ASSIGNMENT

FOR VALUE RECEIVED, the undersigned, the holder of the within Warrant, hereby sells, assigns and transfers all of the rights of the undersigned under the within Warrant, with respect to the number of shares of Common Stock covered thereby set forth herein below, unto:

Name of Assignee	Address	No. of Shares

Dated _____

Holder: _____

By: _____

Its: _____

EXHIBIT "A"

[On letterhead of Company]

Reference is hereby made to that certain Warrant dated November 6, 2026 issued by ADRENYX BIOSCIENCES, INC., a Delaware corporation (the "Company"), to AVENUE VENTURE OPPORTUNITIES FUND II, L.P., a Delaware limited partnership (the "Holder").

[IF APPLICABLE] The Warrant provides that the actual number and type of shares of Company's capital stock issuable upon exercise of the Warrant and the initial exercise price per share are to be determined by reference to one or more events or conditions subsequent to the issuance of the Warrant. Such events or conditions have now occurred or lapsed, and Company wishes to confirm the actual number of shares issuable and the initial exercise price. The provisions of this Supplement to Warrant are incorporated into the Warrant by this reference, and shall control the interpretation and exercise of the Warrant.

[IF APPLICABLE] Notice is hereby given pursuant to Section 4.5 of the Warrant that the following adjustment(s) have been made to the Warrant: [describe adjustments, setting forth details regarding method of calculation and facts upon which calculation is based].

This certifies that Holder is entitled to purchase from Company _____, at the Holder's option, either (i) (_____) fully paid and nonassessable shares of Company's _____ Stock at a price of _____ Dollars ($_____) per share or (ii) (_____) fully paid and nonassessable shares of Company's _____ Stock at a price of _____ Dollars ($_____) per share. The applicable Exercise Price and the number of shares purchasable under the Warrant remain subject to adjustment as provided in Section 4 of the Warrant.

Executed this ___ day of _____, 20___.

ADRENYX BIOSCIENCES, INC.

By: _____

Name: _____

Title: _____

Exhibit 10.1

Certain identified information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

CONSENT AND FIRST AMENDMENT TO LOAN DOCUMENTS

This Consent and First Amendment to Loan Documents (this **"Amendment"**) is entered into as of November 6, 2026 (the "**First Amendment Effective Date**"), by and among AVENUE CAPITAL MANAGEMENT II, L.P., a Delaware limited partnership (**"Agent"**), AVENUE VENTURE OPPORTUNITIES FUND II, L.P., a Delaware limited partnership ("**Avenue 2**"; together with each other lender from time to time party hereto, each "**Lender**" and, collectively, "**Lenders**"), and SPRUCE BIOSCIENCES, INC., a Delaware corporation ("**Borrower**").

RECITALS

Agent, Lenders and Borrower are parties to that certain Loan and Security Agreement dated as of January 7, 2026 (as amended from time to time, the **"Agreement"**) and that certain Supplement to Loan and Security Agreement dated as of January 7, 2026 (as amended from time to time, the **"Supplement"**, and together with the Agreement, collectively, the "**Loan Documents**"). The parties desire to amend the Agreement and the Supplement in accordance with the terms of this Amendment.

NOW, THEREFORE, the parties agree as follows:

1. CONSENT. Borrower has notified the Lenders and Agent that Borrower intends to: (a)(i) contribute its product candidate SPR202 (now known as CRHX-101) and the other "Contributed Assets" (as defined in that certain First Amendment Distribution Agreement, dated as of the First Amendment Effective Date (as each are defined below)), by and between Borrower and Adrenyx (as defined below), a newly formed, wholly-owned Delaware subsidiary of Borrower, and transfer all liabilities to the extent arising out of or relating to product candidate SPR202, to Adrenyx in accordance with the terms of the First Amendment Distribution Agreement, and (ii) enter into the Ancillary Agreements (as defined in the First Amendment Distribution Agreement) and consummate the transactions contemplated thereby (collectively, the "**First Amendment Contribution**"); and (b) following the First Amendment Contribution, and upon written notice to Agent, distribute one hundred percent (100%) of the outstanding equity that Borrower holds in Adrenyx to Borrower's stockholders on a pro rata basis (the "**First Amendment Distribution**"). Notwithstanding anything anywhere in the Loan Documents or any other document to the contrary, Agent and Lenders hereby consent to the execution, delivery and performance by Borrower of the First Amendment Distribution Agreement, and the transactions contemplated thereby, including, without limitation, the First Amendment Contribution and First Amendment Distribution. Borrower hereby acknowledges that the consent provided by Agent and Lenders herein shall apply only to the transactions set forth in this Section, and the terms of the Loan Documents otherwise remain unchanged, except to the extent amended, modified or supplemented by the terms of this Amendment.

2. AMENDMENT.

2.1 The following defined terms and their respective definitions in Part 1 of the Supplement are hereby either amended and restated in their entirety or added in the appropriate alphabetical order to read as follows:

"Commitment" means, subject to the terms and conditions set forth in the Loan and Security Agreement and this Supplement, the commitment of Lenders to make Growth Capital Loans to Borrower up to an aggregate original principal amount of Fifteen Million Dollars ($15,000,000) ("**Tranche 1**") within 5 Business Days after the Closing Date, and up to Fifteen Million Dollars ($15,000,000) to be funded between January 1, 2027 and March 31, 2027, subject to the conditions in Section 1(a)(i) of Part 2 ("**Tranche 2**"). Upon the mutual agreement of Lenders and Borrower, Lenders may make additional Growth Capital Loans to Borrower of (a) up to Fifteen Million Dollars ($15,000,000) to be funded between July 1, 2027 and December 31, 2027 (the "**Discretionary Tranche 3**"), subject to (i) the conditions set forth in this definition,

and (ii) the conditions in Section 1(a)(ii) of Part 2, and (b) up to an additional Ten Million Dollars ($10,000,000) (the "**Discretionary Tranche 4**") to be funded between October 1, 2027 and June 30, 2028, subject to the conditions in Section 1(a)(iii) of Part 2, in each case, as Borrower and Lenders may mutually agree, and subject to approval from Lenders' Investment Committees in their sole discretion; provided that, as of the Closing Date, neither Discretionary Tranche 3 nor Discretionary Tranche 4 shall be considered, and is not, committed hereunder by any Lender, and, provided, further, that there shall be no fees associated with the Discretionary Tranche 4 until any Growth Capital Loans to be made under such tranche are committed by Lenders. Notwithstanding anything to the contrary contained herein, any draw down under Tranche 2 in excess of Ten Million Dollars ($10,000,000), as permitted subject to the terms and conditions set forth in the definition of "Tranche 2 Availability Milestone", shall reduce the amount available under Discretionary Tranche 3 on a dollar-for-dollar basis such that the total aggregate amount available under Tranche 2 and Discretionary Tranche 3 shall not exceed Twenty-Five Million Dollars ($25,000,000).

"**Discretionary Tranche 3 Availability Milestone**" means that, on or before the applicable Termination Date, (a) the FDA has granted approval of the BLA for TA-ERT for commercial distribution in the United States, as evidenced by the FDA's issuance to the Borrower of a written approval letter (including an electronic notification) approving such BLA pursuant to Section 351(a) of the Public Health Service Act (42 U.S.C. § 262(a)) and 21 C.F.R. Part 601 or any successor statute or regulation, all based upon written evidence thereof provided to, and in form and content reasonably acceptable to, and reviewed and approved by Agent in its reasonable discretion, and (b) each Lender shall have received investment committee approval to fund its pro rata share of Discretionary Tranche 3; provided, however, Discretionary Tranche 3 shall not be made available if on the date of the occurrence of the Discretionary Tranche 3 Availability Milestone an Event of Default has occurred and is continuing.

"**Discretionary Tranche 4 Availability Milestone**" means [***].

"Interest-only Milestone 2" means [***].

"Interest-only Period" means the period commencing on the Closing Date and continuing until the fourteen (14) month anniversary of the Closing Date; provided, however, that such period shall be extended for seven (7) months if as of the last day of the Interest-only Period then in effect Borrower has achieved Interest-only Milestone 1; provided, further, that such period shall be extended for an additional twelve (12) months if as of the last day of the Interest-only Period then in effect Borrower has achieved Interest-only Milestone 2; provided, further, however, that the Interest-only Period shall not exceed thirty-three (33) months; and provided, further, however, that no extension of the Interest-only Period shall be available if as of the last day of the Interest-only Period then in effect an Event of Default shall have occurred and be continuing.

"Termination Date" means the earlier of: (i) the date Lender may terminate making Growth Capital Loans or extending other credit pursuant to the rights of Lender under Article 7 of the Loan and Security Agreement; (ii) with respect to Tranche 2, the earlier of (A) March 31, 2027 and (B) the date that is fifteen (15) days after the date which Borrower has achieved the condition set forth in clause (b) of the definition of "Tranche 2 Availability Milestone"; (iii) with respect to Discretionary Tranche 3, December 31, 2027; and (iv) with respect to Discretionary Tranche 4, June 30, 2028.

"**Tranche 2 Availability Milestone**" means [***].

2.2 The following definition in Part 1 of the Supplement is hereby deleted in its entirety: "**Tranche 3 Availability Milestone**".

2.3 Section 1(a) of Part 2 of the Supplement hereby is amended and restated in its entirety to read as follows:

"**1. (a) Additional Condition(s) Precedent Regarding Growth Capital Loan Commitments** . In addition to the satisfaction of all of the other applicable conditions precedent specified in

Sections 4.1 and 4.2 of the Loan and Security Agreement and this Supplement, each Lender's obligation to fund its pro rata share of Tranche 2 and, if applicable, Discretionary Tranche 3 and Discretionary Tranche 4, of Growth Capital Loans is subject to receipt by Agent of evidence that the following conditions precedent have been satisfied, as determined by Agent in its reasonable discretion:

(i) **Tranche 2**. Borrower has achieved the Tranche 2 Availability Milestone.

(ii) **Discretionary Tranche 3**. Borrower has achieved the Discretionary Tranche 3 Availability Milestone (including, for the avoidance of doubt, that each Lender shall have received investment committee approval to fund its pro rata share of Discretionary Tranche 3).

(iii) **Discretionary Tranche 4**. Borrower has achieved the Discretionary Tranche 4 Availability Milestone (including, for the avoidance of doubt, that each Lender shall have received investment committee approval to fund its pro rata share of Discretionary Tranche 4).

Subject to satisfaction of the conditions precedent specified in Sections 4.1 and 4.2 of the Loan and Security Agreement and this Supplement, each Lender agrees to make Growth Capital Loans to Borrower under Lender's Commitment from time to time from and after the Closing Date up to and including the Termination Date in an aggregate, original principal amount up to, but not exceeding, the then-unfunded portion of such Lender's Commitment."

2.4 The following defined terms and their respective definitions in the Agreement are hereby either amended and restated in their entirety or added in the appropriate alphabetical order to read as follows:

"**Adrenyx**" means Adrenyx Biosciences, Inc., a Delaware corporation.

"**Adrenyx Assets**" means all right, title and interest in product candidate SPR202, the other "Contributed Assets" (as defined in the First Amendment Distribution Agreement) and the equity interests of Adrenyx.

"Collateral" means all of Borrower's right, title and interest in and to the following property, whether now owned or hereafter acquired and wherever located: (a) all Receivables; (b) all Equipment; (c) all Fixtures; (d) all General Intangibles; (e) all Inventory; (f) all Investment Property; (g) all Deposit Accounts; (h) all Shares; (i) all other Goods and personal property of Borrower, whether tangible or intangible and whether now or hereafter owned or existing, leased, consigned by or to, or acquired by, Borrower and wherever located; (j) all Records; and (k) all Proceeds of each of the foregoing and all accessions to, substitutions and replacements for, and rents, profits and products of each of the foregoing.

Notwithstanding the foregoing the term "Collateral" shall not include: (i) more than sixty-five percent (65%) of the issued and outstanding capital stock, membership units or other securities entitled to vote owned or held of record by Borrower in any Subsidiary that is a controlled foreign corporation (as defined in the Internal Revenue Code), provided that the Collateral shall include one hundred percent (100%) of the issued and outstanding non-voting capital stock of such Subsidiary; (ii) "intent-to-use" trademarks at all times prior to the first use thereof, whether by the actual use thereof in commerce, the recording of a statement of use with the United States Patent and Trademark Office or otherwise, but only to the extent the granting of a security interest in such "intent to use" trademarks would be contrary to applicable law; (iii) any contract, Instrument or Chattel Paper in which Borrower has any right, title or interest if and to the extent such contract, Instrument or Chattel Paper includes a provision containing a restriction on assignment such that the creation of a security interest in the right, title or interest of Borrower therein would be prohibited and would, in and of itself, cause or result in a default thereunder enabling another person party to such contract, Instrument or Chattel Paper to enforce any remedy with respect thereto; provided, however, that the foregoing exclusion shall not apply if (A) such prohibition has been waived or such other person has

otherwise consented to the creation hereunder of a security interest in such contract, Instrument or Chattel Paper, or (B) such prohibition would be rendered ineffective pursuant to Sections 9-407(a) or 9-408(a) of the UCC, as applicable and as then in effect in any relevant jurisdiction, or any other applicable law (including the Bankruptcy Code or principles of equity); provided, further, that immediately upon the ineffectiveness, lapse or termination of any such provision, the term "Collateral" shall include, and Borrower shall be deemed to have granted a security interest in, all its rights, title and interests in and to such contract, Instrument or Chattel Paper as if such provision had never been in effect; and provided further that the foregoing exclusion shall in no way be construed so as to limit, impair or otherwise affect Agent's unconditional continuing security interest in and to all rights, title and interests of Borrower in or to any payment obligations or other rights to receive monies due or to become due under any such contract, Instrument or Chattel Paper and in any such monies and other proceeds of such contract, Instrument or Chattel Paper, (iv) Deposit Accounts holding cash collateral covered by a Permitted Lien pursuant to clause (p) of the definition of Permitted Liens, or (v) the Adrenyx Assets.

"**First Amendment Distribution Agreement**" means that certain Separation and Distribution Agreement dated as of the First Amendment Effective Date by and between Borrower and Adrenyx whereby Borrower transfers to Adrenyx all of its right, title and interest in and to the Adrenyx Assets and any and all liabilities to the extent arising out of or relating thereto.

3. Agent hereby releases, discharges, cancels and terminates its security interest in and continuing Lien on the Adrenyx Assets, and re-assigns, re-transfers and re-conveys to Borrower any and all right, title or interest Agent may have in and to the Adrenyx Assets. At Borrower's request and sole expense, Agent and Lenders further agree to execute and deliver any other documents necessary to evidence or effectuate the foregoing release and termination. After consummation of the First Amendment Contribution, Adrenyx shall not be required to join the Loan Agreement or other Loan Documents as a co-borrower or guarantor and shall not be subject to any of the covenants or other terms therein.

4. No course of dealing on the part of Agent or any Lender, nor any failure or delay in the exercise of any right by Agent or any Lender, shall operate as a waiver thereof, and any single or partial exercise of any such right shall not preclude any later exercise of any such right. Agent or any Lender's failure at any time to require strict performance by Borrower of any provision shall not affect any right of Agent or any Lender thereafter to demand strict compliance and performance. Any suspension or waiver of a right must be in writing signed by an officer of Agent or Lender.

5. Unless otherwise defined, all initially capitalized terms in this Amendment shall be as defined in the Loan Documents (as defined in the Agreement). The Loan Documents, as amended hereby, shall be and remain in full force and effect in accordance with their respective terms and hereby are ratified and confirmed in all respects. Except as expressly set forth herein, the execution, delivery, and performance of this Amendment shall not operate as a waiver of, or as an amendment of, any right, power, or remedy of Agent or any Lender under the Loan Documents, as in effect prior to the date hereof.

6. Borrower represents and warrants that:

6.1 Immediately upon giving effect to this Amendment (i) the representations and warranties contained in the Agreement are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date), and (ii) no Event of Default has occurred and is continuing.

6.2 Borrower has the organizational power and authority to execute and deliver this Amendment and to perform its obligations under the Agreement, as amended hereby.

6.3 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against it in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

7. As a condition to the effectiveness of this Amendment, Agent shall have received, in form and substance reasonably satisfactory to Agent, the following:

(a) this Amendment, duly executed by Borrower;

(b) a UCC-3 Financing Statement Amendment, which shall exclude the Adrenyx Assets from the Collateral;

(c) (i) a certified copy of the resolutions of the Board of Directors (or equivalent governing body) of Borrower authorizing the execution, delivery and performance by Borrower of this Amendment and (ii) a certificate of the secretary (or other senior officer) of Borrower certifying the names of the officer or officers of Borrower authorized to sign this Amendment, together with a sample of the true signature of each such officer;

(d) copies of the organizational and charter documents of Adrenyx (e.g., Certificate of Incorporation and Bylaws);

(e) a fully executed copy of the First Amendment to Warrant in favor of each Lender, together with a pro forma summary capitalization table;

(f) a fully executed copy of that certain Warrant to Purchase Shares of Common Stock of Adrenyx, in form and in substance satisfactory to Agent, in favor of each Lender, together with a pro forma summary capitalization table;

(g) the duly executed First Amendment Distribution Agreement, together with all related schedules and exhibits thereto and all other material documents and deliverables related thereto, including all Ancillary Agreements (as defined in the First Amendment Distribution Agreement);

(h) all reasonable Lender expenses incurred through the date of this Amendment; and

(i) such other documents, and completion of such other matters, as Agent may reasonably deem necessary or appropriate.

8. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one instrument.

[*Balance of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, the undersigned have executed this Amendment as of the first date above written.

BORROWER:

SPRUCE BIOSCIENCES, INC.

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

AGENT:

AVENUE CAPITAL MANAGEMENT II, L.P.

By: Avenue Capital Management II GenPar, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Member

LENDER:

AVENUE VENTURE OPPORTUNITIES FUND II, L.P.

By: Avenue Venture Opportunities Partners II, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Authorized Signatory

Exhibit 10.2

Certain information in this document identified by brackets has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

Execution Version

SEPARATION AND DISTRIBUTION AGREEMENT

THIS SEPARATION AND DISTRIBUTION AGREEMENT (this "***Agreement***"), dated as of November 6, 2026, is entered into by and between **SPRUCE BIOSCIENCES, INC.**, a Delaware corporation (the "***Company***"), and **ADRENYX BIOSCIENCES, INC.**, a Delaware corporation and wholly owned subsidiary of the Company ("***NewCo***"). The Company and NewCo are referred to herein, collectively, as the "***Parties,***" and, individually, as a "***Party.***" Certain capitalized terms used herein are defined in **Exhibit A**.

RECITALS

A. The Board of Directors of the Company (the "***Board***") has determined that it is appropriate, desirable, and in the best interests of the Company and its stockholders that the SPR202 Business (as defined herein) be separated from the Company's other businesses and conducted by NewCo as an independent company (the "***Separation***"), resulting in, following the completion of the Distribution (as defined below), two separate publicly traded companies.

B. To effect the Separation, (i) the Company will contribute, assign, transfer, convey, and deliver to NewCo, and NewCo will accept and assume from the Company, the Contributed Assets and the Contributed Liabilities (the "***Contribution***") and (ii) NewCo will issue to the Company shares of NewCo Common Stock constituting 100% of the issued and outstanding capital stock of NewCo as of the Contribution Effective Time, in each case, on the terms and subject to the conditions set forth in this Agreement.

C. In connection with the Separation, and substantially concurrently with the Contribution Effective Time (but subject to and conditioned upon the Contribution), NewCo entered into certain convertible debt financing arrangements of up to $10,000,000 with the Lead Purchaser (as defined in the Note Financing Documents)(the "***Note Financing***") pursuant to a Secured Convertible Note Purchase Agreement and Secured Convertible Promissory Note(s) (together, the "***Note Financing Documents***"), in order to fund NewCo's working capital and operations following the Separation.

D. Following the completion of the Separation and the Note Financing, the Company intends to distribute to the Record Holders on a pro rata basis all of the shares of NewCo Common Stock held by the Company (the "***Distribution***") on the terms and subject to the conditions set forth in this Agreement.

E. It is appropriate and desirable to set forth the principal corporate transactions required to effect the Separation, the Distribution and the Note Financing and to set forth certain other agreements that will, following the Distribution, govern certain matters relating to the Separation and the Distribution and the Note Financing and the relationship of the Company, NewCo and their respective Affiliates.

F. (i) The Board has (x) determined that the Separation, the Note Financing, the Distribution and the other transactions contemplated by this Agreement and the Ancillary Agreements have a valid business purpose, are in furtherance of and consistent with its business strategy and are in the best interests of the Company and its stockholders and (y) approved this Agreement and each of the Ancillary Agreements and the consummation of the transactions contemplated hereby and thereby and (ii) the board of directors of NewCo has approved this Agreement and each of the Ancillary Agreements to which NewCo is a party and the consummation of the transactions contemplated hereby and thereby.

G. The Parties acknowledge that the Separation and the Distribution are components of an integrated plan and that this Agreement and the Ancillary Agreements represent the integrated agreement of the Parties relating to the Separation and the Distribution; each has been, or will be, entered into in contemplation of the other, and neither would have been entered into independently.

H. For U.S. federal income tax purposes, it is the intention of the Parties that the Contribution and the Distribution, taken together, shall be treated as a taxable transaction to the Company for U.S. federal income tax purposes, with the Company recognizing gain or loss (if any) under Section 311(b) of the Code on the deemed distribution of NewCo Common Stock to the Company's stockholders.

I. The Parties intend that the Distribution be exempt from the registration requirements of the Securities Act of 1933, as amended (the "***Securities Act***"), and, in the event the Distribution is not so exempt, NewCo shall instead register the issuance of securities in the Distribution on a registration statement on Form S-1 under the Securities Act.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and agreements herein contained, and intending to be legally bound hereby, the Parties agree as follows:

ARTICLE 1

THE SEPARATION

1.1 Contribution of Assets. Upon the terms and subject to the conditions of this Agreement, effective as of the Contribution Effective Time, the Company shall and hereby does contribute, assign, transfer, convey, and deliver to NewCo, and NewCo shall accept from the Company, all of the Company's right, title, and interest in and to all of the Contributed Assets, free and clear of all Liens other than Permitted Liens. The Company is not contributing, and NewCo is not acquiring, any of the Retained Assets.

1.2 Assumption of Liabilities. Effective as of the Contribution Effective Time, NewCo shall and hereby does accept and assume the Contributed Liabilities, in each case regardless of (a) when or where such Liabilities arose or arise, (b) where or against whom such Liabilities are asserted or determined, (c) which entity is named in any action associated with any Liability, and (d) whether the facts on which such Liabilities are based occurred prior to, on, or after the date hereof. Except for the Contributed Liabilities, NewCo shall not assume, and shall have no responsibility or liability of any kind for, any Liability of the Company Group, including

the Retained Liabilities, whether arising before, on, or after the Contribution Effective Time. From and after the Contribution Effective Time, NewCo shall perform, discharge, and fulfill all of the Contributed Liabilities in accordance with their respective terms.

1.3 Retained Liabilities. The Company shall retain, and shall continue to be responsible for, all Retained Liabilities. NewCo shall not assume or have any responsibility or liability with respect to any Retained Liability.

1.4 Issuance of NewCo Common Stock. As of the Contribution Effective Time, in consideration for the Contribution, NewCo shall have issued to the Company, 10,000,000 shares of NewCo Common Stock (the "***NewCo Shares***"), and the NewCo Shares shall constitute 100% of the issued and outstanding capital stock of NewCo as of the Contribution Effective Time. The Parties acknowledge and agree that the distribution of the NewCo Shares to the Company's stockholders shall be governed by and subject to the terms and conditions set forth in Article 2 hereof.

1.5 Conditions Precedent to the Contribution. The obligations of the Parties to consummate the Contribution, and the occurrence of the Contribution Effective Time, are subject to the satisfaction (or written waiver by both Parties) of each of the following conditions: (a) the Required Consents set forth on Schedule 1.5 shall have been obtained and shall remain in full force and effect as of the Contribution Effective Time; and (b) the initial closing of the Note Financing on the terms set forth in the Note Financing Documents shall occur substantially concurrently with the Contribution Effective Time. The Parties hereby acknowledge and agree that, as of the date of this Agreement, each of the Required Consents has been obtained and delivered by the Company and is sufficient in form and substance to satisfy the condition set forth in clause (a) of this Section 1.5, subject to such Required Consent remaining in full force and effect through the Contribution Effective Time.

1.6 Ancillary Agreements. In connection with, but subject to the occurrence of the Contribution Effective Time, the Parties shall execute and deliver:

(a) the Transition Services Agreement, in substantially the form attached hereto as **Exhibit B** (subject to such modifications or additions thereto as may be mutually agreed by the Parties);

(b) a Bill of Sale by and between the Parties providing for the contribution of the Contributed Assets, in substantially the form attached hereto as **Exhibit C**;

(c) an Assignment and Assumption Agreement by and between the Parties providing for the assignment and assumption of the Contributed Liabilities, in substantially the form attached hereto as **Exhibit D**; and

(d) an Intellectual Property Assignment Agreement (the "***IP Assignment Agreement***"), in substantially the form attached hereto as **Exhibit E**.

1.7 Cooperation and Further Assurances.

(a) In addition to and without limiting the actions specifically provided for elsewhere in this Agreement and subject to the limitations expressly set forth in this Agreement, each of the Parties shall cooperate with each other and shall use (and shall cause its respective Group to use) commercially reasonable efforts to take, or to cause to be taken, all actions, and to do, or to cause to be done, all things reasonably necessary on its part under applicable Law or contractual obligations to consummate and make effective the transactions contemplated by this Agreement and the Ancillary Agreements as promptly as reasonably practicable.

(b) Without limiting the foregoing:

(i) any consent fees, transfer taxes or other consideration required to be paid or issued to a Third Party in connection with obtaining a Required Consent shall be allocated between the Parties as set forth in Schedule 1.7(b)(i), subject to Section 1.10;

(ii) other than a Required Consent (which shall be governed by Section 1.7(b)(i) above), with respect to any consent, substitution or amendment required to novate, transfer or assign any Assets that constitute Contributed Assets or Liabilities that constitute Contributed Liabilities so that NewCo will be the sole beneficial owner of such Assets or solely responsible for such Liabilities, as applicable, each Party, at the request of the other Party, shall use its commercially reasonable efforts to obtain, or to cause to be obtained, such consent, substitution or amendment as soon as reasonably practicable; provided, however, that except as expressly provided in any of the Ancillary Agreements, or as otherwise agreed between the Parties, neither the Company nor NewCo shall be obligated to make any payment, incur any Liability or offer or grant any accommodation (financial or otherwise, regardless of any provision to the contrary in any underlying Contract, including any requirements for the securing or posting of any bonds, letters of credit or similar instruments, or the furnishing of any guarantees) to any Third Party from whom any such consent, substitution or amendment is requested;

(iii) if, at any time after the Contribution Effective Time, a Party identifies any Retained Assets or Retained Liabilities held by NewCo, then NewCo shall as promptly as practicable transfer such assets or liabilities to the Company (at NewCo's sole expense) for no additional consideration, and the Company shall accept such transfer.

(iv) if, at any time after the Contribution Effective Time, a Party identifies any Contributed Assets or Contributed Liabilities held by the Company Group, then the Company shall (or shall cause its applicable Subsidiary to) as promptly as practicable transfer such assets or liabilities to NewCo (at the Company's sole expense) for no additional consideration, and NewCo shall accept such transfer; and

(v) to the fullest extent permissible under applicable Law, NewCo hereby waives compliance by the Company with the requirements of any "bulk-sale" or "bulk-transfer" laws of any jurisdiction that may be applicable with respect to the transfer of any Contributed Assets to NewCo.

1.8 Transfer of Assets and Liabilities Subject to Consent. Notwithstanding anything to the contrary in this Agreement, if the transfer, assignment, conveyance or assumption of any Contributed Asset or Contributed Liability would be a violation of applicable Law or require the

consent or approval of a third party (other than the Required Consents) that has not been obtained as of the Contribution Effective Time, such Contributed Asset or Contributed Liability shall not be transferred, assigned, conveyed or assumed at the Contribution Effective Time but shall remain with the Company Group until such time as all legal impediments are removed or such consent or approval is obtained, at which time such Contributed Asset shall be transferred, assigned, or conveyed to NewCo. Until any such legal impediments are removed or such consent or approval is obtained, (a) the Company shall (or shall cause its applicable Subsidiary to) hold such Asset for the use and benefit of NewCo, and (b) NewCo shall, subject to Section 1.10, pay or reimburse the Company for all out-of-pocket costs and expenses paid or incurred in connection with the retention of such Asset or Liability; provided, that for the avoidance of doubt, the Company shall not be required to bear any unreimbursed cost, expense, or Liability in connection with its obligations under this Section 1.8. In addition, the Company or NewCo, as applicable, shall (or shall cause its applicable Subsidiary to) treat, insofar as reasonably practicable and to the extent permitted by applicable Law, such Asset or Liability in the ordinary course of business in accordance with past practice and take such other reasonably requested actions in order to place NewCo or the Company, insofar as reasonably practicable and to the extent permitted by applicable Law, in the same position as if such Asset or Liability had been transferred or assumed as contemplated hereby, and so that all the benefits and burdens relating to such Asset or Liability, including possession, use, risk of loss, potential for income and gain, and dominion, control and command over such Asset or Liability, are to inure from and after the Contribution Effective Time to NewCo. Notwithstanding the foregoing, any such Contributed Asset or Contributed Liability shall continue to constitute a Contributed Asset or Contributed Liability, as applicable, for all other purposes of this Agreement.

1.9 Settlement of Intercompany Accounts. The Parties acknowledge that, prior to the Distribution Effective Time, the Company will have paid or incurred certain expenses on behalf of NewCo (including legal, accounting, tax and other professional fees), resulting in certain Intercompany Accounts owed by NewCo to the Company, subject to Section 1.10. Each Intercompany Account which exists and is reflected immediately prior to the Distribution Effective Time in any general ledger account or other records of the Company, NewCo or any of their respective Affiliates, shall, subject to Section 1.10, be: (a) closed prior to or as of the Distribution Effective Time and satisfied or settled within thirty (30) days following the Distribution Date by the relevant members of the Company Group and the NewCo Group by (i) payment to the relevant obligee or (ii) reimbursement of the Company Group by the NewCo Group or (b) otherwise terminated effective as of the Distribution Effective Time. For the avoidance of doubt, the obligation to satisfy, settle or terminate Intercompany Accounts shall survive the Distribution Effective Time. The Parties confirm that (i) there are no intercompany agreements between the Company Group and the NewCo Group as of the date hereof, other than this Agreement and the Ancillary Agreements (including the Transition Services Agreement) and (ii) the Intercompany Accounts owed by NewCo to the Company will consist of expenses incurred by the Company directly on behalf of NewCo (including legal, accounting, tax and other professional fees) or the Contributed Assets and not in respect of any fees or expenses incurred solely on behalf of, or solely for the benefit of, the Company.

1.10 Settlement of Intercompany Accounts. Notwithstanding anything contained in Section 1.2, Section 1.7(b), Section 1.8, Section 1.9, Section 2.1(a)(ii), Section 5.2, Section 6.1(a), Schedule 1.7(b)(i) or any other provision of this Agreement to the contrary or in Section 6 of the

Assignment and Assumption Agreement, the aggregate liability of NewCo and the other members of the NewCo Group (whether by payment, reimbursement, indemnification, Intercompany Account or otherwise) for, without duplication, (i) any consent fees, transfer taxes or other consideration required to be paid or issued to a Third Party in connection with obtaining a Required Consent (including the Avenue Capital Cash Payment), (ii) expenses resulting in Intercompany Accounts and (iii) all reasonable and documented out-of-pocket fees, costs and expenses incurred or arising on or prior to the Distribution Date primarily in connection with the preparation, execution, delivery, printing and implementation of this Agreement and the Registration Statement (including the Information Statement and the carve-out financial statements required to be included therein), and the Separation and the Distribution and the consummation of the transactions contemplated hereby and thereby (clauses (i), (ii) and (iii), the "***Requisite Expenses***") shall not exceed $3,500,000 (the "***Cap***"); provided that in no event shall this Section 1.10 or the Cap apply (x) in the event of NewCo's Fraud or willful misconduct or (y) to any fees or expenses payable by NewCo under the Transition Services Agreement. The Company shall be solely responsible for all Requisite Expenses in excess of the Cap, and such excess shall (x) be deemed a Retained Liability, (y) not constitute a Contributed Liability or an Intercompany Account, and (z) not be recoverable from any member of the NewCo Group.

ARTICLE 2

THE DISTRIBUTION

2.1 Actions on or Prior to the Distribution Date.

(a) Prior to the Distribution Date, the Company and NewCo shall prepare and, in accordance with applicable Law, file with the SEC the Registration Statement, including the Information Statement, amendments, supplements and any such other documentation which is necessary or desirable to effectuate the Distribution, and shall each use reasonable best efforts to obtain all necessary approvals from the SEC and to cause the Registration Statement to be filed with the SEC and to become effective, as promptly as reasonably practicable. In furtherance of the foregoing:

(i) the Company shall provide NewCo, and NewCo shall provide the Company, with such information concerning itself, its business, operations, and management, and the transactions contemplated hereby, as may be reasonably requested by the other Party for inclusion in the Registration Statement (including the Information Statement);

(ii) the Company and NewCo shall cooperate in the preparation of the carve-out financial statements and any other financial statements of NewCo or the SPR202 Business that are required to be included in the Registration Statement in connection with the Distribution, including by providing reasonable access to books, records, and personnel, and by facilitating engagement with NewCo's independent auditors and, unless otherwise agreed by the Parties, NewCo shall bear the costs of preparing and auditing such carve-out financial statements;

(iii) each Party shall promptly notify the other Party of, and shall cooperate with respect to, any comments received from the SEC or any other Governmental Entity with respect to the Registration Statement, and shall provide the other Party with a reasonable

opportunity to review and comment on any proposed responses to such comments and any amendments or supplements to the Registration Statement prior to filing, which comments the responding Party shall consider in good faith; and

(iv) the Company and NewCo shall prepare, file with the SEC and cause to become effective any registration statements or amendments thereto required to effect the establishment of, or amendments to, any employee benefit and other plans necessary or appropriate in connection with the transactions contemplated by this Agreement.

(b) Subject to the terms and conditions of this Agreement, applicable Law, and the rules and regulations of the Nasdaq, the Board shall set the Record Date in accordance with the terms of this Agreement and establish any appropriate procedures in connection with the Distribution.

(c) The Company shall enter into a distribution agent agreement with the Distribution Agent or otherwise provide instructions to the Distribution Agent regarding the Distribution.

(d) To the extent not already approved and effective, NewCo shall use commercially reasonable efforts to have approved and made effective the application for the original listing on the Nasdaq Stock Market ("***Nasdaq***") of the NewCo Common Stock to be distributed in the Distribution, subject to official notice of distribution.

(e) Nothing in this Section 2.1 shall be deemed to shift or otherwise impose liability for any portion of the Information Statement to the Company.

2.2 Distribution. On or prior to the Distribution Effective Time, NewCo shall take such actions (including by way of a stock split, reverse stock split or stock dividend in respect of the NewCo Common Stock) as the Board determines to be necessary or advisable or the Company otherwise reasonably requests to give effect to the Distribution Ratio approved by the Board and as may otherwise be necessary to ensure that the Company holds the requisite number of shares of NewCo Common Stock as of immediately prior to the Distribution Effective Time to effect the Distribution. Subject to the conditions and other terms set forth in this Article 2, the Company shall cause the Distribution Agent, on the Distribution Date, to make the Distribution, including by crediting the appropriate number of shares of NewCo Common Stock to book-entry accounts for each Record Holder or, subject to proper compliance by such Record Holder with any applicable procedures established by the Distribution Agent, any designated transferee or transferees of such Record Holder. For clarity, the Distribution shall only be made to the Record Holders (and not any holder who holds shares of Company Common Stock indirectly through a broker or other nominee), and accordingly stockholders of the Company who hold shares of the Company Common Stock through a broker or other nominee will receive shares of NewCo Common Stock solely by means of the applicable broker or nominee crediting such shares to their respective accounts with such broker or nominee. No action by any Record Holder shall be necessary to receive the applicable number of shares of NewCo Common Stock to which such stockholder is entitled in the Distribution. Notwithstanding anything to the contrary in this Agreement, any Ancillary Agreement, the Note Financing Documents or the organizational documents of NewCo, at any time prior to the Distribution Effective Time, the Company (in its

sole discretion) may cause NewCo to amend or amend and restate its certificate of incorporation, bylaws or other organizational documents to include lock-up and transfer restriction restrictions that are agreed to, in writing, by the Company and NewCo (with NewCo acting by unanimous approval of the Board).

2.3 Fractional Shares. No fractional shares of NewCo Common Stock will be issued or distributed in the Distribution, and no certificates or book-entry authorizations representing any such fractional shares will be issued. In lieu of any fractional share of NewCo Common Stock that a stockholder of the Company would otherwise be entitled to receive in the Distribution (after aggregating all shares of NewCo Common Stock, including any fractional share interests, to which such stockholder would otherwise be entitled based on such stockholder's aggregate holdings of Company Common Stock as of the Record Date), the number of shares of NewCo Common Stock to be received by such stockholder in the Distribution shall be rounded down to the nearest whole share, and no cash, other property, or other consideration will be paid or distributed to any stockholder in respect of any such fractional share interest so eliminated. Any shares of NewCo Common Stock that are not distributed in the Distribution as a result of the rounding described in this Section 2.3 shall be retained by the Company and, promptly following the Distribution Effective Time, surrendered to NewCo for cancellation for no consideration.

2.4 Sole and Absolute Discretion of the Company. Notwithstanding anything in this Agreement or any Ancillary Agreement to the contrary, (a) the Company, in its sole and absolute discretion, shall determine the Distribution Date, the Distribution Effective Time, and all other terms of the Distribution, including the form, structure, and terms of any transactions and/or offerings to effect the Distribution and the timing of and conditions to the consummation thereof, (b) the Company may, at any time and from time to time until the completion of the Distribution, decide to abandon the Distribution or modify or change the terms of the Distribution, including by accelerating or delaying the timing of the consummation of all or part of the Distribution; and (c) without limiting the foregoing, the Company shall have the right not to complete the Distribution if, at any time prior to the Distribution Effective Time, the Board shall have determined, in its sole and absolute discretion, that the Distribution is not in the best interests of the Company or its stockholders, that another strategic alternative is in the best interests of the Company or its stockholders, or that it is not advisable at that time for the SPR202 Business to separate from the Company or otherwise for the Distribution not to be completed.

2.5 Conditions Precedent to the Distribution. Subject to Section 2.4, the obligation of the Company to consummate the Distribution is subject to prior or simultaneous satisfaction, or, to the extent permitted by applicable Law, waiver by the Company, in its sole and absolute discretion, of the following conditions:

(a) the Contribution shall have been completed in accordance with the terms of this Agreement, including, for the avoidance of doubt, that the transfers of Contributed Assets and assumptions of Contributed Liabilities described in Sections 1.1 and 1.2 shall have been completed;

(b) the initial closing of the Note Financing shall have occurred, and the funding required at such initial closing shall have been made in accordance with the Note Financing Documents;

(c) the SEC shall have declared effective the Registration Statement on Form 10 (or Form S-1, as applicable), no stop order relating thereto shall be in effect, no proceedings seeking any such stop order shall be pending before or threatened by the SEC, and the Information Statement shall have been distributed to holders of the Company Common Stock; provided, that if the Distribution is intended to be effected in reliance on an exemption from such registration requirements, the Parties shall have obtained such advice of counsel as the Board deems necessary or advisable confirming the availability of such exemption;

(d) prior to the Distribution Date, such registration statements on Form S-8 as are necessary to register the equity awards of NewCo held by or made available to directors and employees of NewCo shall have been filed with the SEC;

(e) the shares of NewCo Common Stock to be distributed shall have been approved and accepted for listing on Nasdaq, subject to official notice of distribution;

(f) no order, injunction, or decree issued by any Governmental Entity of competent jurisdiction, or other legal restraint or prohibition preventing the consummation of the Distribution or any of the related transactions, shall be pending, threatened, issued, or in effect, and no other event outside the control of the Company shall have occurred or failed to occur that prevents the consummation of all or any portion of the Distribution;

(g) the Board shall have declared the Distribution and approved all related transactions (and such declaration or approval shall not have been withdrawn);

(h) each of the Company and NewCo shall have executed and delivered each of the other Ancillary Agreements to which it is a party; and

(i) no events or developments shall have occurred or shall exist that, in the sole and absolute judgment of the Board, make it inadvisable to effect the Distribution or would result in the Distribution and related transactions not being in the best interests of the Company or its stockholders.

Neither NewCo, any other member of the NewCo Group, nor any Third Party shall have any right or claim to require the consummation of the Distribution (including to seek an injunction or other equity relief to cause the Company to effect the Distribution), which shall be effected at the sole and absolute discretion of the Board. Any determination by the Company, and any subsequent amendment, revision, withdrawal, or change thereto made by the Company prior to the Distribution concerning the satisfaction or waiver of any or all of the conditions set forth in this Section 2.5, shall be conclusive and binding on the Parties. The conditions are for the sole benefit of the Company and shall not give rise to or create any duty on the part of the Company or the Board to waive or not waive any such condition.

ARTICLE 3

DISCLAIMER OF REPRESENTATIONS AND WARRANTIES

3.1 Disclaimer of Representations and Warranties. EACH OF THE COMPANY (ON BEHALF OF ITSELF AND EACH MEMBER OF THE COMPANY GROUP) AND

NEWCO (ON BEHALF OF ITSELF AND EACH MEMBER OF THE NEWCO GROUP) UNDERSTANDS AND AGREES THAT, EXCEPT AS EXPRESSLY SET FORTH HEREIN OR IN ANY ANCILLARY AGREEMENT, NO PARTY TO THIS AGREEMENT, ANY ANCILLARY AGREEMENT OR ANY OTHER AGREEMENT OR DOCUMENT CONTEMPLATED BY THIS AGREEMENT, ANY ANCILLARY AGREEMENTS OR OTHERWISE, IS REPRESENTING OR WARRANTING IN ANY WAY, AND HEREBY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, AS TO THE ASSETS, BUSINESSES OR LIABILITIES CONTRIBUTED, TRANSFERRED OR ASSUMED AS CONTEMPLATED HEREBY OR THEREBY, AS TO ANY CONSENTS REQUIRED IN CONNECTION HEREWITH OR THEREWITH, AS TO THE VALUE OR FREEDOM FROM ANY SECURITY INTERESTS OF, AS TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, VALIDITY OR ENFORCEABILITY OR ANY OTHER MATTER CONCERNING, ANY ASSETS OR BUSINESS OF SUCH PARTY, OR AS TO THE ABSENCE OF ANY DEFENSES OR RIGHT OF SETOFF OR FREEDOM FROM COUNTERCLAIM WITH RESPECT TO ANY ACTION OR OTHER ASSET OF ANY PARTY, OR AS TO THE LEGAL SUFFICIENCY OF ANY CONTRIBUTION, ASSIGNMENT, DOCUMENT, CERTIFICATE OR INSTRUMENT DELIVERED HEREUNDER TO CONVEY TITLE TO ANY ASSET OR THING OF VALUE UPON THE EXECUTION, DELIVERY AND FILING HEREOF OR THEREOF. EXCEPT AS MAY EXPRESSLY BE SET FORTH HEREIN OR IN ANY ANCILLARY AGREEMENT, ALL SUCH ASSETS ARE BEING TRANSFERRED ON AN "AS IS, WHERE IS" BASIS AND THE RESPECTIVE TRANSFEREES SHALL BEAR THE ECONOMIC AND LEGAL RISKS THAT (I) ANY CONVEYANCE SHALL PROVE TO BE INSUFFICIENT TO VEST IN THE TRANSFEREE GOOD TITLE, FREE AND CLEAR OF ANY SECURITY INTEREST AND (II) ANY NECESSARY CONSENTS OR GOVERNMENTAL APPROVALS ARE NOT OBTAINED OR THAT ANY REQUIREMENTS OF LAWS OR JUDGMENTS ARE NOT COMPLIED WITH. This Section 3.1 shall not limit any Party's liability for fraud.

3.2 Each of the Company (on behalf of itself and each member of the Company Group) and NewCo (on behalf of itself and each member of the NewCo Group) further understands and agrees that if the disclaimer of express or implied representations and warranties contained in Section 3.1 is held unenforceable or is unavailable for any reason under the Laws of any jurisdiction outside the United States or if, under the Laws of a jurisdiction outside the United States, both the Company or any member of the Company Group, on the one hand, and NewCo or any member of the NewCo Group, on the other hand, are jointly or severally liable for any Retained Liability or any Contributed Liability, then the Parties intend that, notwithstanding any provision to the contrary under the Laws of such non-U.S. jurisdictions, the provisions of this Agreement and the Ancillary Agreements (including the disclaimer of all representations and warranties, allocation of Liabilities among the Parties and their respective Subsidiaries, releases, indemnification and contribution of Liabilities) shall prevail for any and all purposes among the Parties and their respective Subsidiaries.

ARTICLE 4

COVENANTS

4.1 Access to Information.

(a) Except as specifically provided in Article 5 (in which event the provisions of Article 5 shall govern), from and after the Contribution Effective Time until the sixth anniversary of the Contribution Effective Time (or such longer period as may be required by applicable Law or any Contributed Contract), upon the prior written request of a Party for specific and identified agreements, documents, books, records, or files (whether written or electronic), including accounting and financial records (collectively, "***Records***"), that relate to the Contributed Assets or Contributed Liabilities (in the case of a request by NewCo) or the Retained Assets or Retained Liabilities (in the case of a request by the Company), in each case as such Records existed as of prior to the Contribution Effective Time or that the requesting Party reasonably determines are necessary or advisable in order to prepare its financial statements or any reports or filings to be made with any Governmental Entity, the other Party shall arrange, as soon as reasonably practicable following receipt of such request, to provide appropriate copies of such Records (or, if the requesting Party has a reasonable purpose for the originals, the originals) in its possession or control, but only to the extent such Records are not already in the possession or control of the requesting Party, subject to customary confidentiality conditions and at the requesting Party's sole cost and expense.

(b) In addition to the foregoing, and subject to applicable Law, for the period described in Section 4.1(a), each Party shall afford the other Party and its representatives reasonable access, during normal business hours and upon reasonable advance written notice, to its employees and properties to the extent relating to the Contributed Assets or Contributed Liabilities in the possession or control of the Company (in the case of the Company) or the Retained Assets or Retained Liabilities in the possession or control of NewCo (in the case of NewCo), in each case to the extent relating to the ownership or operation of such Assets or Liabilities prior to the Contribution Effective Time, and shall furnish promptly all information relating thereto as may be reasonably requested for a proper business purpose; provided that the foregoing in clause (a) or (b) of this Section 4.1 shall not require either Party to (i) permit any inspection, or disclose any information, that in its reasonable judgment would be detrimental to its business or operations, result in the disclosure of any trade secrets or know-how of third parties, or violate any of its confidentiality obligations, (ii) disclose any information that is subject to attorney-client privilege, work product protection, or other applicable privilege, or (iii) if the Parties (or their respective Affiliates) are adverse parties in litigation or another Action, disclose or permit access to information that is reasonably pertinent to such litigation or Action.

(c) At all times from and after the Contribution Effective Time, each Party shall use commercially reasonable efforts to make available to the other Party, upon reasonable written request, its and its Subsidiaries' former and then-current representatives as witnesses, and any Records within its control or that it otherwise has the ability to make available without undue burden, to the extent such persons or Records may reasonably be required in connection with the prosecution or defense of any Action in which the requesting Party is involved (other than a proceeding between the Parties, which shall be governed by applicable discovery rules). The requesting Party shall bear all reasonable out-of-pocket costs and expenses incurred by the other Party in connection therewith. The Parties shall cooperate and consult with each other to the extent reasonably necessary with respect to any such proceedings and, where appropriate, shall enter into a mutually acceptable joint defense or common interest agreement to preserve any applicable privilege or work product protection.

(d) The access to information and Records provided under this Section 4.1, and the furnishing of witnesses and cooperation contemplated hereby, shall not be deemed a waiver of any privilege, including any privilege addressed in Section 4.10 (*Privileged Matters*), that has been or may be asserted under this Agreement or otherwise.

4.2 Retention of Records. Without limiting Section 4.1, for a period of six years following the Contribution Effective Time, each Party shall retain all documents and records in its possession or under its control relating to the Contributed Assets, Contributed Liabilities, Retained Assets, or Retained Liabilities; provided that, prior to destroying or disposing of any such documents or records that are at least three years old, the Party proposing to destroy such documents or records shall provide no less than 45 days' prior written notice to the other Party, and if the other Party timely requests delivery of any such documents or records, the notifying Party shall arrange for delivery thereof at the requesting Party's expense.

4.3 Confidentiality.

(a) Each Party has acquired Confidential Information of the other Party and its Affiliates, the use or disclosure of which could cause substantial loss and damage. Accordingly, from and after the Contribution Effective Time until the earlier of (i) seven years after the Contribution Effective Time or (ii) the date such information no longer qualifies as Confidential Information, each Party shall not, directly or indirectly, use, disclose, or authorize other Persons to use or disclose any Confidential Information of the other Party, and shall hold such Confidential Information in confidence using a standard of care no less protective than that used to protect its own confidential information of similar importance, and in any event no less than a reasonable standard of care, except (A) with the prior written consent of the other Party, (B) if the information becomes generally available to the public through no fault of the using or disclosing Party (including to the extent included or filed in connection with the Information Statement or the Registration Statement), (C) if the Confidential Information was independently developed by the disclosing Party without reference to the other Party's Confidential Information, (D) as required by applicable Law or order of a Governmental Entity, provided that, to the extent permitted by Law, the disclosing Party provides prior written notice to the other Party and cooperates with the other Party's efforts to seek a protective order, (E) to its own auditors, attorneys, financial advisors, bankers, and other advisors who have a need to know such information and are informed of, and bound by, confidentiality obligations no less protective than those set forth herein, or (F) to actual or potential investors, financing sources, strategic partners, licensees, or acquirors in connection with a potential financing, investment, or strategic transaction, provided that such recipient is bound by a customary confidentiality agreement or obligation with respect thereto. Notwithstanding the foregoing, the disclosure and use of any privileged information shall be governed solely by Section 4.10 (*Privileged Matters*), and to the extent any other Contract or policy to which a Party is bound provides for confidentiality protections that are more protective, or for a longer duration, than those set forth in this Section 4.3, such other Contract or policy shall control with respect thereto. Each Party shall, and shall cause its Subsidiaries to, comply with all applicable Laws relating to the privacy, security, and protection of any personal information or protected health information disclosed by a Party pursuant to this Agreement.

(b) "***Confidential Information***" means (i) with respect to Confidential Information of NewCo, any information included in the Contributed Assets and Contributed

Liabilities, (ii) with respect to Confidential Information of the Company, any information included in the Retained Assets and Retained Liabilities, and (iii) with respect to each Party, the contents of this Agreement and the Ancillary Agreements (subject to each Party's right to disclose the same to actual and potential investors, strategic partners, licensees, advisors, and acquirors subject to commercially reasonable confidentiality obligations), and (iv) any other non-public information of a Party that the other Party would reasonably believe to be of value to the owning Party.

4.4 Publicity. After the Distribution Effective Time, no Party will issue or cause the publication of any press release or other public announcement with respect to this Agreement or the transactions contemplated hereby without the prior written consent of the other Party (not to be unreasonably withheld, conditioned, or delayed); provided that nothing herein will prohibit a Party from (i) issuing any public announcement to the extent required by applicable Law, in which case the disclosing Party shall, if practicable, use its reasonable best efforts to provide the other Party reasonable advance notice and opportunity to comment or (ii) making any public announcement or statement that is consistent in all material respects with public statements or disclosures previously made in compliance with this Agreement or otherwise as approved by, or made with the consent of, the other Party.

4.5 Compliance. From and after the Contribution Effective Time:

(a) NewCo shall comply in all material respects with all Laws applicable to it that have been enacted, issued, or imposed by a Governmental Entity as a condition to, or otherwise in connection with, the Separation or the Distribution; and

(b) NewCo shall not knowingly breach any Contributed Contract in any material respect and shall use its reasonable best efforts to enforce the material rights available to it under each Contributed Contract.

4.6 Tax Cooperation. The Parties shall cooperate as reasonably necessary in connection with Tax matters relating to the Separation and the Distribution.

4.7 Employee Matters.

(a) NewCo Personnel. The identity, roles, and terms of appointment or engagement of certain personnel of NewCo, including the agreements to be entered into and the allocation of compensation, benefits and other obligations in respect thereof, are set forth in Schedule 4.7(a) (such individuals, the "***Key NewCo Personnel***"). NewCo shall offer each Key NewCo Personnel an employment agreement or consulting agreement, each to be effective as of the Distribution Effective Time, pursuant to the terms and conditions set forth on Schedule 4.7(a). Effective as of the Distribution Effective Time, the Company Group shall, as applicable, terminate any existing employment or other contractor relationship with such Key NewCo Personnel, and NewCo shall have no Liability for any severance or other Liabilities due and owing to such Key NewCo Personnel by the Company Group as a result of such termination. The Parties may from time to time identify and agree upon additional Company Group personnel who may be offered an employment or consulting relationship with NewCo (the "***Additional NewCo Personnel***"). Effective as of the Distribution Effective Time, or such other date as agreed upon by the Parties, the Company Group shall, as applicable, terminate any existing employment or other contractor

relationship with such Additional NewCo Personnel (the Additional NewCo Personnel and the Key NewCo Personnel, collectively, the "***NewCo Personnel***").

(b) NewCo Personnel Compensation and Benefits. NewCo acknowledges and agrees that, except as otherwise expressly provided in this Agreement or any Ancillary Agreement, NewCo shall have full responsibility with respect to any Liabilities and the payment or performance of any obligations arising out of or relating to any employment, consulting, non-competition, retention, change in control, indemnification or other compensatory arrangement entered into between any member of the NewCo Group and any NewCo Personnel, in each case from and after the Distribution Effective Time. The Parties agree that the hiring of any Key NewCo Personnel into the NewCo Group as contemplated hereby shall not trigger any obligation to pay severance, separation pay, salary continuation or other similar benefits to any such individual. For the avoidance of doubt, any Liabilities arising under any such arrangement that relate to any period prior to the Distribution Effective Time shall be allocated between the Parties in accordance with Schedule 4.7(a).

(c) Company Consulting Agreements. The Parties intend that, effective as of the Distribution Effective Time, the Company and each of the NewCo Personnel set forth on Schedule 4.7(c) and as may otherwise be agreed to by the Parties will enter into a consulting agreement (a "***Company Consulting Agreement***") pursuant to which such NewCo Personnel will provide services directly to the Company as an independent contractor on a part-time basis (each such individual, a "***Company Consultant***"). NewCo shall permit each Company Consultant to provide such services and shall not impose on, or enforce against, each Company Consultant any exclusivity, non-competition or similar restriction that would prevent him or her from doing so; provided, that the services provided under the Company Consulting Agreement shall not unreasonably interfere with the performance of his or her duties to NewCo and shall be subject to confidentiality obligations no less protective of each Party than those set forth in Section 4.3.

(d) Treatment of Company Equity Awards; NewCo Equity Awards.

(i) No NewCo equity awards shall be issued as an adjustment or replacement for any Company equity awards outstanding as of the Distribution Effective Time. All outstanding Company equity awards shall instead be adjusted solely at the Company level in accordance with the terms of the applicable Company Equity Plan, pursuant to an equitable adjustment methodology to be determined by the Company's Compensation Committee in accordance therewith and consistent with the following (the "***Company Adjustment***"), in each case, regardless of whether the holder of such Company equity award continues to provide service to the Company, becomes NewCo Personnel, or both:

(1) The Company Adjustment will consist solely of an adjustment to the per-share exercise price of each outstanding option to purchase Company Common Stock to reflect the diminution in value of the Company Common Stock resulting from the Separation and the Distribution, with the number of shares of Company Common Stock subject to each such option remaining unchanged.

(2) No adjustment shall be made under this Section 4.7(d)(i) to the number of shares subject to any outstanding restricted stock unit award (whether time- or performance-vesting).

(3) The Company Adjustment shall be effected in a manner intended to comply with Sections 409A and, if applicable, 422 and 424(a) of the Code.

(ii) Following the Contribution Effective Time, any outstanding Company equity awards (as adjusted pursuant to the Company Adjustment) held by a person who continues to provide service to the Company (whether as an employee, non-employee consultant, or director) shall continue to vest based on such individual's continued Company service, in accordance with the terms of the applicable Company equity incentive plan and award agreement, including with respect to the individuals and on the terms set forth on Schedule 4.7(d)(ii); provided, that any Company equity award that was intended to be an "incentive stock option" for purposes of Section 422 of the Code shall automatically become a nonstatutory stock option in accordance with its terms, to the extent then outstanding, three (3) months following the termination of such individual's status as an employee of the Company.

(iii) Following the Contribution Effective Time, any person providing service to NewCo (as an employee, non-employee consultant, or director) shall be eligible to receive new equity awards granted directly by NewCo under the Adrenyx Biosciences, Inc. Omnibus Incentive Plan (or any successor equity plan of NewCo), which shall be sized based on such person's role at NewCo and shall be independent of, and separate from and in addition to, any Company equity awards held by such person.

(e) Employee Benefit Plans. The Parties acknowledge that eligibility to participate in the employee benefit plans of the Company Group is limited to employees of the Company Group and, accordingly, that, except as set forth in Section 4.7(c), from and after the Distribution Effective Time no employee, officer, director or other service provider of the NewCo Group, including the NewCo Personnel, shall be eligible to participate in, or accrue any benefit under, any employee benefit plan of the Company Group. The Parties agree that NewCo is not adopting or continuing any employment agreement or employee benefit plan of the Company Group, or assuming any liability under any such employment agreement or employee benefit plan. By way of expansion and not in limitation of the foregoing, NewCo shall have no responsibility to pay or carry-over any unused or accrued vacation, nor any accrued but unpaid or unfunded amounts due to or for the benefit of any NewCo Personnel pursuant to any employee benefit plans of the Company Group. NewCo shall establish its own employee benefit plans and payroll arrangements providing coverage for NewCo's employees from and after the Distribution Effective Time.

(f) Cooperation; No Third Party Rights. The Parties shall cooperate in good faith with respect to any notice, consent or filing required under any Contract or applicable Law in connection with the arrangements described in this Section 4.7. Nothing in this Section 4.7 shall (i) create any right in any employee, consultant or other service provider, or any beneficiary or dependent thereof, as a third party beneficiary of this Agreement, (ii) be construed as an amendment to any employee benefit plan or equity incentive plan of either Party, (iii) limit the right of either Party to amend or terminate any of its employee benefit plans in accordance with their terms, (iv) create any obligation on the part of any member of the Company Group or any

member of the NewCo Group to continue the employment of any employee or permit the return from a leave of absence for any period following the date of this Agreement or the Distribution Effective Time (except as required by applicable Law), or (v) change the at-will employment status of any employee.

(g) Personnel Records; Data Privacy. At all times following the Distribution Effective Time, the Parties shall, or shall cause any member of their respective Groups to, cooperate in good faith as necessary to facilitate the resolution of employee benefit claims and the administration of any employee-related matters arising under this Section 4.7 or any Ancillary Agreement, including with respect to the provision of employee-level information reasonably necessary for the other Party to manage, administer, finance, and file required reports with respect to such administration. The Parties shall provide each other such personnel records and information as necessary or appropriate to carry out their obligations under applicable Law, this Agreement, or the Transition Services Agreement, as soon as administratively practicable after the Distribution Effective Time or upon reasonable request by the other Party. All information and records regarding employment and personnel matters of the employees identified on Schedule 4.7(a) shall be accessed, retained, held, used, copied, and transmitted after the Distribution Effective Time by the Parties in accordance with all applicable Laws and policies relating to the collection, storage, retention, use, transmittal, disclosure, and destruction of such records, including any applicable data privacy or data protection Laws.

4.8 Non-Solicit; No Hire. Commencing on and for a period of twelve (12) months following the Distribution Effective Time, neither Group will: (a) without the prior written consent of the other Party, directly or indirectly, on their own behalf or in the service or on behalf of others, solicit, aid, induce or knowingly encourage any employee of the other Party to terminate or breach an employment, contractual or other relationship with the other Group, or (b) hire or otherwise employ any employee of the other Group; provided, however, that nothing in this Section 4.8 shall be deemed to prohibit (i) any general solicitation for employment through advertisements and search firms not specifically directed at employees of such other Group, provided that the soliciting Person has not directed, advised or knowingly encouraged such firm to approach any such employee, (ii) the solicitation or hiring of an individual whose employment was terminated by such other Party (or any of its Subsidiaries), (iii) the solicitation or hiring of an individual formerly employed by the other Group at any time after six months following such individual's termination of his or her employment with such other Party, or (iv) the hiring by any Party of any individual (x) not solicited by such Party in breach of this Section 4.8 and (y) with the prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed), it being understood that the Party whose consent is requested may take into account, among other things, its own hiring needs and competitive considerations. Notwithstanding the foregoing, neither the employment of the NewCo Personnel by NewCo as contemplated by Section 4.7(a) nor the engagement of any NewCo Personnel by the Company under a Company Consulting Agreement as contemplated by Section 4.7(c) shall constitute a breach of this Section 4.8.

4.9 Insurance Matters.

(a) NewCo acknowledges and agrees that, from and after the Distribution Effective Time, except as expressly provided in this Agreement or any Ancillary Agreement, neither NewCo nor any member of the NewCo Group shall have any rights to or under any

insurance policies of the Company or the Company Group, other than any insurance policies acquired prior to the Distribution Effective Time, including any renewal or tail period thereof, (i) directly by and in the name of NewCo or a member of the NewCo Group or (ii) to the extent permitted under the terms of the applicable insurance policy or program, transferred to NewCo or a member of the NewCo Group. For the avoidance of doubt, except to the extent a policy is so transferred pursuant to the foregoing, NewCo, and not any member of the Company Group, shall be responsible for establishing any and all insurance programs covering the NewCo Group for its activities after the Contribution Effective Time as may be required to comply with the NewCo Group's contractual obligations and such other insurance policies required by Law or as necessary or appropriate to operate the SPR202 Business, including with respect to general liability, product liability, workers' compensation, directors' and officers' liability, and fiduciary liability.

(b) The Company acknowledges and agrees that, from and after the Distribution Effective Time, no member of the Company Group shall have any rights to or under any insurance policies of NewCo or the NewCo Group.

(c) The Parties acknowledge that, as of the Distribution Date, the Company's director and officer liability insurance policies will continue to provide insurance coverage for directors and officers of NewCo who served as directors or officers of the Company Group prior to the Distribution Effective Time, but such coverage shall only extend to acts occurring prior to the Distribution Effective Time that would have been covered by the Company's director and officer liability insurance policy if such individual remained a director or officer of the Company. Such coverage shall also extend to employees with respect to securities law claims only. The Company agrees not to terminate or amend this coverage in a manner materially adverse to these individuals.

(d) No member of the Company Group shall have any obligation to secure extended reporting for any claims under any of the Company Group's claims-made or occurrence-reported liability policies for any acts or omissions by any member of the NewCo Group occurring prior to the Distribution Effective Time.

(e) This Agreement shall not be considered as an attempted assignment of any policy of insurance or as a contract of insurance, and shall not be construed to waive any right or remedy of any member of the Company Group in respect of any of the Company's insurance policies and programs or any other contract or policy of insurance. Except as set forth in Section 4.9(c), the Company Group may, at any time after the date of this Agreement, without liability or obligation to any member of the NewCo Group, amend, commute, terminate, buy-out, extinguish liability under, or otherwise modify any of its insurance policies (and any permitted claims of the NewCo Group under this Section 4.9 shall be subject to any such amendments, commutations, terminations, buy-outs, extinguishments, and modifications).

(f) Nothing in this Section 4.9 shall be construed to limit or otherwise alter in any way the indemnity obligations of the Parties under this Agreement or any Ancillary Agreement, including (i) with respect to the NewCo Group, any Contributed Liabilities, and (ii) with respect to the Company Group, any Retained Liabilities. The Parties acknowledge that the Company has used its commercially reasonable efforts to structure its director and officer insurance policies consistent with such indemnity obligations.

4.10 Privileged Matters.

(a) The Parties recognize that legal and other professional services that have been and will be provided prior to the Contribution Effective Time have been rendered for the collective benefit of both the Company and NewCo, and that each of the Company and NewCo that was in privity with the applicable professional service provider should be deemed to be the client with respect to such services for purposes of asserting all privileges which may be asserted under applicable Law in connection therewith. For purposes of this Section 4.10, privileges shall include the attorney-client privilege, the work product doctrine, and any other legal principles and doctrines that protect information and documents from disclosure to third parties.

(b) The Company shall be entitled, in perpetuity, to control the assertion or waiver of all privileges in connection with any privileged information that relates solely to the Retained Assets or Retained Liabilities and not to the Contributed Assets or Contributed Liabilities, notwithstanding that such privileged information might have been known to, in the possession of, or under the control of NewCo. NewCo shall be entitled, in perpetuity, to control the assertion or waiver of all privileges in connection with any privileged information that relates solely to the Contributed Assets or Contributed Liabilities and not to the Retained Assets or Retained Liabilities, notwithstanding that such privileged information might have been known to, in the possession of, or under the control of the Company.

(c) Subject to the restrictions set forth in this Section 4.10, the Parties agree that they shall have a joint privilege, each with the right to assert or waive such joint privilege, with respect to all privileges not allocated pursuant to Section 4.10(b) and all privileges relating to any Actions or other matters that involve the interests of both Parties and in respect of which both Parties have Liabilities under this Agreement, and that no such joint privilege may be waived by either Party without the consent of the other Party.

(d) If any dispute arises between the Parties regarding whether a privilege should be waived or privileged information should be disclosed to protect or advance the interests of either Party, each Party agrees that it shall (i) negotiate with the other Party in good faith, (ii) endeavor to minimize any prejudice to the rights of the other Party, and (iii) not unreasonably withhold, condition, or delay consent to any request for waiver or disclosure by the other Party.

4.11 Force Majeure. Neither Party (nor any Person acting on its behalf) shall have any liability or responsibility for any failure to fulfill any obligation (other than a payment obligation) under this Agreement so long as, and to the extent that, such failure results from a Force Majeure. A Party claiming the benefit of this Section 4.11 shall, as soon as reasonably practicable after the occurrence of a Force Majeure, (a) notify the other Party of the nature and expected duration of such Force Majeure and (b) use commercially reasonable efforts to remove the causes of such Force Majeure and resume performance of its obligations under this Agreement as soon as reasonably practicable. For purposes of this Section 4.11, "***Force Majeure***" means, with respect to a Party, an event beyond the reasonable control of such Party (or any Person acting on its behalf) that could not reasonably have been foreseen or, if foreseeable, was unavoidable, including acts of God, natural disasters, fires, floods, riots, civil unrest, acts of war or terrorism, and epidemics or pandemics; provided that the receipt by a Party of an unsolicited acquisition proposal or similar offer, and such Party's response thereto, shall not constitute a Force Majeure.

4.12 Board Observers . Following the Contribution Effective Time until the end of the Observer Period, the Company shall have the right to nominate an individual to serve as a non-voting observer (the "***Observer***") to the board of directors of NewCo (the "***NewCo Board***"), who shall be entitled to attend and participate in all meetings of the NewCo Board and any and all committees thereof during such period. Pursuant to the foregoing, the Company hereby designates the individual set forth in Schedule 4.12 as the initial Observer. In no event shall NewCo or the NewCo Board have any right to remove the individual appointed to serve as an Observer pursuant to this Section 4.12 without the Company's prior written consent. During the Observer Period, the Observer shall be provided with all notices of meetings, minutes and other materials (financial or otherwise) provided to members of the NewCo Board or any and all committees thereof simultaneously with, and in the same manner as, the provision of such materials to the members of the NewCo Board or such committees, as the case may be. The Observer shall agree to hold in confidence all information provided to the Observer and, notwithstanding anything contained in this Section 4.12, NewCo reserves the right, only to the extent necessary, to withhold any information from, or exclude the Observer from any meeting or portion thereof if (y) NewCo reasonably determines, upon advice of counsel, that access to such information or attendance at such meeting would reasonably be expected to adversely affect the attorney-client privilege between NewCo and its counsel, or (z) the portion as to which the Observer is excluded relates solely to subject matter in which the Company or the Observer has a conflict of interest; provided that NewCo shall use commercially reasonable efforts to provide the Observer with non-privileged information regarding the applicable matter to the extent practicable.

4.13 Board Designee. NewCo shall take all actions necessary to cause the individual set forth on Schedule 4.12 (or any replacement thereof reasonably identified by the Company prior to the finalization of NewCo's slate of directors for such annual meeting) to be nominated for election at the first annual meeting of NewCo's stockholders to be held following the Distribution Effective Time (and shall use its reasonable best efforts to cause the election of such individual to the NewCo Board at such meeting (including by supporting such individual's candidacy in a manner no less rigorous than the other nominees to the NewCo Board)).

ARTICLE 5

INDEMNIFICATION

5.1 Release of Pre-Distribution Claims.

(a) Except (x) as provided in Section 5.1(b), (y) as may be otherwise expressly provided in this Agreement or in any Ancillary Agreement, and (z) for any matter for which either Party is entitled to indemnification pursuant to this Article 5 or under any Ancillary Agreement:

(i) the Company, for itself and each member of the Company Group and, to the extent permitted by Law, all Persons who at any time prior to the Contribution Effective Time were directors, officers, agents or employees of any member of the Company Group (in their respective capacities as such), in each case together with their respective heirs, executors, administrators, successors and assigns, does hereby remise, release and forever discharge NewCo and the other members of the NewCo Group and all Persons who at any time prior to the Contribution Effective Time were stockholders, directors, officers, agents or employees of any

member of the NewCo Group (in their respective capacities as such), in each case, together with their respective heirs, executors, administrators, successors and assigns (collectively, the "***NewCo Released Parties***"), from any and all (A) Retained Liabilities and (B) Liabilities existing or arising (i) in connection with the implementation of the Separation (including the Distribution), or (ii) from actions, inactions, events, omissions, conditions, facts, or circumstances occurring or existing prior to the Contribution Effective Time (whether or not such Liabilities cease being contingent, mature, become known, are asserted or foreseen, or accrue, in each case before, at, or after the Contribution Effective Time), in each case to the extent relating to, arising out of, or resulting from the Retained Assets or the Retained Liabilities, whether at Law or in equity (including any right of contribution), whether arising under any Contract, by operation of Law or otherwise, in each case, existing or arising from any acts or events occurring or failing to occur or alleged to have occurred or to have failed to occur or any conditions existing or alleged to have existed on or before the Contribution Effective Time, including in connection with the Separation and any of the other transactions contemplated hereunder and under the Ancillary Agreements (such Liabilities, the "***Company Released Liabilities***"), and the Company shall not, and shall cause the other members of the Company Group not to, bring any Action against any member of the NewCo Group in respect of any Company Released Liabilities. Notwithstanding the foregoing, nothing in this Agreement shall be deemed to limit the Company, any member of the Company Group, or their respective Affiliates from commencing any Action against any NewCo officer, director, agent, or employee, or their respective heirs, executors, administrators, successors, and assigns, with regard to matters arising from, or relating to, criminal acts by any such officer, director, agent, or employee.

(ii) NewCo, for itself and each member of the NewCo Group and, to the extent permitted by Law, all Persons who at any time prior to the Contribution Effective Time were directors, officers, agents, or employees of any member of the NewCo Group (in their respective capacities as such), in each case together with their respective heirs, executors, administrators, successors, and assigns, does hereby remise, release, and forever discharge the Company and the other members of the Company Group and all Persons who at any time prior to the Contribution Effective Time were stockholders, directors, officers, agents, or employees of any member of the Company Group (in their respective capacities as such), in each case together with their respective heirs, executors, administrators, successors, and assigns (collectively, the "***Company Released Parties***"), from any and all (A) Contributed Liabilities and (B) Liabilities existing or arising (i) in connection with the implementation of the Separation (including the Distribution), or (ii) from actions, inactions, events, omissions, conditions, facts, or circumstances occurring or existing prior to the Contribution Effective Time (whether or not such Liabilities cease being contingent, mature, become known, are asserted or foreseen, or accrue, in each case before, at, or after the Contribution Effective Time), in each case to the extent relating to, arising out of, or resulting from the Contributed Assets or the Contributed Liabilities, whether at Law or in equity (including any right of contribution), whether arising under any Contract, by operation of Law or otherwise, in each case, existing or arising from any acts or events occurring or failing to occur or alleged to have occurred or to have failed to occur or any conditions existing or alleged to have existed on or before the Contribution Effective Time, including in connection with the Separation and any of the other transactions contemplated hereunder and under the Ancillary Agreements (such Liabilities, the "***NewCo Released Liabilities***"), and NewCo shall not, and shall cause the other members of the NewCo Group not to, bring any Action against any member of the Company Group in respect of any NewCo Released Liabilities; provided, however, that for

purposes of this Section 5.1(a)(ii), NewCo shall also release and discharge any officers or other employees of any member of the Company Group, to the extent any such officers or employees served as directors or officers of any member of the NewCo Group prior to the Distribution, from any and all Liabilities or responsibilities for any and all past actions or failures to take action, in each case in their respective capacities as directors or officers, as applicable, of any such member of the NewCo Group, prior to the Distribution Effective Time. Notwithstanding the foregoing, nothing in this Agreement shall be deemed to limit NewCo, any member of the NewCo Group, or their respective Affiliates from commencing any Action against any Company officer, director, agent, or employee, or their respective heirs, executors, administrators, successors, and assigns, with regard to matters arising from, or relating to criminal acts by any such officer, director, agent, or employee.

(b) Nothing contained in this Agreement, including Section 5.1(a), shall impair or otherwise affect any right of any Party and, as applicable, a member of such Party's Group, as well as their respective heirs, executors, administrators, successors, and assigns, to enforce this Agreement, any Ancillary Agreement, or any agreements, arrangements, commitments, or understandings contemplated in this Agreement or in any Ancillary Agreement to continue in effect after the Distribution Effective Time. In addition, nothing contained in Section 5.1(a) shall (i) release any Person from any Liability assumed, transferred, or expressly assigned to a Party or a member of such Party's Group pursuant to or as contemplated by, or any other Liability of any member of such Group under, this Agreement or any Ancillary Agreement, including (A) with respect to the Company, any Retained Liability, (B) with respect to NewCo, any Contributed Liability, and (C) any Liability that the Parties may have with respect to indemnification or contribution pursuant to this Agreement or any Ancillary Agreement or otherwise for Actions brought against the Parties by Third Parties, which Liability shall be governed by the provisions of this Article 5 and, if applicable, the appropriate provisions of the Ancillary Agreements; (ii) release any Person from any Liability provided for in or resulting from any other Contract or understanding that is entered into after the Distribution Effective Time between any Party (and/or a member of such Party's Group), on the one hand, and the other Party (and/or a member of such Party's Group), on the other hand; or (iii) release any Person other than the Persons released in Section 5.1(a). In addition, nothing contained in Section 5.1(a) shall release the Company from indemnification or contribution with respect to any director, officer, or employee of NewCo who was a director, officer, or employee of the Company or any of its Affiliates prior to the Distribution Effective Time, as applicable, with respect to which he or she was entitled to such indemnification or contribution pursuant to an obligation existing immediately prior to the Distribution Effective Time; it being understood that if the underlying obligation giving rise to such Action is established by a court of competent jurisdiction to be a Contributed Liability, NewCo shall indemnify the Company for such Liability (including the Company's costs to indemnify the director, officer, or employee) in accordance with the provisions set forth in this Article 5.

(c) Each Party shall not, and shall not permit any member of its Group to, make any claim for offset, or commence any Action, including any claim of contribution or any indemnification, against any other Party or any member of any other Party's Group, or any other Person released pursuant to Section 5.1(a), with respect to any Liabilities released pursuant to Section 5.1(a). If any Person associated with a Party (including any director, officer, or employee of a Party) initiates any Action with respect to claims released by this Section 5.1, the Party with which such Person is associated shall be responsible for the reasonable fees and expenses of

counsel of the other Party and/or the members of such Party's Group, as applicable, and such other Party shall be indemnified for all Liabilities incurred in connection with such Action in accordance with the provisions set forth in this Article 5.

5.2 Indemnification by NewCo. From and after the Contribution Effective Time, NewCo shall indemnify and hold harmless the Company and its Affiliates and their current, future and former respective directors, officers, employees, agents and other representatives and the successors and permitted assigns of the foregoing (collectively, the "***Company Indemnitees***") from and against any and all Losses incurred or asserted by any such Person in connection with any claim or demand of a third party ("***Third Party Claim***") to the extent relating to, arising out of, by reason of or otherwise in connection with: (i) the Contributed Assets or Contributed Liabilities, whether arising prior to, on or after the Distribution Effective Time, including the failure of any member of the NewCo Group or any other Person to pay, perform or otherwise discharge any Contributed Liability in accordance with its respective terms; (ii) any action taken by NewCo or any member of the NewCo Group outside the ordinary course of business after the Contribution Effective Time (including any tax election, tax position, or restructuring step) that would reasonably be expected to increase the Company's Tax liability with respect to the Contribution, the Distribution or any pre-Distribution period, but only to the extent of any such increase directly resulting from such action; (iii) NewCo's material breach of any of its representations, warranties, covenants, or other obligations under this Agreement or any Ancillary Agreement (unless such Ancillary Agreement expressly provides for separate indemnification therein, in which case any such indemnification claims shall be made thereunder); or (iv) any untrue statement or alleged untrue statement of a material fact, or any omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, contained in the Registration Statement, except to the extent specifically enumerated in clause (iii) of Section 5.3.

5.3 Indemnification by the Company. From and after the Contribution Effective Time, the Company shall indemnify and hold harmless NewCo and its Affiliates and their current, future and former respective directors, officers, employees, agents and other representatives and the successors and permitted assigns of the foregoing (collectively, the "***NewCo Indemnitees***") from and against any and all Losses incurred or asserted by any such Person in connection with any Third Party Claim to the extent relating to, arising out of, by reason of or otherwise in connection with: (i) the Retained Assets or Retained Liabilities, whether arising prior to, on or after the Distribution Effective Time, including the failure of any member of the Company Group or any other Person to pay, perform or otherwise discharge any Retained Liability in accordance with its respective terms; (ii) the Company's material breach of any of its representations, warranties, covenants, or other obligations under this Agreement or any Ancillary Agreement (unless such Ancillary Agreement expressly provides for separate indemnification therein, in which case any such indemnification claims shall be made thereunder); or (iii) any untrue statement or alleged untrue statement of a material fact, or any omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, contained in the Registration Statement, solely to the extent such untrue statement or omission is based upon information relating to the Company or the Retained Assets that was supplied by the Company in writing expressly for inclusion therein.

5.4 Indemnification Procedures. Upon receipt of notice of a Third Party Claim, the indemnified Party shall promptly notify the indemnifying Party in writing, specifying the basis for such claim and a good-faith estimate of the potential Losses. The indemnifying Party shall have the right to assume the defense of such Third Party Claim with counsel reasonably acceptable to the indemnified Party, and the indemnified Party may participate in such defense at its own expense; provided that the indemnifying Party shall not be entitled to assume or continue the defense if (i) the Third Party Claim relates to any criminal Action, (ii) such claim seeks injunctive relief against the indemnified Party, or (iii) the indemnifying Party has failed to reasonably and in good faith prosecute or defend such claim. The indemnifying Party shall not settle any Third Party Claim without the prior written consent of the indemnified Party (not to be unreasonably withheld, conditioned, or delayed) unless such settlement includes an unconditional release of the indemnified Party from all liability in respect of such claim. The Parties agree to cooperate fully with each other in connection with the defense, negotiation, or settlement of any Third Party Claim. In connection with any fact, matter, event, or circumstance that may give rise to a claim against an indemnifying Party under this Agreement, the indemnified Party shall: (A) preserve all material evidence relevant to the claim; (B) allow the indemnifying Party's representatives to investigate the fact, matter, event, or circumstance alleged to give rise to such claim and whether and to what extent any amount is payable in respect of such claim; and (C) disclose (at its own expense) to the indemnifying Party and its representatives all material of which it is aware which relates to the claim and provide all such information and assistance, including access to premises and personnel, and the right to examine and copy or photograph any assets, accounts, documents, and records, as the indemnifying Party or its representatives may reasonably request, subject to the indemnifying Party or its representatives agreeing in such form as the indemnified Party may reasonably require to keep all such information confidential and to use it only for the purpose of investigating and defending the claim in question.

5.5 Mitigation. Each indemnified Party shall use commercially reasonable efforts to pursue all legal rights and remedies available to mitigate and minimize any Losses in respect of which such indemnified Party is entitled to recover from an indemnifying Party pursuant to this Article 5 promptly upon becoming aware of any event or circumstance that could reasonably be expected to constitute or give rise to such Losses.

5.6 No Duplicative Recovery; Insurance Proceeds. No Party may obtain duplicative indemnification or other recovery for Losses under one or more provisions of this Agreement, any Ancillary Agreement, or any other Contract, agreement, arrangement, or understanding. Any Losses subject to indemnification pursuant to this Article 5 shall be net of any insurance proceeds actually received by the indemnified Party (or its Affiliates) in respect of the related Losses. If an indemnified Party receives a payment from an indemnifying Party in respect of any Losses pursuant to this Article 5 and subsequently receives insurance proceeds in respect of such Losses, the indemnified Party shall promptly pay to the indemnifying Party an amount equal to such insurance proceeds, but not exceeding the amount of the indemnification payment previously paid by the indemnifying Party in respect of such Losses. An insurer that would otherwise be obligated to pay any claim shall not be relieved of the responsibility with respect thereto, nor shall it acquire any subrogation rights with respect thereto, solely by virtue of the indemnification provisions of this Article 5. The indemnified Party shall use commercially reasonable efforts to seek to collect or recover any insurance proceeds to which it is entitled in connection with any Losses for which it seeks indemnification pursuant to this Article 5, provided that the indemnified Party's inability

or failure to collect or recover any such insurance proceeds shall not limit the indemnifying Party's obligations hereunder.

5.7 Limitation of Liability. Notwithstanding anything to the contrary in this Agreement, neither the Company nor NewCo (nor any of their respective Affiliates) shall be liable to the other under this Article 5 or otherwise in connection with this Agreement for any punitive damages or other damages that are not reasonably foreseeable, other than any such damages included in a Loss actually paid to a third party in connection with a Third Party Claim.

5.8 Exclusive Remedy. Except in the case of fraud or to the extent arising under any Ancillary Agreement, the rights and remedies under this Article 5 are exclusive and in lieu of any and all other rights and remedies that any Party may have against any other Party for any failure to perform any covenant or agreement set forth in this Agreement, and each Party expressly waives any and all other rights, remedies, and causes of action it or its Affiliates may have against the other Party, or their respective Affiliates, now or in the future under any Law with respect to the transactions contemplated by this Agreement, such that the remedies expressly provided in this Agreement shall constitute the sole and exclusive basis for and means of recourse between the Parties with respect to such transactions. For the avoidance of doubt, this Section 5.8 shall not be deemed to limit, in any manner, any of the rights or remedies of the Lead Purchaser under the Note Financing Documents.

5.9 Survival of Indemnities. The rights and obligations of each of the Company and NewCo and their respective Company Indemnitees and NewCo Indemnitees under this Article 5 shall survive the sale or other transfer by any Party of any Assets or the assignment by it of any Liabilities.

ARTICLE 6

GENERAL PROVISIONS

6.1 Fees and Expenses.

(a) Except as otherwise agreed in writing by the Parties, all reasonable and documented out-of-pocket fees, costs and expenses incurred or arising on or prior to the Distribution Date primarily in connection with the preparation, execution, delivery, printing and implementation of this Agreement, the Transition Services Agreement, and the Registration Statement (including the Information Statement), and the Separation and the Distribution and the consummation of the transactions contemplated hereby and thereby (including, for the avoidance of doubt, any fees and expenses (x) of attorneys, accountants, consultants and other advisors or professionals or (y) paid in connection with any Required Consent), shall be charged to and paid by NewCo, and shall be deemed to be Contributed Liabilities, except as otherwise provided in Section 1.10.

(b) Except as otherwise set forth in this Agreement or the Transition Services Agreement, each Party shall bear its own costs and expenses incurred after the Distribution Date.

(c) Any amount or expense to be paid or reimbursed by any Party to any other Party shall be so paid or reimbursed promptly after the existence and amount of such obligation is determined and written demand therefor is made.

6.2 Amendment. Subject to applicable Law and as otherwise provided in this Agreement, at any time prior to the Distribution Effective Time, this Agreement may be amended, modified and supplemented, by written agreement of the Parties; *provided* that, no amendment, modification or supplement of this Agreement that would materially and adversely affect the Lead Purchaser's express rights under the Note Financing Documents prior to the Distribution Effective Time (including with respect to the Note Financing) shall be effective without the prior written consent of the Lead Purchaser (not to be unreasonably withheld, conditioned or delayed); *provided, further*, that in no event shall the Lead Purchaser's consent be required with respect to the matters subject to Section 2.4 of this Agreement. This Agreement may not otherwise be amended except by an instrument in writing signed on behalf of each of the Parties.

6.3 Waiver. Waiver of any term or condition of this Agreement by any Party shall only be effective if in writing and shall not be construed as a waiver of any subsequent breach or failure of the same term or condition.

6.4 Entire Agreement. This Agreement, together with the Ancillary Agreements and the exhibits and schedules hereto, constitutes the entire agreement of the Parties with respect to the subject matter hereof and supersedes all prior and contemporaneous agreements, negotiations, and communications of the Parties relating to such subject matter. The Parties acknowledge that this Agreement and the Ancillary Agreements represent the integrated agreement of the Parties relating to the Separation and the Distribution, and each has been entered into, or will be entered into, in contemplation of the other; none would have been entered into independently.

6.5 Successors. No Party shall consolidate with or merge with or into, or sell, convey, transfer, or lease all or substantially all of its capital stock or assets to, any Person, unless the resulting, surviving, or transferee Person expressly assumes by written instrument all obligations of such Party under this Agreement.

6.6 Notices. Any notice or other communication required or permitted under this Agreement shall be in writing and shall be deemed duly given if served by personal delivery, certified mail (return receipt requested), reputable overnight courier, or electronic mail with written confirmation, addressed as follows:

To the Company:

Spruce Biosciences, Inc.
611 Gateway Boulevard
Suite 740
South San Francisco, CA 94080
Attn: Legal
Email: [***]

With a copy to (which shall not constitute notice):

[***]

To NewCo:

Adrenyx Biosciences, Inc.
611 Gateway Boulevard
Suite 740
South San Francisco, CA 94080
Attn: Samir Gharib, President and CEO
Email: [***]

With a copy to (which shall not constitute notice):

[***]

6.7 Termination. This Agreement may be terminated and the Distribution may be amended, modified or abandoned at any time prior to the Distribution by any written instrument executed by the Company, without the approval of NewCo. In the event of such termination, no Party shall have any Liability of any kind to any other Party or any other Person. After the Distribution, this Agreement may not be terminated except by an agreement in writing signed by the Parties; provided, however, that Article 5 shall not be terminated or amended after the Distribution in respect of a Third Party beneficiary thereto without the consent of such Person.

6.8 Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware, without giving effect to any choice or conflict of law provision.

6.9 Dispute Resolution; Jurisdiction. Prior to commencing any Action arising out of or relating to this Agreement or the transactions contemplated hereby, the Party seeking relief (the "***Claimant***") shall deliver written notice to the other Party (the "***Respondent***") describing the dispute in reasonable detail. Senior executives of both Parties with authority to settle the dispute shall meet (in person or by videoconference) within 15 Business Days of such notice and attempt in good faith to negotiate a resolution; provided that if the dispute concerns whether an Asset or Liability constitutes a Contributed Asset, Contributed Liability, Retained Asset, or Retained Liability, or the interpretation of any Schedule identifying such Assets or Liabilities, the general counsel (or most senior legal officer) of each Party shall also participate in such meeting. If the Parties are unable to resolve the dispute within 30 calendar days following delivery of such notice (or such longer period as the Parties may agree in writing), either Party may pursue its available rights and remedies in accordance with this Agreement, including by submitting the dispute to the courts specified below. Each of the Parties (a) consents to the exclusive personal jurisdiction of the Court of Chancery of the State of Delaware, New Castle County, or, if that court does not have jurisdiction, a federal court sitting in Wilmington, Delaware; (b) agrees that all claims may be heard and determined in any such court; and (c) agrees not to bring any action arising out of or relating to this Agreement in any other court. Each Party waives any defense of inconvenient forum to the maintenance of any action so brought. Notwithstanding the foregoing, either Party may seek emergency or interim injunctive or other equitable relief from any court of competent jurisdiction without first complying with the negotiation procedure set forth in this Section 6.9.

6.10 WAIVER OF JURY TRIAL. EACH PARTY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

6.11 Specific Performance. The Parties agree that irreparable damage would occur if any provision of this Agreement were not performed in accordance with its specific terms, and that money damages or other legal remedies would not be an adequate remedy for any such failure to perform. Accordingly, the Parties acknowledge and agree that each Party shall be entitled to seek an injunction or injunctions, or other appropriate forms of specific performance or equitable relief, to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof, in each case in accordance with Section 6.9, this being in addition to any other remedy to which such Party is entitled at law or in equity. Each Party further agrees not to assert, and hereby waives, any defense that a remedy at law would be adequate in any action for specific performance or injunctive relief hereunder, and any requirement under any Law that a party post security as a prerequisite to obtaining equitable relief. Notwithstanding the foregoing, nothing in this Section 6.11 shall be construed to grant NewCo, any member of the NewCo Group, or any other Person the right to seek specific performance, injunctive relief, or any other equitable remedy to require the Company to consummate or effect the Distribution, it being acknowledged that the consummation of the Distribution is subject to the sole and absolute discretion of the Company pursuant to Section 2.4 and Section 2.5.

6.12 Assignment. This Agreement shall be binding upon and shall inure to the benefit of the Parties and their successors and permitted assigns. No Party may assign or delegate all or any portion of its rights, obligations, or liabilities under this Agreement without the prior written consent of the other Party. Any purported assignment without such consent shall be void. The foregoing in this Section 6.12 shall not restrict or prohibit any Party from consummating a change of control transaction in which such Party is the surviving entity in such transaction.

6.13 Severability. If any term or provision of this Agreement is held by a court of competent jurisdiction to be invalid, void, or unenforceable, the remainder of this Agreement shall remain in full force and effect. The Parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible.

6.14 No Third Party Beneficiaries. Nothing in this Agreement shall confer any rights, remedies, or claims upon any Person other than a Party or a permitted assignee of a Party, except that the Lead Purchaser is an express third-party beneficiary of Section 6.2, and shall be entitled to enforce its rights thereunder.

6.15 Headings. The headings contained in this Agreement are intended solely for convenience and shall not affect the rights of the Parties.

6.16 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original but all of which together will constitute one and the same instrument. Delivery of an executed counterpart by electronic means (including by PDF or DocuSign) shall be effective as delivery of a manually executed counterpart.

6.17 Prior Company Counsel. Each of the Parties acknowledges that Cooley LLP ("***Prior Company Counsel***") has, on or prior to the Distribution Effective Time, represented one or more of the Parties and their Subsidiaries and other Affiliates, and their respective officers, employees, and directors (each such Person, other than a member of the Company Group, a "***Designated Person***") in one or more matters relating to this Agreement (including any matter that may be related to a litigation, claim, or dispute arising under or related to this Agreement) (each, an "***Existing Representation***"), and that, in the event of any post-Distribution matters (x) relating to this Agreement (including any matter that may be related to a litigation, claim, or dispute arising under or related to this Agreement) and (y) in which the Company or any of its Affiliates, on the one hand, and one or more Designated Persons, on the other hand, are or may be adverse to each other (each, a "***Post-Distribution Matter***"), the Designated Persons reasonably anticipate that Prior Company Counsel will represent them in connection with such matters. Accordingly, the Company hereby (i) waives and shall not assert, and agrees after the Distribution Effective Time to cause its Affiliates to waive and to not assert, any conflict of interest arising out of or relating to the representation by Prior Company Counsel of one or more Designated Persons in connection with one or more Post-Distribution Matters (the "***Post-Distribution Representation***") and (ii) agrees that, in the event that a Post-Distribution Matter arises, Prior Company Counsel may represent one or more Designated Persons in such Post-Distribution Matter even though the interests of such Person(s) may be directly adverse to the Company or any of its Affiliates, and even though Prior Company Counsel may (A) have represented the Company Group in a matter substantially related to such dispute or (B) be currently representing the Company Group. Without limiting the foregoing, the Company (on behalf of itself and its Affiliates) consents to the disclosure by Prior Company Counsel, in connection with one or more Post-Distribution Representations, to the Designated Persons of any information substantially related to such Post-Distribution Representations learned by Prior Company Counsel in the course of one or more Existing Representations, whether or not such information is subject to the attorney-client privilege of the Company Group or Prior Company Counsel's duty of confidentiality as to the Company Group and whether or not such disclosure is made before or after the Distribution Effective Time.

6.18 Rules of Construction. Interpretation of this Agreement shall be governed by the following rules of construction: (a) words in the singular shall be held to include the plural and vice versa, and words of one gender shall be held to include the other gender as the context requires; (b) references to the terms Article, Section, paragraph, clause, Exhibit, and Schedule are references to the Articles, Sections, paragraphs, clauses, Exhibits, and Schedules of this Agreement unless otherwise specified; (c) the terms "hereof," "herein," "hereby," "hereto," and derivative or similar words refer to this entire Agreement, including the Schedules and Exhibits hereto; (d) references to "$" shall mean U.S. dollars; (e) the word "including" and words of similar import when used in this Agreement shall mean "including, without limitation," unless otherwise specified; (f) the word "or" shall not be exclusive; (g) references to "written" or "in writing" include in electronic form; (h) references to "days" shall mean calendar days unless otherwise specified; (i) provisions of this Agreement shall apply, when appropriate, to successive events and transactions; (j) the headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement; (k) the Company and NewCo have each participated in the negotiation and drafting of this Agreement, and if an ambiguity or question of interpretation should arise, this Agreement shall be construed as if drafted jointly by the Parties, and no presumption or burden of proof shall arise favoring or disfavoring either Party by virtue of the authorship of any provision of this Agreement or any interim drafts

hereof; (l) a reference to any Person includes such Person's successors and permitted assigns; (m) references to any Law shall be deemed to refer to such Law as amended from time to time and to any rules or regulations promulgated thereunder; and (n) references to "related to" or "exclusively related to," when used with respect to any Asset or Liability of the Company Group, refer to such Asset or Liability's relation to the SPR202 Business in the ordinary course of business, disregarding the presence of such Asset or Liability on the consolidated financial statements or other books or records of the Company prior to the Separation.

[*Signature Page Follows*]

***

In Witness Whereof, the Parties have caused this Agreement to be executed as of the date first written above by their respective duly authorized officers.

Spruce Biosciences, Inc.

By: /s/ Javier Szwarcberg

Name: Javier Szwarcberg, M.D.,MPH

Title: Chief Executive Officer

Adrenyx Biosciences, Inc.

By: /s/ Samir Gharib

Name: Samir Gharib

Title: Chief Executive Officer

Exhibit 10.3
CONFIDENTIAL

Certain information in this document identified by brackets has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

TRANSITION SERVICES AGREEMENT

THIS TRANSITION SERVICES AGREEMENT (this "***Agreement***") is made and entered into as of November 6, 2026, by and between Spruce Biosciences, Inc., a Delaware corporation (the "***Company***"), and Adrenyx Biosciences, Inc., a Delaware corporation and wholly-owned subsidiary of the Company ("***NewCo***"). The Company and NewCo are sometimes referred to herein individually as a "***Party***" and collectively, the "***Parties***". Capitalized terms not defined in this Agreement have the meanings set forth in the Separation Agreement (as defined below).

A. The Company and NewCo are parties to that certain Separation and Distribution Agreement dated as of November 6, 2026 (as may be amended from time to time, the "***Separation Agreement***"), pursuant to which the Company has agreed to sell, assign and transfer to NewCo, and NewCo has agreed to purchase and acquire from the Company, all of the right, title and interest of the Company in and to the Contributed Assets and the Contributed Liabilities (the "***Contribution***"), subject to the terms and conditions of the Separation Agreement.

B. Following the Contribution and effective as of the Distribution Effective Time, the Company intends to distribute to its stockholders, on a pro rata basis, all of the outstanding shares of common stock of NewCo held by the Company (the "***Distribution***"), on the terms and subject to the conditions set forth in the Separation Agreement.

C. On or after the date hereof, in connection with the Separation and Distribution, NewCo may enter into employment or consulting agreements with certain NewCo Personnel (as defined in the Separation Agreement).

D. In connection with the Separation and Distribution, the Company has agreed to provide to NewCo certain Services (as defined below) in accordance with the terms of this Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. Provision of Services.

1.1 Services. The Company shall provide, or otherwise make available, to NewCo certain transition services described on Schedule A (the "***Services***") for the time periods specified with respect to each of such Services as set forth on Schedule A (the "***Service Period***").

1.2 Use of Contractors. The Company may engage the services of independent contractors to deliver or assist the Company in the delivery of the Services solely to the extent such independent contractors delivered or assisted in the delivery of the applicable Services prior to the date of the Distribution Effective Time, and otherwise the Company shall not, without NewCo's prior written consent (not to be unreasonably withheld, conditioned or delayed) utilize independent contractors to deliver or assist the Company in the delivery of the Services.

1.3Level of Services. The Company shall perform the Services (a) in accordance with the provisions of this Agreement, (b) in a professional, competent and workmanlike manner in accordance with generally accepted industry standards and practices, and (c) at a level of quality substantially similar to that at which the Services were provided by the Company prior to the date of the Distribution Effective Time and consistent with the manner in which the Company provides the Services for its own business. The Company shall notify NewCo promptly whether the Company becomes aware of any circumstances that adversely impact or are likely to adversely impact the Company's performance of the Services or NewCo's receipt of such Services.

1.4Cooperation. Each Party shall reasonably cooperate with the employees of the other to the extent required for delivery of the Services. In addition, each Party shall name a point of contact who will be responsible for the day-to-day implementation of this Agreement, including attempted resolution of any issues that may arise during the performance of a Party's obligations under this Agreement (the "***TSA Coordinators***").

1.5Additional Services. NewCo may at any time, upon provision of written notice to the Company's TSA Coordinator, request that new or additional services be added to Schedule A (such services, "***Requested Services***"). Within 10 days following such request, the Company's TSA Coordinator shall propose in good faith the terms under which the Requested Service will be added to Schedule A. Upon confirmation from NewCo's TSA Coordinator of acceptance of such terms or upon the Parties mutually agreeing upon alternative terms for such Requested Service, such Requested Service will be deemed added to Schedule A, for purposes of this Agreement and will thereafter constitute one of the Services. Notwithstanding the foregoing, if NewCo requests a Requested Service that the Company provided in support of the SPR202 Business during the twelve (12) months prior to the Distribution Effective Time and that is reasonably necessary for NewCo to operate the SPR202 Business substantially in the manner previously operated, and the Parties fail to reach agreement on the pricing or other terms of the Requested Service within a reasonable period (not to exceed thirty (30) days from the date of the request), the Company shall nonetheless remain obligated to provide such Requested Service on the cost methodology applicable to comparable Services set forth on Schedule A; provided, that the Company shall not be obligated to provide any Requested Service to the extent that the Company does not then have, and cannot obtain using commercially reasonable efforts, the personnel, systems, licenses or third party rights reasonably necessary to provide it, or to the extent that providing it would violate applicable Law, any Contract with a third party to which the Company is a party or other applicable legal obligations of the Company; provided further, that any Contributed Contract that has not been assigned as of the Contribution Effective Time shall be governed solely by Section 1.8 of the Separation Agreement.

1.6Compliance with Law; Consents. Each Party shall comply with all applicable Laws in connection with its performance or receipt of the Services (as applicable). The Company shall obtain all licenses and consents, and pay all fees, required by applicable Law and necessary for the Company's performance and/or NewCo's receipt of the applicable Services.

1.7Force Majeure. If the Company is unable to timely perform any of the Services by reason of a Force Majeure Event (as defined below), the provision of such Services by the Company shall be excused and suspended, and NewCo shall be relieved of the obligation to pay any amounts for the provision of the affected Services, for the duration and to the extent of such

Force Majeure Event. In the event of a Force Majeure Event, the Parties shall in good faith make the best possible arrangements by mutual agreement and according to the circumstances to resume the performance of such Services consistent with the intent of this Agreement. A "***Force Majeure Event***" means any military operation, an act of terrorism, an act of any federal, state or local government, agency or department thereof, an embargo, an act of subversive activity or sabotage, natural disasters (including, without limitation, earthquakes, storms or floods), a fire, an explosion, a power or telephone outage, insurrection, riots or other civil disorder, strike or other labor stoppage, slowdown or dispute or any other like material event and which is beyond the reasonable control of the Company.

2. Fees.

2.1Service Fees. NewCo shall pay to the Company the fees for the Services, in cash, as set forth on Schedule A(the "***Service Fees***"). In addition to the applicable Service Fees, NewCo shall reimburse the Company, in cash, for the pre-approved, out-of-pocket costs and expenses of third parties actually incurred by the Company on NewCo's behalf in the provision of the Services at the cost (without markup) to the Company (the "***Third-Party Costs***"), taking into account whether the Company also incurs those out-of-pocket costs and expenses on behalf of itself (in which case, the Company shall allocate any such Third-Party Costs to NewCo). If the provision of a Service is terminated in accordance with Section 7.2 or 7.3 of this Agreement prior to the expiration of a Service Period, NewCo shall only be liable for the Service Fees and Third-Party Costs incurred (or otherwise subject to non-cancellable commitments) by the Company for such Service through the effective date of termination.

2.2Compensation of Personnel. Each Party is solely responsible for compensating its own personnel (including, in the case of NewCo, the NewCo Personnel (as defined in the Separation Agreement) and any other employees or individual service providers of NewCo) (such Party's "***Personnel***"), for maintaining applicable workers' compensation, personal liability, property, and other insurance coverage relating to its Personnel, and for any and all other liabilities associated with or related to its Personnel. The Company may increase the rate of compensation for any of its Personnel; provided, that any resulting increase in the Service Fees payable by NewCo hereunder shall be limited to increases made in the ordinary course of the Company's compensation practices, and any other increase in the Service Fees resulting therefrom shall require NewCo's prior written consent (not to be unreasonably withheld, conditioned or delayed); provided, further, that if NewCo does not consent to any such increase in the Service Fees, the Company shall not be obligated to continue to perform the applicable Services to the extent that the Company's cost of performing such Services would exceed the Service Fees payable therefor absent such increase.

2.3Payment.

(a) Within 30 days following the end of each calendar month during the Term and within 30 days following any termination of this Agreement, the Company shall provide to NewCo a single invoice for all Services provided by the Company (including all Service Fees and Third-Party Costs payable to the Company, together with supporting documentation, such as third-party invoices issued to the Company) during the applicable calendar month (each, an "***Invoice***").

(b) Subject to Section 2.3(c) below, NewCo will pay amounts due on each Invoice in U.S. dollars within 45 days after receiving the Invoice. For clarity, NewCo will not have any obligation to pay any amount included on any Invoice that is not a Service Fee or Third-Party Cost that NewCo is obligated to pay under the terms of this Agreement.

(c) NewCo may withhold payment of any invoiced amount that NewCo disputes in good faith. The Company acknowledges that (i) failure by NewCo to pay any amount NewCo disputes in good faith is not a breach of this Agreement, and (ii) NewCo's failure to identify a disputed amount before payment does not limit or waive any of NewCo's rights or remedies with respect to that amount, including NewCo's right to withhold amounts it disputes in good faith from amounts subsequently due to the Company.

2.4Taxes.

(a) The Service Fees are exclusive of any and all sales, use, value added, goods and services or similar taxes (collectively, and together with any interest, penalties or additions to tax imposed with respect thereto, "***Sales Taxes***"). NewCo shall pay and be responsible for any Sales Taxes imposed with respect to the provision of the Services by the Company.

(b) The Parties acknowledge that the Company and NewCo shall each pay and be responsible for their own personal property taxes and taxes based on their own income, receipts, capital, profits, or assets.

(c) Payments for the Services or any other amounts payable under this Agreement must be made without any deduction or withholding in respect of taxes except to the extent such deduction or withholding is required under applicable Law. The Company agrees to provide NewCo with reasonably requested assistance to enable the due deduction by NewCo and appropriate recovery by the Company, which assistance includes, but is not limited to, provision of any tax forms and other information that may be reasonably necessary in order for NewCo not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. To the extent such deduction or withholding is so required with respect to the making of any payment hereunder, NewCo shall deduct or withhold amounts so required to be deducted or withheld, and shall promptly remit any such deducted or withheld amounts to the appropriate taxing authority, and such deducted or withheld amounts shall be treated for all purposes of this Agreement as having been paid to or on behalf of the Company. Prior to making any deduction or withholding pursuant to the foregoing provisions of this Section 2.4(c) with respect to any payment to be made hereunder, NewCo shall notify the Company of its intention to so deduct or withhold and provide the Company with reasonable opportunity to provide such forms, certificates, or other documentation as would permit such payment to be made without any such deduction or withholding or at a reduced rate of deduction or withholding.

2.5Records; Audits. The Company shall prepare and maintain, during the Term and for at least three years thereafter, in accordance with generally accepted accounting principles and applicable Law, complete and accurate books, time sheets, and records sufficient to document fees, costs and expenses and the provision of the Services. The Company shall also maintain backup, security, and other measures sufficient to protect such documentation from loss, alteration, destruction, or unauthorized disclosure, and shall promptly provide that documentation to NewCo

at NewCo's request. At any time during the Term and for the three-year period immediately following the Term, NewCo and its designees (including independent auditors) may, at any time during normal business hours and upon at least 30 days' notice, inspect and audit the books and records of the Company that relate to the performance of the Services by the Company. The Company shall cooperate with NewCo and its designees in connection with any such inspection or audit.

3. Confidential Information. The provisions of Section 4.3 of the Separation Agreement shall apply to disclosures of information made pursuant to this Agreement *mutatis mutandis* and shall be deemed incorporated into, and made a part of, this Agreement.

4. Work Product. All work product, deliverables, reports, documents, data, developments, improvements, enhancements, modifications, inventions, derivative works, works of authorship, discoveries, technology, processes, procedures, techniques, design or technical specifications, and Intellectual Property developed, made, created, or authored by the Company while performing its Services (the "***Work Product***") and primarily related to the SPR202 Business (the "***Program-Related Work Product***") is and will be the sole property of NewCo and (a) to the extent permitted by Law, all Program-Related Work Product constitutes a "work made for hire" commissioned by NewCo or (b) to the extent any Program-Related Work Product is not a "work made for hire," the Company hereby irrevocably assigns to NewCo all right, title, and interest in and to such Program-Related Work Product. Any Work Product that is not Program-Related Work Product is and will be the sole property of the Company; provided that, any such Work Product resulting from performance of the Services shall be licensed to NewCo pursuant to the license grants to NewCo under this Agreement.

5. Indemnification.

5.1 Indemnification by Company. The Company shall indemnify, defend, and hold harmless NewCo from and against any and all Losses arising out of or relating to Third Party Claims arising out of or relating to (a) the gross negligence or willful misconduct of the Company in connection with the provision of any Services, or (b) the breach by the Company of this Agreement, except in each case to the extent such Losses arise from or are otherwise related to NewCo's breach of this Agreement or gross negligence or willful misconduct.

5.2 Indemnification by NewCo. NewCo shall indemnify, defend, and hold harmless the Company from and against any and all Losses arising out of or relating to Third Party Claims arising out of or relating to (a) the gross negligence or willful misconduct of NewCo in connection with this Agreement, or (b) the breach by NewCo of this Agreement, except in each case to the extent such Losses arise from or are otherwise related to the Company's breach of this Agreement or gross negligence or willful misconduct.

5.3 Indemnification Procedures. The terms set forth in Article 5 of the Separation Agreement shall govern claims for indemnification under this Agreement *mutatis mutandis* and shall be deemed incorporated into, and made a part of, this Agreement; provided that, for purposes of this Article 5, in the event of any conflict between the provisions of Article 5 of the Separation Agreement and this Article 5, the provisions of this Agreement shall control.

5.4Indemnification pursuant to this Article 5 represents the Parties' sole and exclusive remedy under this Agreement; provided that, if the Company commits an error with respect to, incorrectly performs or fails to perform any Service, at NewCo's request, without prejudice to any other rights or remedies NewCo may have, the Company shall use commercially reasonable efforts to correct such error, re-perform such Service or perform such Service, as applicable, at no additional cost to NewCo. Nothing in this Article 5 shall be deemed to eliminate or limit, in any respect, either Party's express obligation in this Agreement to pay any fees, expenses or costs in accordance with the terms of this Agreement. Notwithstanding anything to the contrary in this Agreement, (a) in no event shall either Party be liable to the other Party under this Agreement for any special, indirect, incidental, consequential, exemplary, or punitive damages (including damages for lost profits, lost revenues, diminution in value, business interruption, or loss of goodwill), regardless of the theory of liability and even if such Party has been advised of the possibility of such damages; and (b) each Party's aggregate liability under this Agreement in any given calendar year shall not exceed the aggregate Service Fees actually paid or payable under this Agreement in respect of such calendar year. The limitations in this Section shall not apply to (i) either Party's breach of its confidentiality obligations, or (ii) liabilities arising from a Party's fraud or willful misconduct.

6. Representations and Warranties.

6.1Mutual Representations and Warranties. Each Party represents and warrants to the other Party that it has full power and authority to enter into this Agreement and to carry out the transactions contemplated by this Agreement.

6.2Disclaimer of Additional Warranties. EXCEPT WITH RESPECT TO THE REPRESENTATIONS AND WARRANTIES SET FORTH IN SECTION 6.1 OR AS OTHERWISE PROVIDED IN SECTION 1.3, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS, IMPLIED, OR STATUTORY, WITH RESPECT TO THE SERVICES, INCLUDING ANY WARRANTIES OF MERCHANTABILITY, SUITABILITY OR FITNESS FOR A PARTICULAR PURPOSE, TITLE, NON-INFRINGEMENT, AND ANY WARRANTIES ARISING FROM COURSE OF DEALING, COURSE OF PERFORMANCE, OR TRADE USAGE.

7. Term and Termination.

7.1Term. This Agreement is effective as of the date hereof and will continue in effect for 12 months (the "***Initial Term***," and the period for which this Agreement is in effect, the "***Term***"). NewCo may, upon no less than 30 Business Days' notice prior to the end of the Initial Term, provide written notification to the Company that it wishes to extend the Service Period for a period of up to six months with respect to any or all ongoing Services at the time of such notice. Any such extension of the Term shall be effective only with respect to such Services, and for such period, as the Parties may mutually agree in writing on a Service-by-Service basis, and the Company shall have no obligation to continue providing any Service beyond its then-current Service Period absent such agreement. Upon any such agreed extension, the Term shall be deemed extended through the end of the latest Service Period as so extended. NewCo shall identify in such

notice the Services that NewCo desires the Company to continue providing and the new Service Period for such Services.

7.2Termination for Breach. A Party may terminate this Agreement at any time by providing notice of termination to the other Party (the "***Breaching Party***") if the Breaching Party commits a material breach of this Agreement, and the breach continues unremedied for a period of 30 days after the Party provides notice to the Breaching Party describing the nature of the breach.

7.3Termination without Cause. NewCo may terminate a portion or all of the Services being performed by the Company without cause on 15 Business Days' prior notice to the Company. Upon any such termination, the Company shall provide reasonable wind-down cooperation to NewCo or NewCo's designated third-party service provider, including delivery of relevant data, files, and records, transition of vendor relationships, and reasonable knowledge transfer, at no additional cost to NewCo beyond fees and Third-Party Costs actually incurred through the effective date of termination. The Company may terminate any individual Service upon 30 days' prior notice (or such shorter period if so required by law or to maintain legal compliance) to NewCo if (a) the provision of such Service would violate applicable Law or would require a consent, license or grant of other rights by or from a third party that the Company, using its commercially reasonable efforts, is unable to obtain or maintain, or (b) the Company ceases to use or provide the equivalent service for its own business, in which case the Company shall provide the wind-down cooperation described above and shall reasonably cooperate with NewCo to identify and transition to an alternative provider. Except as set forth in this Section 7.3 and in Section 7.2, the Company shall have no right to terminate any Service prior to the end of its Service Period without NewCo's consent.

7.4Effect of Termination. Upon termination of this Agreement in its entirety pursuant to Section 7.1 or 7.2, or upon termination of any individual Service pursuant to Section 7.3, all obligations of the Parties with respect to such terminated Services shall terminate, except for the provisions of Sections 2.3, 2.4, 2.5, 6.2 and 7.4 and Articles 3, 4, 5 and 8, which shall survive termination of this Agreement.

8. Miscellaneous.

8.1Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware without reference to any rules of conflict of laws.

8.2Dispute Resolution.

(a) Authorized Representatives.

(i) Each Party may treat an act of the TSA Coordinator of any other Party as being authorized by such other Party to act for and bind such Party. Each Party may replace its TSA Coordinator by giving written notice of the replacement to the other Party.

(ii) The TSA Coordinators shall review, discuss and attempt to resolve any service or performance issues and any alleged breaches of this Agreement. If the TSA Coordinators are unable to resolve any such issue or alleged breach within 15 calendar days

after the date of the meeting at which such issue or alleged breach was first discussed, then such issues or breaches shall be referred to an executive officer designated by each Party. The designated executive officers will meet promptly to review and resolve such issues and breaches in good faith. If the designated executive officers are unable to resolve any such issue or alleged breach of this Agreement within 10 calendar days, then any remaining disputes will be resolved in accordance with Section 8.2(b).

(b) Arbitration.

(iii)Subject to Section 8.2(a), if a Party wishes to pursue an unresolved dispute, any such dispute shall be finally resolved by binding arbitration before JAMS pursuant to the Comprehensive Arbitration Rules and Procedures of JAMS then in effect, except as may be modified herein. Any disputes concerning the propriety of the commencement of the arbitration or relating to the scope or applicability of this Agreement to arbitrate shall be finally settled by the arbitrator.

(iv)The arbitration shall be conducted by a single arbitrator experienced in the business of pharmaceuticals (including biologicals). If the issues in dispute involve scientific or technical matters, the arbitrator chosen hereunder may, at its option, engage one or more experts that have educational training or industry experience sufficient to demonstrate a reasonable level of relevant scientific, medical and industry knowledge, to advise it with respect to any issue in the arbitration within that expert's field of expertise. If any expert is so engaged, the Parties shall have the right to review such expert's reports to the arbitrator and examine such expert at the hearings. Within 30 days after initiation of arbitration, the Parties shall jointly select the arbitrator. If the Parties are unable or fail to agree upon the arbitrator within such 30 day period, the arbitrator shall be appointed by JAMS and shall be deemed to meet the qualifications as set forth above unless a Party objects within 10 days after an arbitrator candidate is proposed. The seat, or legal place of arbitration, shall be Delaware unless otherwise mutually agreed by the Parties, and all proceedings and communications shall be in English. The arbitrator shall use commercially reasonable efforts to render a final award on the merits no later than 90 calendar days after the later of (x) the close of any hearing or (y) the Parties' final written submissions; provided, that no award shall be rendered invalid or improper by reason of its being rendered after the expiration of such period.

(v) Prior to the arbitrator being appointed, any Party, without waiving any remedy under this Agreement, may seek from any court having jurisdiction any temporary injunctive or provisional relief necessary to protect the rights or property of that Party until final resolution of the issue by the arbitrator or other resolution of the controversy among the Parties. After the arbitrator is appointed, any Party may only apply to the arbitrator for interim injunctive relief or other interim relief until the arbitration award is rendered or the controversy is otherwise resolved, and any Party may apply to a court of competent jurisdiction to enforce interim injunctive relief granted by the arbitrator. Any award by the arbitrator shall be final and binding, and the Parties undertake to carry out any award without delay. Judgment upon the award may be entered by any Party in any court having appropriate jurisdiction for a judicial recognition of the decision and applicable orders of enforcement. The arbitrator shall have no authority to award punitive

or any other type of damages not measured by a Party's compensatory damages. The arbitrator shall award to the prevailing Party its reasonable costs and expenses (including reasonable attorneys' fees) and the fees of the arbitrator and any administrative fees of arbitration, unless the arbitrator determines that a different allocation is warranted under the circumstances. Notwithstanding anything to the contrary in this Agreement, this arbitration agreement, and any question regarding its existence, validity, scope or enforceability, shall be governed by the Federal Arbitration Act, 9 U.S.C. § 1 et seq. Each Party shall continue to perform its undisputed obligations under this Agreement, including NewCo's obligation to pay all undisputed Service Fees and Third-Party Costs when due, pending the final resolution of any dispute under this Section 8.2; provided, that the Company shall not be obligated to continue performing any Service that is the subject of a bona fide dispute to the extent the Company's cost of performing such Service would exceed the amounts NewCo has paid or remains obligated to pay with respect thereto.

(vi)Except to the extent necessary to confirm or challenge an award or as may be required by Law or for a Party to protect or pursue a legal right, neither a Party nor an arbitrator may disclose the existence, content, or results of the arbitral proceedings or any rulings or awards, or any information or documents produced, generated or exchanged in connection with settlement discussions relating to the dispute, without the prior written consent of the other Party, and this obligation shall survive the termination or expiration of this Agreement. The arbitrator shall ensure that document disclosure is conducted on a timely basis, may limit the scope and cost of such disclosure as the arbitrator deems appropriate to the matters in dispute, and may impose sanctions, including by allocating costs of arbitration or making adverse inferences, for any Party's abuse of, or undue delay in, the document disclosure process. In no event shall an arbitration be initiated after the date when commencement of a legal or equitable Action based on the dispute, controversy or claim would be barred by the applicable Delaware statute of limitations.

(vii)Upon the request of any Party, the arbitrator may consolidate the arbitration with any other arbitration relating to this Agreement or the Separation Agreement upon a finding that (x) there are issues of fact or law common to the two arbitrations so that a consolidated proceeding would be more efficient than separate proceedings, and (y) no Party would be prejudiced as a result of such consolidation through undue delay or otherwise. In the event of different rulings on this question by arbitrators appointed hereunder, the ruling of the first arbitrator appointed shall control.

(c) Specific Performance. The Parties agree that irreparable damage may occur in the event that certain of the terms or provisions of this Agreement are not performed in accordance with their specific wording or are otherwise breached. The Parties accordingly agree that, in the event of any breach or threatened breach by any Party of any covenant, obligation or other provision set forth in this Agreement, for the benefit of the other Party: (i) such other Party shall be entitled (in addition to any other remedy that may be available to it) to seek: (x) a decree or order of specific performance or mandamus to enforce the observance and performance of such covenant, obligation or other provision, and (y) an injunction restraining such breach or threatened breach; and (ii) such other Party shall not be required to provide any bond or other security in connection with any such decree, order or injunction or in connection with any related Action.

8.3Waiver of Trial by Jury. EACH PARTY HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, LEGAL ACTION OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT, OR THE ACTS OF ANY PARTY IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE AND ENFORCEMENT HEREOF.

8.4Entire Agreement. This Agreement, together with the Schedules hereto, the Separation Agreement and the Ancillary Agreements, constitute the entire agreement of the Parties relating to the subject matter hereof and supersede all prior contracts or agreements, whether oral or written. If a provision in this Agreement conflicts with any provision in the Separation Agreement, the applicable provision in this Agreement shall control to the extent of the conflict.

8.5Assignment. Neither Party may assign, delegate, or otherwise transfer this Agreement or any of its rights, remedies, or obligations under this Agreement (including by merger, consolidation, dissolution, or operation of Law, and whether voluntarily or by a Governmental Entity's action or order) without the other Party's prior written consent, which may not be unreasonably withheld, conditioned or delayed; except that either Party may assign, delegate, or otherwise transfer this Agreement (and its rights, remedies, and obligations under this Agreement) to (a) an Affiliate; provided that the assigning Party remains primarily liable under this Agreement or (b) a successor in connection with the sale of all or substantially all of the business to which this Agreement relates. Any purported assignment, delegation, or other transfer in contravention of this Section 8.5 is void. This Agreement binds and inures to the benefit of the Parties and their respective permitted assignees and successors.

8.6Interpretation. The descriptive headings in this Agreement are used solely for convenience and are not intended to affect its meaning or interpretation. The words "including," "include," and "includes" are not limiting and are to be read as if they were followed by the phrase "without limitation." Unless stated otherwise, all references to a date or time of day in this Agreement are references to that date or time of day in New York, New York and references to "$" shall mean U.S. dollars. If any date specified in this Agreement as the only day, or the last day, for taking action falls on a day that is not a Business Day, then that action may be taken on the next Business Day.

8.7Notices. All notices, requests, claims, and other communications between the Parties described in or otherwise regarding this Agreement must be in writing and be given or made (and will be effective on receipt) by delivery in person, by nationally recognized overnight courier service (with signature required and all fees prepaid), by e-mail (with confirmation by another method set forth in this Section) or by registered or certified mail (postage prepaid, return receipt requested) to a Party at its address identified below its signature to this Agreement or at any other address of which that Party has notified the other Party in accordance with this Section.

8.8Severability. Should any provision of this Agreement or the application thereof to any Person or circumstance be held invalid or unenforceable to any extent: (a) such provision shall be ineffective to the extent, and only to the extent, of such unenforceability or prohibition and shall be enforced to the greatest extent permitted by Law, (b) such unenforceability or prohibition in any jurisdiction shall not invalidate or render unenforceable such provision as applied (i) to other

Persons or circumstances or (ii) in any other jurisdiction, and (c) such unenforceability or prohibition shall not affect or invalidate any other provision of this Agreement.

8.9Amendment. This Agreement may be amended or modified only by a written instrument that refers specifically to this Agreement and is executed in accordance with Section 8.14, but "written instrument" does not include the text of e-mails or similar electronic communications.

8.10Waiver. A Party's failure to enforce any provisions of or rights deriving from this Agreement does not waive those provisions or rights, or that Party's right to enforce those provisions or rights. Except to the extent stated otherwise in this Agreement, each Party's rights and remedies under this Agreement are cumulative and are in addition to any other rights and remedies available at Law or in equity.

8.11Third Parties. Except to the extent stated otherwise in this Agreement, nothing in this Agreement confers any legal or equitable right, benefit, or remedy upon any Person other than the Parties.

8.12No Presumption. The Parties acknowledge that the provisions of this Agreement are the language the Parties chose to express their mutual intent and hereby waive any remedy and the applicability of any Law that would require interpretation of any claimed ambiguity, omission or conflict in this Agreement against the Party that drafted it.

8.13Independent Relationship. The Parties acknowledge that the Company is performing its Services as an independent contractor; and each Party's Personnel are not entitled to participate in the other Party's employee pension, health, welfare or other fringe benefit plans. Nothing in this Agreement creates an employment, agency, joint venture or partnership relationship between the Parties or any of their personnel, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever. The Parties (and any successor, assignee, transferee, or Affiliate of a Party) shall not treat or report the relationship between the Parties arising under this Agreement as a partnership for United States tax purposes, without the prior written consent of the other Party unless required by a final "determination" as defined in Section 1313 of the Code. Nothing in this Agreement precludes either Party from retaining the services of any Person or from independently developing or acquiring any materials. If a Party contracts with any Person to provide services or assist in performing the Services, the other Party shall cooperate with such Party and that Person to the extent such Party reasonably requires.

8.14Counterparts. This Agreement may be executed in any number of counterparts with the same effect as if both signatory parties had signed the same document. All counterparts shall be construed together and shall constitute one and the same instrument. Signatures to this Agreement transmitted by electronic mail in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document will have the same effect as physical delivery of the paper document bearing the original signature.

The Parties have caused this Transition Services Agreement to be executed by their respective duly authorized representatives as of the date set forth above.

Spruce Biosciences, Inc.

By /s/Javier Szwarcberg

Name: Javier Szwarcberg, M.D., MPH

Title: Chief Executive Officer

Address for notices:

611 Gateway Boulevard, Suite 740
South San Francisco, CA 94080
Attn: Legal
Email: [***]

Adrenyx Biosciences, Inc.

By /s/ Samir Gharib

Name: Samir Gharib

Title: Chief Executive Officer

Address for notices:

611 Gateway Boulevard, Suite 740
South San Francisco, CA 94080
Attn: Samir Gharib
Email: [***]

Schedule A

Service Fees:

[***]

Services

[***]

Exhibit 10.4

Certain information in this document identified by brackets has been omitted because it is both not material and would be competitively harmful if publicly disclosed.

SECURED CONVERTIBLE NOTE PURCHASE AGREEMENT

This Secured Convertible Note Purchase Agreement (this "**Agreement**"), dated as of November 6, 2026, is entered into by and among Adrenyx Biosciences, Inc., a Delaware corporation (the "**Company**"), the Collateral Agent (as defined herein) and each purchaser listed on the Schedule of Purchasers (as defined below) (each, a "**Purchaser**" and collectively, the "**Purchasers**").

WHEREAS, subject to the terms and conditions set forth herein, the Company wishes to issue and sell to the Purchasers, and the Purchasers wish to purchase from the Company, one or more secured convertible promissory notes in exchange for the consideration (the "**Consideration**") set forth opposite each Purchaser's name on the Schedule of Purchasers attached hereto as Schedule A (as may be updated from time to time in accordance with the terms of this Agreement, the "**Schedule of Purchasers**").

NOW, THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. Definitions. Capitalized terms not otherwise defined in this Agreement shall have the meaning ascribed to them by the Code. The following terms shall have the following meanings:

1.1 "**Assets**" means product candidate SPR202, an anti-CRH antibody for the treatment of congenital adrenal hyperplasia (the "**Program**") and all corresponding Program Assets, which are to be contributed from Spruce Biosciences, Inc., a Delaware corporation ("**Parent**"), to the Company.

1.2 "**Cashless Warrants**" means the cashless exercise warrants to be issued to the Lead Purchaser at the closing of the Qualified Equity Financing as contemplated by the Term Sheet (as defined herein).

1.3 "**Closing**" means each closing of the issuance and sale of Notes under this Agreement.

1.4 "**Code**" means the Uniform Commercial Code as from time to time in effect in the State of Delaware.

1.5 "**Collaboration and License Agreement**" means that certain Collaboration and License Agreement, dated as of January 15, 2025, by and between HBM Alpha Therapeutics, Inc. and Parent.

1.6 "**Common Stock**" means the Company's common stock, par value US$0.00001 per share.

1.7 "**Conversion Price**" means:

(a)with respect to a conversion pursuant to Section 4.1, ninety percent (90%) of the per Unit (as defined herein) price issued to investors in the Qualified Equity Financing; and

(b)with respect to a conversion pursuant to Section 4.2, ninety percent (90%) of the per share purchase price of the Equity Securities issued in the Nonqualified Equity Financing.

1.8 "**Conversion Securities**" means, (i) in the case of a conversion in connection with a Qualified Equity Financing, the Units to be issued to the investors participating in the Qualified Equity Financing and (ii) in the case of a conversion in connection with a Nonqualified Equity Financing, the Equity Securities to be issued to the investors participating in the Nonqualified Equity Financing.

1.9 "**Copyrights**" means all copyrights (registered or otherwise), mask works and registrations and applications for registration thereof, and all rights therein provided by multinational treaties or conventions.

1.10 "**Equity Securities**" means Common Stock and Preferred Stock, or any securities (that are not debt securities) convertible into or exchangeable for Common Stock or Preferred Stock.

1.11 "**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

1.12 "**Extraordinary Corporate Transaction**" means the occurrence of any of the following (unless waived by the Requisite Noteholders):

(a)the closing of the sale, transfer or other disposition, in a single transaction or series of related transactions, of all or substantially all of the Company's assets;

(b)the consummation of a merger or consolidation of the Company with or into another entity (except a merger or consolidation in which the holders of capital stock of the Company immediately prior to such merger or consolidation continue to hold a majority of the outstanding voting securities of the capital stock of the Company or the surviving or acquiring entity immediately following the consummation of such transaction);

(c)the closing of the transfer (whether by merger, consolidation or otherwise), in a single transaction or series of related transactions, to a "person" or "group" (within the meaning of Section 13(d) and Section 14(d) of the Exchange Act) of the Company's capital stock if, after such closing, such person or group would become the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act) of more than 50% of the outstanding voting securities of the Company (or the surviving or acquiring entity); or

(d)a liquidation, dissolution or winding up of the Company.

1.13 "**Intellectual Property**" means, without limitation, all intellectual property, including any and all (A) Patents; (B) Trademarks; (C) Copyrights; (D) computer programs

and software and related data and documentation; (E) licenses, permits, license rights to or of technologies, contract rights with employees, consultants or third parties; (F) inventions, discoveries, trade secrets and confidential business information, whether patentable or nonpatentable and whether or not reduced to practice, know-how, manufacturing and product processes and techniques, biological or chemical processes and techniques, formulae, compounds, DNA sequences, cell lines, fungi, yeast, laboratory notebooks, algorithms, databases, research and development information, copyrightable works, financial, marketing and business data, pricing and cost information, business and marketing plans and customer and supplier lists and information; and (G) the Company's goodwill associated with any of the foregoing together with Company's rights to sue for past, present and future infringement of Intellectual Property and the goodwill associated therewith, and other such rights generally classified as intangible, intellectual property assets in accordance with generally accepted accounting principles in the United States possessed or owned by Company, or which the Company now or hereafter has a right to use or in which the Company now or hereafter has an interest.

1.14 "**Lead Purchaser**" means the Purchasers listed on the Schedule of Purchasers as the Lead Purchaser.

1.15 "**Maturity Date**" means, with respect to each Note issued under this Agreement, November 6, 2027.

1.16 "**Nonqualified Equity Financing**" means any sale (or series of related sales) by the Company of its Equity Securities following the date of this Agreement in a bona fide equity financing transaction which does not constitute a Qualified Equity Financing.

1.17 "**Notes**" means the convertible promissory notes issued to each Purchaser pursuant to Section 2, the form of which is attached hereto as Exhibit A.

1.18 "**Obligations**" means the unpaid principal amount of, interest on, and fees and expenses payable pursuant to, the Notes, as well as any other payment obligations of any kind due and owing to the Purchasers or the Collateral Agent by the Company, whether under this Agreement or otherwise.

1.19 "**Patents**" means all national (including the United States) and multinational statutory invention registrations, patents, design patents, patent disclosures, patent registrations and patent applications, including all reissues, divisions, continuations, continuations-in-part, extensions, utility models, certificates of invention and reexaminations, and all rights therein provided by multinational treaties or conventions and all improvements to the inventions disclosed in each such registration, patent or application.

1.20 "**Permitted Lien**" means (a) any liens existing on the date of this Agreement and disclosed to the Purchaser on Schedule 1.20 to this Agreement; and (b) liens for taxes, fees, assessments or other governmental charges or levies, either not delinquent or being contested in good faith by appropriate proceedings.

1.21 "**Preferred Stock**" means the Company's preferred stock, par value US$0.00001 per share, whether now existing or hereafter created.

1.22 "**Pro Rata Portion**", with respect to the Lead Purchaser, means the product of (i) the aggregate amount of Equity Securities sold in the particular Nonqualified Equity Financing (but excluding Equity Securities issued or issuable upon conversion of the Notes) and (ii) the ratio of (A) the Conversion Securities held by such Lead Purchaser assuming conversion of its Notes pursuant to Section 4.2 in connection with such particular Nonqualified Equity Financing, plus any other Equity Securities then held by such Lead Purchaser, to (B) the number of shares of Common Stock deemed to be outstanding on a fully-diluted, pre-money basis for purposes of such particular Nonqualified Equity Financing (specifically including in such number of shares, without duplication, any shares reserved for issuance under the Company's equity incentive plans, as well as any increase to such reserve to be effected on a "pre-money" basis pursuant to such Nonqualified Equity Financing, and any shares issuable upon conversion of the Notes).

1.23 "**Program Assets**" means any Patents, Patent applications, and other Intellectual Property and Intellectual Property rights covering the Program and/or elements or derivatives thereof, and all technology, know-how, data, regulatory filings, regulatory documentation, stock and supply of drug product (including API) and other materials and contracts to the extent relating to the Program, and including any of the foregoing applicable to formulations, compositions or products or to their manufacture, development, registration, use or marketing or to methods of assaying or testing them.

1.24 "**Qualified Equity Financing**" means [***].

1.25 "**Requisite Noteholders**" means the holders of a majority-in-interest of the aggregate principal amount of the Notes.

1.26 **"SAFE**" means any simple agreement for future equity (or other similar agreement) which is issued by the Company for bona fide financing purposes and which may convert into the Company's capital stock in accordance with its terms.

1.27 "**Securities Act**" means the Securities Act of 1933, as amended.

1.28 "**Trademarks**" means all trademarks, service marks, trade dress, Internet domain names, logos, trade names and corporate names, whether or not registered, including all common law rights, and registrations and applications for registration thereof, including, but not limited to, all marks registered in the United States Patent and Trademark Office, the trademark offices of the States and Territories of the United States of America, and the trademark offices of other nations throughout the world, and all rights therein provided by multinational treaties or conventions.

1.29 "**Unit**" means, in respect of the Qualified Equity Financing, a Unit to purchase Equity Securities consisting of (i) shares of Common Stock or pre-funded warrants to purchase shares of Common Stock ("**Pre-Funded Warrants**") (the shares of Common Stock issued upon the closing of the Qualified Equity Financing and the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants issued at the closing of the Qualified Equity Financing are collectively referred to as the "**Closing Shares**") and (ii) cash warrants

to purchase a number of shares of Common Stock equal to the Closing Shares (the "**Cash Warrants**").

2. Purchase and Sale of Notes; Commitments. In exchange for the Consideration paid by each Purchaser at a Closing, the Company will sell and issue to such Purchaser a Note. Each Note will have a principal balance equal to that portion of the Consideration paid by such Purchaser for such Note at such Closing, as set forth opposite such Purchaser's name on the Schedule of Purchasers. Each Purchaser has made the commitment (such Purchaser's "**Commitment**") to purchase Notes in an aggregate principal amount set forth opposite such Purchaser's name on the Schedule of Purchasers, subject to the terms and conditions set forth in this Agreement.

3. Closings.

3.1 Initial Closing; Conditions to Closing.

(a)The initial closing of the sale of the Notes (the "**Initial Closing**") in return for the Consideration paid by each Purchaser at the Initial Closing will take place remotely via the exchange of documents and signatures on the date immediately following the satisfaction of the conditions to the Initial Closing set forth in Section 3.1(b) below, or at such other time and place as the Company and the Purchasers agree upon orally or in writing. At the Initial Closing, each Purchaser will deliver to the Company Consideration in an amount equal to fifty percent (50%) of such Purchaser's Commitment (the "**Initial Closing Consideration**"), and the Company will deliver to each Purchaser one or more executed Notes in return for the respective Initial Closing Consideration provided to the Company by such Purchaser.

(b)Prior to, and as a condition to the consummation of, the Initial Closing: (i) Parent shall have contributed the Assets to the Company and transferred to the Company all liabilities to the extent arising out of or relating to the Program, in each case, pursuant to the terms of a Separation and Distribution Agreement between Parent and the Company (the "**Separation and Distribution Agreement**"), which shall be in form and substance reasonably satisfactory to the Lead Purchaser; (ii) the Company shall have obtained and delivered to the Lead Purchaser the consent of Avenue Capital to the transactions contemplated by clause (i) above and to the release of all Liens (as defined herein) granted by Parent to Avenue Capital on the Collateral, which consent shall be in form and substance reasonably satisfactory to the Lead Purchaser; and (iii) the Company shall have obtained and delivered to the Lead Purchaser (x) the consent of HBM Alpha Therapeutics, Inc. ("**HBM Alpha**") (which consent shall be in form and substance reasonably satisfactory to the Lead Purchaser) to the grant of the Lien on the Collateral (including the Company's right, title and interest in and to the Collaboration and License Agreement), (y) the consent of HBM Alpha (which consent shall be in form and substance reasonably satisfactory to the Lead Purchaser) to the assignment of the Collaboration and License Agreement to the Lead Purchaser upon foreclosure by the Collateral Agent or Lead Purchaser in respect of the exercise of their rights and remedies in respect of the Collateral and (z) evidence of written notice provided by the Company to HBM Alpha of the assignment of the Collaboration and License Agreement to the Company.

3.2 Subsequent Closings. From time to time following the Initial Closing, upon (x) the mutual agreement of the Company and the Lead Purchaser, or (y) pursuant to prior written notice by the Lead Purchaser to the Company, the Company and the Purchasers shall conduct one or more additional Closings (each, a "**Subsequent Closing**") pursuant to which (i) each Purchaser shall fund a portion or all of its remaining Commitment as specified in the draw-down notice approved, in the case of Section 3.2(x), by the Company and the Lead Purchaser, or in the case of Section 3.2(y), by the Lead Purchaser, and (ii) the Company will deliver to each Purchaser a Note in the amount of the Consideration funded by such Purchaser at such Subsequent Closing. The Schedule of Purchasers will be updated to reflect the additional Notes purchased at the Subsequent Closing(s).

3.3 Aggregate Amount of Notes. The aggregate principal amount of Notes issued pursuant to this Agreement shall not exceed $10 million, and no Purchaser shall have an obligation to provide Consideration to the Company in excess of its Commitment.

4. Conversion. Each Note will be convertible into Conversion Securities pursuant to this Section 4.

4.1 Qualified Equity Financing Conversion. The principal balance and unpaid accrued interest on each Note will automatically convert into Conversion Securities upon the closing of the Qualified Equity Financing. The number of Conversion Securities the Company issues upon such conversion will equal the quotient (rounded up to the nearest whole share) obtained by dividing (x) the outstanding principal balance and unpaid accrued interest under each Note on the date of the closing of the Qualified Equity Financing by (y) the Conversion Price. Upon any such conversion, all accrued and unpaid interest on the converted Note shall be deemed paid in full.

4.2 Nonqualified Equity Financing Conversion. In the event of a Nonqualified Equity Financing prior to the conversion of a Note pursuant to Section 4.1 or the repayment of such Note in accordance with the terms of this Agreement, at the election of the particular holder thereof, the principal balance and unpaid accrued interest on such holder's Note will convert into Conversion Securities upon the closing of the Nonqualified Equity Financing. The number of Conversion Securities to be issued by the Company upon such conversion will equal the quotient (rounded up to the nearest whole share) obtained by dividing (x) the outstanding principal balance and unpaid accrued interest under each such converting Note on the date of the closing of the Nonqualified Equity Financing by (y) the Conversion Price. At least five (5) days prior to the closing of the Nonqualified Equity Financing, the Company will notify the holder of each Note in writing (the "**Nonqualified Equity Financing Notice**") of the material terms of the Equity Securities that are expected to be issued in such Nonqualified Equity Financing. For a holder to elect to convert the Note into Conversion Securities pursuant to this Section 4.2, such holder must notify the Company, in writing, of its irrevocable election to convert the Note into Conversion Securities within five (5) days following receipt of the Nonqualified Equity Financing Notice.

4.3 Mechanics of Conversion.

(a)Financing Agreements. Each Purchaser acknowledges that the conversion of the Notes into Conversion Securities pursuant to Section 4.1 or Section 4.2 may require such Purchaser's execution of certain customary agreements by and among the Company and certain of the Company's investors and shareholders relating to the purchase and sale of the Conversion Securities (collectively, the "**Financing Agreements**"). Each Purchaser agrees to execute all of the Financing Agreements in connection with the Qualified Equity Financing or Nonqualified Equity Financing in such Purchaser's capacity as a holder of Conversion Securities.

(b)Certificates. As promptly as practicable after the conversion of a Note and the issuance of the Conversion Securities, the Company (at its expense) will issue and deliver to the applicable holder thereof a certificate or certificates evidencing the Conversion Securities (if certificated), or if the Conversion Securities are not certificated, will deliver a true and correct copy of the Company's share register reflecting the Conversion Securities held by such holder. The Company will not be required to issue or deliver the Conversion Securities until the holder of such Note has surrendered the Note to the Company (or provided an instrument of cancellation or affidavit of loss in a form reasonably acceptable to the Company). The conversion of the Notes pursuant to Section 4.1 and Section 4.2 may be made contingent upon the closing of the Qualified Equity Financing or Nonqualified Equity Financing, respectively.

4.4 No Prepayment. The Company may not prepay the Notes prior to the Maturity Date without the prior written consent of the Requisite Noteholders. From and after the Maturity Date, upon five (5) business days advance written election of the Requisite Noteholders, the Company shall repay the outstanding principal and accrued and unpaid interest on the Notes in cash (and, without such written election, the Company may not repay the Notes following the Maturity Date, other than pursuant to Section 5 hereof).

5. Repayment Upon an Extraordinary Corporate Transaction. In the event of an Extraordinary Corporate Transaction prior to the conversion of a Note pursuant to Section 4.1 or Section 4.2, the Company shall pay to the holder of each Note, at the closing of such Extraordinary Corporate Transaction, the outstanding principal and accrued interest then outstanding under such Note.

6. Representations and Warranties of the Company. In connection with the transactions contemplated by this Agreement, the Company hereby represents and warrants to the Purchasers as follows:

6.1 Due Organization; Qualification and Good Standing. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all requisite corporate power and authority to carry on its business as now conducted. The Company is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify or to be in good standing would have a material adverse effect on the Company.

6.2 Authorization and Enforceability. Except for the authorization and issuance of the Conversion Securities, all corporate action has been taken on the part of the Company and its officers, directors and stockholders necessary for the authorization, execution and delivery of this Agreement and the issuance of the Notes. This Agreement constitutes and, when issued, the Notes will constitute, the Company's valid and legally binding obligations, enforceable against the Company in accordance with their terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance and any other laws of general application affecting enforcement of creditors' rights generally and (b) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

6.3 Compliance with Other Instruments. Neither the authorization, execution and delivery of this Agreement, nor the issuance and delivery of the Notes will constitute or result in a material default or violation of any law or regulation applicable to the Company or any material term or provision of the Company's current Certificate of Incorporation or bylaws or any agreement or instrument by which it is bound or to which its properties or assets are subject.

6.4 Valid Issuance of Stock. The Conversion Securities to be issued, sold and delivered upon conversion of the Notes to be issued to the Purchasers and the securities issuable upon exercise thereof will, at the time of issuance, be duly authorized and validly issued, fully paid and nonassessable and, based in part upon the representations and warranties of the Purchasers in this Agreement, will be issued in compliance with all applicable federal and state securities laws.

6.5 Capitalization. The outstanding capitalization of the Company as of the effective date is set forth on Schedule 6.5. Except as set forth on Schedule 6.5, there are no rights, options or warrants to purchase any securities of the Company.

6.6 Bad Actor Disqualifying Event. No "bad actor" disqualifying event described in Rule 506(d)(1)(i)-(viii) of the Securities Act (such event, a "**Disqualification Event**") is applicable to the Company or, to the Company's knowledge, any Company Covered Person, except for a Disqualification Event as to which Rule 506(d)(2)(ii)-(iv) or (d)(3), is applicable. As used herein, the term "**Company Covered Person**" means, with respect to the Company as an "issuer" for purposes of Rule 506 promulgated under the Securities Act, any person or entity listed in the first paragraph of Rule 506(d)(1).

6.7 Collaboration and License Agreement. As of the Initial Closing (and after giving effect to the assignment of the Collaboration and License Agreement to the Company), the Company is in material compliance with, and not in material breach of, the Collaboration and License Agreement. To the Company's actual knowledge, no event has occurred that, with notice or lapse of time or both, would constitute a material breach or material default by the Company or Parent under the HBM License Agreement. Neither the Company nor Parent has received any written notice from HBM Alpha Therapeutics, Inc. alleging any such breach or default or indicating its intent to terminate the HBM License Agreement. No Cessation Period (as defined in the HBM License Agreement) has occurred and the Company and Parent are in compliance in all respects with Section 13.4 of the HBM License Agreement, such that HBM

Alpha Therapeutics, Inc. has no right to terminate the HBM License Agreement pursuant to Section 13.4 of the HBM License Agreement.

6.8 Title to Assets. As of the Initial Closing, the Company owns or has a valid license in or to the Assets, free and clear of all Liens, other than (i) Permitted Liens, (ii) the Lien granted to the Collateral Agent under this Agreement and (iii) the residual rights of HBM Alpha Therapeutics, Inc. as licensor under the Collaboration and License Agreement (it being understood that the Company's rights in the Assets to the extent derived from the Collaboration and License Agreement are as licensee thereunder).

6.9 No Litigation. There is no action, suit, or other legal or administrative proceeding or governmental investigation pending, or to the Company's actual knowledge, threatened against or involving the SPR202 Business or the Contributed Assets (as such terms are defined in the Separation and Distribution Agreement).

6.10 No Infringement. Neither the Company nor Parent has received any written notice that the SPR202 Business or the Contributed Intellectual Property (as defined in the Separation and Distribution Agreement) infringes the intellectual property rights of any person or entity.

6.11 Sufficiency of Contributed Assets. The Contributed Assets, together with the services contemplated by the Transition Services Agreement, constitute all assets, properties and rights reasonably necessary for the Company to conduct the SPR202 Business on the date hereof in substantially the same manner as conducted by the Parent immediately prior to the date hereof.

7. Representations and Warranties of the Purchasers. In connection with the transactions contemplated by this Agreement, each Purchaser, severally and not jointly, represents and warrants to the Company as follows:

7.1 Authorization. Such Purchaser has full power and authority to enter into this Agreement and to perform all obligations required to be performed by such Purchaser hereunder. This Agreement constitutes such Purchaser's valid and legally binding obligation, enforceable against such Purchaser in accordance with its terms, except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, fraudulent conveyance and any other laws of general application affecting enforcement of creditors' rights generally and (b) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

7.2 Purchase Entirely for Own Account. Such Purchaser acknowledges that this Agreement is made with such Purchaser in reliance upon such Purchaser's representations to the Company that the Notes and the Conversion Securities and any Common Stock issuable upon exercise thereof (collectively, the "**Securities**") will be acquired for investment for such Purchaser's own account, not as a nominee or agent, and not with a view to the resale or distribution of any part thereof, and that such Purchaser has no present intention of selling, granting any participation in, or otherwise distributing the same. By executing this Agreement, such Purchaser further represents that such Purchaser does not have any contract, undertaking,

agreement or arrangement with any person to sell, transfer or grant participations to such person or to any third person, with respect to the Securities.

7.3 Disclosure of Information; Non-Reliance. Such Purchaser acknowledges that it has received all the information it considers necessary or appropriate to enable it to make an informed decision concerning an investment in the Securities. Such Purchaser further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of the Securities. Such Purchaser confirms that the Company has not given any guarantee or representation as to the potential success, return, effect or benefit (either legal, regulatory, tax, financial, accounting or otherwise) of an investment in the Securities. In deciding to purchase the Securities, such Purchaser is not relying on the advice or recommendations of the Company, and such Purchaser has made its own independent decision that the investment in the Securities is suitable and appropriate for such Purchaser. Such Purchaser understands that no federal or state agency has passed upon the merits or risks of an investment in the Securities or made any finding or determination concerning the fairness or advisability of this investment. The foregoing, however, does not limit or modify the representations and warranties of the Company in Section 6 of this Agreement or the right of the Purchasers to rely thereon.

7.4 Investment Experience. Such Purchaser is an investor in securities of companies in the development stage and acknowledges that it is able to fend for itself, can bear the economic risk of its investment and has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Securities.

7.5 Accredited Investor. Such Purchaser is an "accredited investor" within the meaning of Rule 501 of Regulation D promulgated under the Securities Act. Such Purchaser agrees to furnish any additional information requested by the Company to assure compliance with applicable U.S. federal and state securities laws in connection with the purchase and sale of the Securities.

7.6 Restricted Securities. Such Purchaser understands that the Securities have not been, and will not be, registered under the Securities Act or any state securities laws, by reason of specific exemptions under the provisions thereof which depend upon, among other things, the bona fide nature of the investment intent and the accuracy of the Purchasers' representations as expressed herein. Such Purchaser understands that the Securities are "restricted securities" under U.S. federal and applicable state securities laws and that, pursuant to these laws, such Purchaser must hold the Securities indefinitely unless they are registered with the Securities and Exchange Commission ("**SEC**") and registered or qualified by state authorities, or an exemption from such registration and qualification requirements is available. Such Purchaser acknowledges that the Company has no obligation to register or qualify the Securities for resale and further acknowledges that, if an exemption from registration or qualification is available, it may be conditioned on various requirements including, but not limited to, the time and manner of sale, the holding period for the Securities, and on requirements relating to the Company which are outside of such Purchaser's control, and which the Company is under no obligation, and may not be able, to satisfy.

7.7 No Public Market. Such Purchaser understands that no public market now exists for the Securities.

7.8 No General Solicitation. Such Purchaser acknowledges that neither the Company nor any other person offered to sell the Securities to such Purchaser by means of any form of general solicitation or advertising within the meaning of Rule 502 of Regulation D under the Securities Act or in any manner involving a public offering within the meaning of Section 4(a)(2) of the Securities Act.

7.9 Residence. Such Purchaser's principal place of business is located in the state or province identified in the address shown on such Purchaser's signature page hereto.

7.10 Foreign Investors. If such Purchaser is not a United States person (as defined by Section 7701(a)(30) of the Internal Revenue Code of 1986, as amended), such Purchaser hereby represents that it has satisfied itself as to the full observance of the laws of its jurisdiction in connection with any invitation to subscribe for the Securities or any use of this Agreement, including (a) the legal requirements within its jurisdiction for the purchase of the Securities; (b) any foreign exchange restrictions applicable to such purchase; (c) any governmental or other consents that may need to be obtained; and (d) the income tax and other tax consequences, if any, that may be relevant to the purchase, holding, conversion, redemption, sale, or transfer of the Securities. Such Purchaser's subscription and payment for and continued beneficial ownership of the Securities will not violate any applicable securities or other laws of such Purchaser's jurisdiction. Such Purchaser acknowledges that the Company has taken no action in foreign jurisdictions with respect to the Securities.

7.11 "Bad Actor" Disqualification. Such Purchaser hereby represents that neither it nor any of its affiliates or other related parties is a "bad actor," as defined in Rule 506(d) of the Securities Act.

8. Covenants.

8.1 Use of Proceeds. The Company will use the proceeds from the sale of the Notes for developing and commercializing the Assets and for other general corporate purposes.

8.2 Negative Covenants. For so long as the Notes are outstanding, the Company will not, without the prior written consent of the Requisite Noteholders: (i) incur additional borrowed money indebtedness, other than (A) equipment financing and capital lease obligations incurred in the ordinary course of business in an aggregate principal amount not to exceed $500,000 outstanding at any time and (B) trade payables and other accrued expenses incurred in the ordinary course of business; (ii) grant any additional Liens on the Collateral (as defined herein) other than Permitted Liens; (iii) declare or pay any dividends or repurchase or redeem any securities of the Company, other than repurchases of capital stock of the Company from former employees, officers, directors, consultants or other persons who performed services for the Company or any subsidiary in connection with the cessation of such employment or service at no greater than the original purchase price thereof; (iv) enter into any equity or equity-linked financing transaction other than (A) the Qualified Equity Financing, (B) equity issuances or option grants to vendors, consultants or employees

primarily for compensatory purposes and not for the purpose of raising capital and (C) a bridge financing in an aggregate amount not to exceed $5,000,000; provided that, before entering into or consummating such bridge financing, (1) the Company shall have received from a bona fide third party financing source a signed, non-binding term sheet setting forth all material terms of such bridge financing (the "**Bridge Financing Term Sheet**"), (2) the Company shall have delivered to the Lead Purchaser a true, correct and complete copy of the Bridge Financing Term Sheet and written notice offering the Lead Purchaser the right to provide the entire bridge financing on the same terms set forth therein (the "**ROFR Notice**"), and (3) the Lead Purchaser shall have either declined such offer in writing or failed to accept such offer in writing within ten (10) days after its receipt of the ROFR Notice; provided further that, if the Lead Purchaser does not exercise such right, the Company may consummate such bridge financing with the applicable third party only on terms, taken as a whole, no more favorable to such third party than those set forth in the Bridge Financing Term Sheet and only within 60 days after expiration of such ten (10)-day period; (v) enter into, or consummate, an Extraordinary Corporate Transaction; (vi) enter into any transaction between the Company, on the one hand, and the Parent or any officer, director or stockholder of the Company or the Parent or any family member thereof or any entity affiliated with any of the foregoing, on the other hand, other than (A) any employment, compensation, reimbursement or indemnification agreement or arrangement in the ordinary course of business; provided that any compensation agreement or arrangement providing for aggregate annual cash compensation in excess of Two Hundred Fifty Thousand Dollars ($250,000) shall require the prior approval of the Lead Purchaser Director (as defined below), (B) the transactions contemplated by, and any agreement or arrangement entered into pursuant to, the Separation and Distribution Agreement, the Transition Services Agreement, and the transactions contemplated by the Term Sheet (including the Spin-Out, the Distribution (as defined in the Separation and Distribution Agreement) and the Qualified Equity Financing), (C) the transactions and consents contemplated by Section 3.1 (including the Avenue Capital consent and lien release and the HBM Alpha consent), and (D) the settlement of intercompany accounts arising from the Parent's payment, prior to the Closing, of expenses on behalf of the Company that relate directly to the Program or the Program Assets; provided that any individual expense in excess of $250,000 or aggregate expense reimbursements in excess of $500,000 shall require the prior approval of the Lead Purchaser; (vii) make loans or advances to third parties other than advances to employees for travel and business expenses or prepaid expenses or deposits, in each case, made in the ordinary course of business; (viii) amend, modify, supplement, restate or terminate the Separation and Distribution Agreement (including any schedule or exhibit thereto), or waive, release, forgive or compromise any right, claim or remedy of the Company thereunder in each case in a manner that would be adverse to the Lead Purchaser in any material respect; or (ix) take any action that would reasonably be expected to cause or result in the Company becoming obligated to indemnify the Parent pursuant to Section 5.2(ii) of the Separation and Distribution Agreement.

8.3 Information and Inspection Rights. Effective ninety (90) days following the Initial Closing, each Purchaser shall be entitled to receive, within forty-five (45) days following the end of each fiscal quarter (or ninety (90) days in the case of the last fiscal quarter of any fiscal year), internally prepared unaudited statements of income for such fiscal quarter, and an unaudited balance sheet as of the end of such fiscal quarter; provided that such financial statements shall be deemed to have been delivered to the Purchaser(s) to the extent publicly

filed with the SEC. The Company shall permit each Purchaser, at such Purchaser's expense, to visit and inspect the Company's properties; examine its books of account and records; and discuss the Company's affairs, finances, and accounts with its officers, during normal business hours of the Company as may be reasonably requested by such Purchaser; provided that, absent an ongoing Event of Default, such inspection or exam shall be limited to once during the term of this Agreement.

8.4 Participation Rights. The Company hereby grants to the Lead Purchaser the right to purchase up to its Pro Rata Portion of any Equity Securities that are issued by the Company in a Nonqualified Equity Financing at the price and on the terms the Equity Securities are offered to other investors in such Nonqualified Equity Financing. The Company shall give the Lead Purchaser a written notice of its bona fide intention to issue the Equity Securities, describing the type of Equity Securities and the price and the general terms upon which the Company proposes to issue the Equity Securities (the "**Notice**"). The Lead Purchaser shall have ten (10) days from the date such Notice is effective, to deliver to the Company its irrevocable agreement in writing to purchase up to its Pro Rata Portion of the Equity Securities. Such purchase shall be completed at the same closing as that of any third party purchasers and shall be subject to such Lead Purchaser signing any stock purchase and other documents signed by the other investors in the particular Nonqualified Equity Financing. The rights provided by this Section 8.4 shall continue until the closing of the Qualified Equity Financing, at which time the Lead Purchaser shall have the right to participate in any subsequent equity financing transaction of the Company, and to purchase its Pro Rata Portion of the Equity Securities to be issued in such subsequent equity financing transaction (based on its fully-diluted percentage ownership of the Company immediately prior to such subsequent equity financing transaction). The rights of participation set forth in this Section 8.4 shall terminate on the earlier to occur of (i) such time following the closing of the Qualified Equity Financing where the Lead Purchaser and its affiliates' collective beneficial ownership of the Company falls below ten percent (10%) or (ii) the closing of an underwritten public offering by the Company, whether or not the Lead Purchaser or its affiliates elect to participate in such underwritten public offering.

8.5 Board Matters. Following the Initial Closing and until the consummation of the Qualified Equity Financing, the board of directors of the Company (the "**Board**") shall consist of five (5) members with (i) one (1) member designated by the Lead Purchaser (the "**Lead Purchaser Director**"), (ii) one member who is the then-current Chief Executive Officer of the Company; (iii) two (2) members mutually agreed upon by the Lead Purchaser and the Parent, each of whom shall qualify as "independent" within the meaning of Nasdaq Marketplace Rule 5605(a)(2), and (iv) one member appointed by the Parent. In addition, the Lead Purchaser shall have the right to designate one non-voting board observer to the Board; provided, however, that such right, and if such observer is appointed, the right to observe meetings of the Board, shall cease if the Lead Purchaser's and its affiliates collective beneficial ownership of the Company falls below ten percent (10%).

9. Security Interest.

9.1 Grant of Security Interest. To secure the Company's prompt, punctual, and faithful performance of all and each of the Obligations (whether at the stated maturity, upon an Event

of Default (as defined herein), by acceleration or otherwise), the Company hereby grants to the Collateral Agent (as defined below) a continuing lien on and security interest in (a "**Lien**") and to all of the Company's right, title and interest, whether ownership, license, contractual right, or otherwise, in and to the Assets and the Program Assets (including the Company's right, title and interest in, to and under the Collaboration and License Agreement), in each case whether now owned or hereafter acquired or arising, and all Products, proceeds, substitutions, and accessions of or to the same, and (solely to the extent constituting Assets or Program Assets or proceeds thereof) the following categories of property (collectively, the "**Collateral**"):

(a) all Accounts and accounts receivable;

(b) all Inventory;

(c) all contract rights;

(d) all General Intangibles;

(e) all Goods;

(f) all Chattel Paper;

(g) all Fixtures;

(h) all Intellectual Property;

(i) all Equipment;

(j) all books, records, and information relating to the Collateral and/or to the operation of the Company's business, and all rights of access to such books, records, and information, and all property in which such books, records, and information are stored, recorded, and maintained;

(k) all Instruments, documents of title, Documents, policies and certificates of insurance, securities, deposits, deposit accounts, money, cash, or other property;

(l) all federal, state and local tax refunds to which the Company is, or becomes entitled, no matter how or when arising;

(m) all insurance proceeds, refunds, and premium rebates, including, without limitation, proceeds of fire and credit insurance, whether any of such proceeds, refunds and premium rebates arise out of any of the foregoing, or otherwise;

(n) all liens, guaranties, rights, remedies, and privileges pertaining to any of the foregoing, including the right of stoppage in transit; and

(o) all other assets of every nature and description, whether they be now existing or hereafter arising and whether now or hereafter belonging to the Company.

The Lien granted to the Collateral Agent hereunder shall be prior to all other interests in the Collateral.

9.2 Notwithstanding the foregoing provisions of this Section 9, the grant, assignment and transfer of a Lien as provided herein shall not extend to, and the term "Collateral" shall not include (i) any "intent-to-use" trademark application and (ii) any Contract, Instrument or Chattel Paper in which the Company has any right, title or interest if and to the extent such Contract, Instrument or Chattel Paper includes a provision containing a restriction on assignment such that the creation of a Lien in the right, title or interest of the Company therein would be prohibited and would, in and of itself, cause or result in a default thereunder, automatic termination thereof or enable another person party to such Contract, Instrument or Chattel Paper to enforce any remedy with respect thereto; provided that the foregoing exclusion in clause (ii) shall not apply if (A) such prohibition has been waived or such other person has otherwise consented to the creation hereunder of a Lien in such Contract, Instrument or Chattel Paper or (B) such prohibition would be rendered ineffective pursuant to Sections 9-407(a) or 9-408(a) of the Code, as applicable and as then in effect in any relevant jurisdiction, or any other applicable law (including the U.S. Bankruptcy Code) or principles of equity; provided further that immediately upon the ineffectiveness, lapse or termination of any such provision, the Collateral shall include, and the Company shall be deemed to have granted a Lien in, all its rights, title and interests in and to such Contract, Instrument or Chattel Paper as if such provision had never been in effect; and provided further that the foregoing exclusion shall in no way be construed so as to limit, impair or otherwise affect the Collateral Agent's or the Company's unconditional continuing Lien in and to all rights, title and interests of the Company in or to any payment obligations or other rights to receive monies due or to become due under any such Contract, Instrument or Chattel Paper and in any such monies and other proceeds of such Contract, Instrument or Chattel Paper, in each case, that constitutes Collateral.

9.3 The Company hereby agrees that the Collateral Agent shall have all the rights and remedies of a secured party under the Uniform Commercial Code as in effect from time to time in the State of Delaware. The Company agrees that at any time, and from time to time, at the reasonable request of the Collateral Agent, the Company shall execute and deliver (or cause to be executed and delivered) any and all such further instruments and/or documents (including without limitation, UCC-1 financing statements and filings with the USPTO) as the Collateral Agent may reasonably consider necessary or desirable in order to effectuate, complete, perfect or preserve and maintain the Lien created hereby. Upon any failure by the Company to do so, the Collateral Agent may make, execute, record, file, re-record or refile any and all such instruments and documents for and in the name of the Company; the Company hereby irrevocably appoints the Collateral Agent as the agent and attorney-in-fact of the Company to do so; and the Company shall reimburse the Collateral Agent, on demand, for all reasonable and documented out-of-pocket costs and expenses incurred by the Collateral Agent in connection therewith.

9.4 Covenants in favor of Collateral Agent. The Company hereby agrees that, so long as any of the Notes remain outstanding and unpaid:

(a)The Company will not, without providing at least fifteen (15) days' prior written notice to the Collateral Agent, change its legal name, identity, type of organization, jurisdiction of organization, corporate structure, location of its chief executive office or its principal place of business or its organizational identification number. The Company will, prior to any change described in the preceding sentence, take all actions requested by the Collateral Agent to maintain the perfection and priority of the Collateral Agent's security interest in the Collateral.

(b)The Company shall, at its own cost and expense, use commercially reasonable efforts to defend title to the Collateral and the Lien of the Collateral Agent therein against the claim of any person claiming against or through the Company and shall maintain and preserve such perfected security interest for so long as the Notes shall remain in effect.

(c)The Company will not sell, offer to sell, dispose of, convey, assign or otherwise transfer, grant any option with respect to, restrict, or grant, create, permit or suffer to exist any mortgage, pledge, Lien, option, right of first offer, encumbrance or other restriction or limitation of any nature whatsoever on, any of the Collateral or any interest therein except (i) for the sale of inventory in the ordinary course of business and disposition of immaterial assets, (ii) the existence of any Permitted Lien or (iii) with the prior written consent of the Collateral Agent.

(d)The Company will pay promptly when due all taxes, assessments, governmental charges, and levies upon the Collateral or incurred in connection with the use or operation of the Collateral or incurred in connection with this Agreement.

9.5 Events of Default; Acceleration of Maturity. If an Event of Default (as defined herein) shall have occurred and be continuing (whatever the reason for such Event of Default and whether it shall be voluntary or involuntary or be effected by operation of law or pursuant to any judgment, decree or order of any court or any order, rule or regulation of any governmental authority), then, in addition to the remedies provided for elsewhere in this Agreement or the Notes or as a matter of law and without limitation thereof, at the option of the Collateral Agent exercised by written notice to the Company, the Collateral Agent may (A) foreclose the Liens created under this Agreement and the Notes or under any other agreement relating to the Collateral, by any available judicial process, (B) enter any premises where any of the Collateral may be located for the purpose of taking possession or removing the same, and (C) sell, assign, lease or otherwise dispose of the Collateral or any part thereof, either at public or private sale or at any broker's board, in lots or in bulk, for cash, on credit or otherwise, with or without representations or warranties, and upon such terms as shall be acceptable to the Collateral Agent, all at the sole option of the Collateral Agent and as the Collateral Agent, in its sole discretion, may deem advisable and to the extent permitted by law, the Collateral Agent, on behalf of the Purchasers, may bid or become a purchaser at any such sale, and the Collateral Agent shall have the right, at its option, to apply or be credited with the amount of all or any part of the obligations owing by the Company under this Agreement and the Notes, against the purchase price bid by the Collateral Agent at any such sale. The net cash proceeds resulting from the collection, liquidation, sale, lease or other disposition of the Collateral (including, without limitation a sale where the Purchasers or the

Collateral Agent, on behalf of the Purchasers, are the purchaser) shall be applied first to the expenses (including reasonable and documented out-of-pocket attorneys' and other professional fees) of retaking, holding, storing, processing and preparing the Collateral for sale, selling, collecting, liquidating and the like, and then to the satisfaction of all such obligations, application as to particular obligations or against principal or any interest to be in the sole discretion of the Collateral Agent. The Collateral Agent shall give the Company at least ten (10) business days prior written notice of the time and place of any public sale of Collateral.

9.6 Suits for Enforcement. In case any one or more Events of Default shall have occurred and be continuing, the Collateral Agent may proceed to protect and enforce rights of the Collateral Agent and the Purchasers hereunder either by suit in equity or by action at law, or both, whether for the specific performance of any covenant or agreement in this Agreement or the Notes or in aid of the exercise of any power granted in the Notes, including without limitation, possession or foreclosure on the Collateral securing the Notes, or the Purchasers may proceed to enforce the payment of the Notes or to enforce any other legal or equitable right of the Purchasers.

9.7 Remedies Cumulative. No remedy herein conferred upon the Purchasers or Collateral Agent is intended to be exclusive of any other remedy, and each and every such remedy shall be cumulative and shall be in addition to every other remedy given hereunder or now or hereafter existing at law or in equity or by statute or otherwise.

9.8 Remedies Not Waived. No course of dealing between the Company, on the one hand, and the Purchasers or the Collateral Agent, on the other hand, and no delay in exercising any rights hereunder shall operate as a waiver of any rights of the Purchasers or the Collateral Agent.

9.9 Third Party Beneficiary. The Collateral Agent is an express third party beneficiary of this Section 9.

9.10 Termination. The Lien created hereunder shall terminate upon the earlier of (i) the conversion of all outstanding Notes issued hereunder and (ii) the irrevocable payment in full (to the extent permitted under this Agreement) by the Company to the Purchasers of all Obligations.

10. Defaults and Remedies.

10.1 Events of Default. The following events shall each be considered an "**Event of Default**" with respect to each Note:

(a)The Company shall default in the payment of any part of the principal or unpaid accrued interest on any Note;

(b)The Company shall default in any of its material covenants or obligations set forth in this Agreement, which default is not cured within thirty (30) days following receipt of written notice thereof by the Requisite Noteholders;

(c)The Company shall make an assignment for the benefit of creditors, or shall admit in writing its inability to pay its debts as they become due, or shall file a voluntary petition for bankruptcy, or shall file any petition or answer seeking for itself any reorganization, arrangement, composition, readjustment, dissolution or similar relief under any present or future statute, law or regulation, or shall file any answer admitting the material allegations of a petition filed against the Company in any such proceeding, or shall seek or consent to or acquiesce in the appointment of any trustee, receiver or liquidator of the Company, or of all or any substantial part of the properties of the Company;

(d)Within sixty (60) days after the commencement of any proceeding against the Company seeking any bankruptcy reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any present or future statute, law or regulation, such proceeding shall not have been dismissed, or within sixty (60) days after the appointment without the consent or acquiescence of the Company of any trustee, receiver or liquidator of the Company or of all or any substantial part of the properties of the Company, such appointment shall not have been vacated;

(e)The Distribution (as defined in the Separation and Distribution Agreement) shall not have occurred by May 6, 2027; provided, however, that such date shall be automatically extended to August 6, 2027 if the registration statement registering the issuance of the securities in the Distribution remains under review by the SEC and the Company is continuing to use commercially reasonable efforts to cause such registration statement to become effective; or

(f) Any representation or warranty of the Company set forth in this Agreement shall not be true and correct in all material respects as of the date made if, and only if, the failure of such representation or warranty to be true and correct in all material respects as of such date would reasonably be expected to have a material adverse effect on the Company's business, financial condition or results of operations.

10.2 Remedies. Upon the occurrence of an Event of Default under Section 10.1 hereof, at the option and upon the declaration of the Requisite Noteholders, the entire unpaid principal and accrued and unpaid interest on the Notes shall, and upon written notice to the Company (which notice shall not be required in the case of an Event of Default under Section 10.1(c) or Section 10.1(d)), be forthwith due and payable, and the Requisite Noteholders may, immediately and without expiration of any period of grace, enforce payment of all amounts due and owing under the Notes and exercise any and all other remedies granted to them at law, in equity or otherwise.

11. Appointment of Agent; No Effect on the Obligations of the Company.

(a) The Lead Purchaser (the "**Collateral Agent**") is hereby appointed by the Purchasers (and their permitted successors and assigns) as the Collateral Agent hereunder and under the Notes (collectively, the "**Loan Documents**"), and each Purchaser hereby authorizes the Lead Purchaser to act as the Collateral Agent in accordance with the terms hereof and under each other Loan Document. The Collateral Agent hereby agrees to act in its capacity as such upon the

express conditions contained herein and the other Loan Documents, as applicable. The provisions of this Section 11 are solely for the benefit of the Collateral Agent and the Purchasers (and their permitted successors and assigns), and the Company shall not have any rights as a third party beneficiary of any of the provisions hereof or thereof. Each Purchaser shall ratably, in accordance with the aggregate outstanding principal amount of the Notes held by it, indemnify the Collateral Agent (to the extent not reimbursed by the Company) against any cost, expense (including outside counsel fees and disbursements), claim, demand, action, loss or liability (except such as result from the Collateral Agent's gross negligence, willful misconduct or a material breach of this Agreement) that the Collateral Agent may suffer or incur in connection with the Loan Documents or any action taken or omitted by the Collateral Agent hereunder or thereunder. The obligations of the Purchasers under this Section 11 shall survive the payment in full of the Obligations and the termination of this Agreement. This Section 11 sets forth the rights and obligations solely as between the Collateral Agent and the Purchasers, and nothing in this Section 11 creates any rights for the Company or releases the Company from its obligations under the Notes or this Agreement, including without limitation the obligation of the Company to reimburse the Purchasers for any payments made by the Purchasers to the Collateral Agent hereunder on the Company's behalf.

(b) Each Purchaser irrevocably authorizes the Collateral Agent to take such action on such Purchaser's behalf and to exercise such powers, rights, and remedies hereunder and under the other Loan Documents as are specifically delegated or granted to the Collateral Agent by the terms hereof and thereof, together with such powers, rights, and remedies as are incidental thereto. Each Purchaser hereby further irrevocably authorizes the Collateral Agent to act as the secured party under each of the Loan Documents. The Collateral Agent may exercise such powers, rights and remedies and perform such duties by or through its agents or employees and may consult with legal counsel, independent public accountants and other experts selected by it and shall not be liable for any action taken or omitted to be taken by it in good faith in accordance with the advice of such counsel, accountants or expert.

(c) Each Purchaser hereby agrees that any action taken by the Collateral Agent in accordance with the provisions of the Loan Documents, and the exercise by the Collateral Agent of the powers set forth herein or therein, together with such other powers as are incidental thereto, shall be authorized and binding upon all of the Purchasers. The Collateral Agent is hereby authorized on behalf of all of the Purchasers, without the necessity of any notice to or further consent from any Purchaser, from time to time, to take any action with respect to any Collateral or any Loan Document which may be necessary or appropriate to perfect and maintain perfected the Lien in the Collateral granted pursuant to the Loan Documents.

(d) The Collateral Agent shall have no obligation whatsoever to the Purchasers or to any other person or entity to assure that any Collateral exists or is owned by the Company or is cared for, protected or insured or that the Liens granted to the Collateral Agent herein or pursuant to the other Loan Documents have been properly or sufficiently or lawfully created, perfected, protected or enforced or are entitled to any particular priority, or to exercise or to continue exercising at all or in any manner or under any duty of care, disclosure or fidelity any of the rights, authorities and powers granted or available to the Collateral Agent in this Section 11 or in any of the Loan Documents, it being understood and agreed that in respect of the Collateral, or any act, omission or event related thereto, the Collateral Agent may act in any manner it may deem appropriate given the Collateral Agent's own interest in any Collateral as one of the Purchasers

(or an affiliate thereof) and that the Collateral Agent shall have no duty or liability whatsoever to the Purchasers, except for its gross negligence, willful misconduct or a material breach of this Agreement. Neither the Collateral Agent nor any of its directors, officers, partners, managers, agents or employees shall be responsible for or have any duty to ascertain, inquire into or verify (i) any statement, warranty or representation made in connection with any Loan Document or any borrowing hereunder; (ii) the performance or observance of any of the covenants or agreements specified in any Loan Document; (iii) the satisfaction of any condition specified in any Loan Document; (iv) the validity, effectiveness, sufficiency or genuineness of any Loan Document or any other instrument or writing furnished in connection therewith; (v) the existence or non-existence of any Event of Default; or (vi) the financial condition of the Company. Each Purchaser acknowledges that it has, independently and without reliance upon the Collateral Agent or any other Purchaser, and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into the Loan Documents to which it is a party. Each Purchaser also acknowledges that it will, independently and without reliance upon the Collateral Agent or any other Purchaser, and based on such documents and information as it shall deem appropriate at the time, continue to make its own credit decisions in taking or not taking any action under the Loan Documents to which it is a party.

(e) The Collateral Agent shall not be deemed to have knowledge or notice of the occurrence of any Event of Default, unless the Collateral Agent shall have received written notice from a Purchaser or the Company referring to the Loan Documents, describing such Event of Default and stating that such notice is a "notice of default". The Collateral Agent may at any time request instructions from the Requisite Noteholders with respect to any actions or approvals which by the terms of the Loan Documents the Collateral Agent is permitted or desires to take or to grant, and if such instructions are promptly requested, the Collateral Agent shall be absolutely entitled to refrain from taking any action or to withhold any approval and shall not be under any liability whatsoever to any person for refraining from any action or withholding any approval under any of the Loan Documents until it shall have received such instructions from the Purchasers. Without limiting the foregoing, no Purchaser shall have any right of action whatsoever against the Collateral Agent solely as a result of the Collateral Agent acting or refraining from acting under any of the Loan Documents, except with respect to its gross negligence, willful misconduct or a material breach of this Agreement.

(f) The Collateral Agent may at any time give notice of its resignation to the Purchasers and the Company. Upon receipt of any such notice of resignation, the Requisite Noteholders shall have the right to appoint a successor Collateral Agent. If no such successor shall have been so appointed by the Purchasers and shall have accepted such appointment within thirty (30) days after the retiring Collateral Agent gives notice of its resignation, then (a) the resignation of the Collateral Agent shall become effective on such thirtieth (30^{th}) day, (b) the Purchasers (acting by the Requisite Noteholders) shall perform the duties of the Collateral Agent under the Loan Documents until the Purchasers appoint a successor Collateral Agent and (c) the retiring Collateral Agent shall be discharged from its duties and obligations hereunder and under the other Loan Documents. Upon the acceptance of a successor's appointment as the Collateral Agent hereunder, such successor shall succeed to and become vested with all of the rights, powers, privileges and duties of the retiring (or retired) Collateral Agent, and the retiring Collateral Agent shall be discharged from all of its duties and obligations hereunder (if not already discharged therefrom as provided herein).

12. Miscellaneous.

12.1 Survival. The representations, warranties, covenants and agreements made herein shall survive the execution and delivery of this Agreement.

12.2 Successors and Assigns. Except as otherwise provided herein, the terms and conditions of this Agreement will inure to the benefit of, and be binding upon, the respective successors and assigns of the parties; provided, however, that (i) the Company may not assign its obligations under this Agreement without the written consent of the Requisite Noteholders and (ii) a Purchaser may not assign its obligations under this Agreement without the written consent of the Company, except to an affiliate of such Purchaser. This Agreement is for the sole benefit of the parties hereto and their respective successors and permitted assigns, and nothing herein, express or implied, is intended to or will confer upon any other person or entity any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

12.3 Governing Law. This Agreement and the Notes will be governed by and construed in accordance with the internal laws of the State of New York without giving effect to any choice or conflict of law provision or rule (whether of the State of New York or any other jurisdiction). Each party irrevocably and unconditionally submits to the jurisdiction of the courts of the State of New York and of the U.S. District Court for the Southern District of New York, in all actions or proceedings arising out of or relating to this Agreement and the Notes, and agrees that all actions or proceedings arising out of or relating to this Agreement may be litigated in any such state or federal court, and accordingly, each party irrevocably waives any objection which it may now or hereafter have to the laying of the venue of any such actions or proceedings in any such court.

12.4 Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will be deemed to be one and the same agreement. Counterparts may be delivered via email (including PDF or any electronic signature complying with the U.S. federal ESIGN Act of 2000, *e.g.*, www.docusign.com) or other transmission method, and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

12.5 Titles and Subtitles. The titles and subtitles used in this Agreement are included for convenience only and are not to be considered in construing or interpreting this Agreement.

12.6 Notices. All notices and other communications given or made pursuant hereto will be in writing and will be deemed effectively given: (a) upon personal delivery to the party to be notified; (b) when sent by email (if sent on a business day prior to 5:00 p.m. Eastern on such business day or, if not sent on a business day or if sent after 5:00 p.m. Eastern on such business day, on the next business day); (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications will be sent to the respective parties at the addresses shown on the signature pages hereto (or to such email address or other address as subsequently modified by written notice given in accordance with this Section 12.6).

12.7 No Finder's Fee. Each party represents that it neither is nor will be obligated to pay any finder's fee, broker's fee or commission in connection with the transactions contemplated by this Agreement. Each Purchaser agrees to indemnify and to hold the Company harmless from any liability for any commission or compensation in the nature of a finder's or broker's fee arising out of the transactions contemplated by this Agreement (and the costs and expenses of defending against such liability or asserted liability) for which such Purchaser or any of its officers, employees or representatives is responsible. The Company agrees to indemnify and hold each Purchaser harmless from any liability for any commission or compensation in the nature of a finder's or broker's fee arising out of the transactions contemplated by this Agreement (and the costs and expenses of defending against such liability or asserted liability) for which the Company or any of its officers, employees or representatives is responsible.

12.8 Expenses. Each party hereto shall pay its own costs and expenses that it incurs with respect to the negotiation, execution, delivery and performance of this Agreement.

12.9 Attorneys' Fees. If any action at law or in equity is necessary to enforce or interpret the terms of this Agreement, the prevailing party will be entitled to reasonable attorneys' fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.

12.10 Entire Agreement; Amendments and Waivers. This Agreement, the Notes and the other documents delivered pursuant hereto constitute the full and entire understanding and agreement between the parties with regard to the subjects hereof and thereof. The Company's agreements with each of the Purchasers are separate agreements, and the sales of the Notes to each of the Purchasers are separate sales. Notwithstanding the foregoing, any term of this Agreement or the Notes may be amended and the observance of any term of this Agreement or the Notes may be waived (either generally or in a particular instance and either retroactively or prospectively) with the written consent of the Company and the Requisite Noteholders; provided, that, any such amendment or waiver treats all Purchasers equally. Any waiver or amendment effected in accordance with this Section 12.10 will be binding upon each party to this Agreement and each holder of a Note purchased under this Agreement then outstanding and each future holder of all such Notes.

12.11 Effect of Amendment or Waiver. Each Purchaser acknowledges and agrees that by the operation of Section 12.10 hereof, the Requisite Noteholders will have the right and power to diminish or eliminate all rights of such Purchaser under this Agreement and each Note issued to such Purchaser.

12.12 Severability. If one or more provisions of this Agreement are held to be unenforceable under applicable law, such provisions will be excluded from this Agreement and the balance of the Agreement will be interpreted as if such provisions were so excluded and this Agreement will be enforceable in accordance with its terms.

12.13 Transfer Restrictions.

(a) Further Limitations on Disposition. Without in any way limiting the representations and warranties set forth in this Agreement, each Purchaser agrees not to

make any disposition of all or any portion of the Securities unless and until the transferee has agreed in writing for the benefit of the Company to make the representations and warranties set out in Section 7 and:

(i) there is then in effect a registration statement under the Securities Act covering such proposed disposition, and such disposition is made in connection with such registration statement; or

(ii) such Purchaser has (A) notified the Company of the proposed disposition; (B) furnished the Company with a detailed statement of the circumstances surrounding the proposed disposition; and (C) if requested by the Company, furnished the Company with an opinion of counsel reasonably satisfactory to the Company that such disposition will not require registration under the Securities Act (which opinion of counsel will not be required in connection with any transfer to an affiliate of such Purchaser).

(b)Legends. Each Purchaser understands and acknowledges that the Securities may bear the following legend:

THIS INSTRUMENT AND THE SECURITIES ISSUABLE UPON THE CONVERSION HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"). THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT OR UPON RECEIPT BY THE COMPANY OF AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT REGISTRATION IS NOT REQUIRED UNDER THE ACT.

12.14 Exculpation among Purchasers. Each Purchaser acknowledges that it is not relying upon any person, firm, corporation or stockholder, other than the Company and its officers and directors in their capacities as such, in making its investment or decision to invest in the Company. Each Purchaser agrees that no other Purchaser, nor the controlling persons, officers, directors, partners, agents, stockholders or employees of any other Purchaser, will be liable for any action heretofore or hereafter taken or not taken by any of them in connection with the purchase and sale of the Securities.

12.15 Further Assurances. From time to time, the parties will execute and deliver such additional documents and will provide such additional information as may reasonably be required to carry out the terms of this Agreement and the Notes and any agreements executed in connection herewith or therewith.

12.16 Pari Passu Notes. Each Purchaser acknowledges and agrees that any cash payment of the Notes made, in accordance with the terms of this Agreement, shall be made to all Purchasers on a pro rata basis based on the respective indebtedness then due and owing under their respective Notes. In the event any Purchaser receives cash payments in excess of its *pro rata* share, then such Purchaser shall hold in trust all such excess payments for the

benefit of the holders of the other Notes and shall pay such amounts held in trust to such other holders upon demand by such holders.

12.17 Waiver of Jury Trial. EACH PARTY HEREBY WAIVES ITS RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, THE SECURITIES OR THE SUBJECT MATTER HEREOF OR THEREOF. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL-ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS TRANSACTION, INCLUDING, WITHOUT LIMITATION, CONTRACT CLAIMS, TORT CLAIMS (INCLUDING NEGLIGENCE), BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. THIS SECTION HAS BEEN FULLY DISCUSSED BY EACH OF THE PARTIES HERETO AND THESE PROVISIONS WILL NOT BE SUBJECT TO ANY EXCEPTIONS. EACH PARTY HERETO HEREBY FURTHER REPRESENTS AND WARRANTS THAT SUCH PARTY HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL, AND THAT SUCH PARTY KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

[*SIGNATURE PAGES FOLLOW*]

IN WITNESS WHEREOF, the parties hereto have executed this Secured Convertible Note Purchase Agreement as of the date set forth above.

COMPANY:

ADRENYX BIOSCIENCES, INC.

By: /s/ Samir Gharib
Name: Samir Gharib
Title: President and Chief Executive Officer

Address: 611 Gateway Boulevard, Suite 740
South San Francisco, CA 94080

Email Address: [***]

IN WITNESS WHEREOF, the parties hereto have executed this Secured Convertible Note Purchase Agreement as of the date set forth above.

[***]

By: _____
Name: [***]
Title: Member

Address: [***]

Email Address: [***]

[***]

By: _____
Name: [***]
Title: [***]

Address: [***]

Email Address: [***]

SCHEDULE A

SCHEDULE OF PURCHASERS

Initial Closing Date: November 6, 2026

Lead Purchaser: [***]

Purchaser	Consideration and Principal Amount of Promissory Note	Commitment
[***]	[***]	[***]
[***]	[***]	[***]
TOTAL	**$5,000,000**	

Subsequent Closing Date:

Purchaser	Consideration and Principal Amount of Promissory Note
TOTAL	**$**

EXHIBIT A

Form of Secured Convertible Promissory Note

THIS INSTRUMENT AND THE SECURITIES ISSUABLE UPON CONVERSION HEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"). THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT OR UPON RECEIPT BY THE COMPANY OF AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY THAT REGISTRATION IS NOT REQUIRED UNDER THE ACT.

SECURED CONVERTIBLE PROMISSORY NOTE

No. CN-[NUMBER]	**Date of Issuance**
US$[PRINCIPAL AMOUNT]	[_____ __], 202[_]

FOR VALUE RECEIVED, Adrenyx Biosciences, Inc., a Delaware corporation (the "**Company**"), hereby promises to pay to the order of **[PURCHASER NAME]** (the "**Holder**"), the principal sum of US$**[PRINCIPAL AMOUNT]**, together with interest thereon from the date of this Note. Interest shall accrue on the outstanding principal amount of this Note at a rate of six percent (6.0%) per annum, computed on the basis of a 365-day year and the actual number of days elapsed. Interest shall accrue from and including the Date of Issuance to but excluding the date on which this Note is paid in full or converted in accordance with Section 4 of the Purchase Agreement (as defined below). Unless earlier converted into Conversion Securities pursuant to Section 4 of that certain Secured Convertible Note Purchase Agreement dated November 6, 2026, by and among the Company, the Holder and the other parties thereto (the "**Purchase Agreement**"), the principal and accrued interest of this Note will be due and payable on or after the Maturity Date upon demand by the Requisite Noteholders or, following an Extraordinary Corporate Transaction, in accordance with Section 5 of the Purchase Agreement.

This Note is one of a series of Notes issued pursuant to the Purchase Agreement, and capitalized terms not defined herein will have the meanings set forth in the Purchase Agreement (or, if not defined therein, in the Code).

13. Payment. Unless this Note is converted into Conversion Securities, all payments will be made in lawful money of the United States of America at the principal office of the Company, or at such other place as the Holder may from time to time designate in writing to the Company. Payment will be credited first to accrued interest due and payable, with any remainder applied to principal. Prepayment of the Notes may not be made without the written consent of the Requisite Noteholders, except as otherwise permitted under the Purchase Agreement.

14. Security. This Note is secured by the Collateral.

15. Conversion of the Notes. This Note and any amounts due hereunder will be convertible into Conversion Securities in accordance with the terms of Section 4 of the Purchase Agreement.

16. Amendments and Waivers; Resolutions of Dispute; Notice. The amendment or waiver of any term of this Note, the resolution of any controversy or claim arising out of or relating to this Note and the provision of notice among the Company and the Holder will be governed by the terms of the Purchase Agreement.

17. Successors and Assigns. This Note applies to, inures to the benefit of, and binds the respective successors and assigns of the parties hereto; provided, however, that the Company may not assign its obligations under this Note without the written consent of the Holder. Any assignment by the Holder is subject to Section 12.2 of the Purchase Agreement. Any transfer of this Note may be effected only pursuant to the Purchase Agreement and by surrender of this Note to the Company and reissuance of a new note to the transferee. The Holder and any subsequent holder of this Note receives this Note subject to the foregoing terms and conditions, and agrees to comply with the foregoing terms and conditions for the benefit of the Company and any other Purchasers (or their respective successors or assigns).

18. Officers and Directors not Liable. In no event will any officer or director of the Company be liable for any amounts due and payable pursuant to this Note.

19. Limitation on Interest. In no event will any interest charged, collected or reserved under this Note exceed the maximum rate then permitted by applicable law, and if any payment made by the Company under this Note exceeds such maximum rate, then such excess sum will be credited by the Holder as a payment of principal.

20. Governing Law. This Note will be governed by and construed in accordance with the internal laws of the State of New York without giving effect to any choice or conflict of law provision or rule (whether of the State of New York or any other jurisdiction); provided that the perfection and priority of the Lien in the Collateral shall be governed by the Uniform Commercial Code as in effect in the State of Delaware. The Company irrevocably and unconditionally submits to the jurisdiction of the courts of the State of New York and of the U.S. District Court for the Southern District of New York, in all actions or proceedings arising out of or relating to this Note, and agrees that all actions or proceedings arising out of or relating to this Note may be litigated in any such state or federal court, and accordingly, the Company irrevocably waives any objection which it may now or hereafter have to the laying of the venue of any such actions or proceedings in any such court.

21. Conflicting Provisions. In the event of any conflict between the terms of the Purchase Agreement and this Note, the terms of the Purchase Agreement shall control.

Adrenyx Biosciences, Inc.

By:_____
Name: Samir Gharib
Title: President and Chief Executive Officer

Exhibit 31.1

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

I, 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: November 9, 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: November 9, 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 September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 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: November 9, 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 September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 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: November 9, 2026

By: */s/ Samir Gharib*

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