Spruce Biosciences Reports Third Quarter 2026 Financial Results and Provides Corporate Updates

November 9, 2026

Biologics License Application ("BLA") Submission for Tralesinidase Alfa Enzyme Replacement Therapy ("TA-ERT") for the Treatment of MPS IIIB Remains on Track for December 2026

Amended Avenue Loan Agreement to Increase Tranche 2 Availability to $15 Million and Extend Interest-Only Period

Announced Separation of CRHX-101 (Formerly SPR-202) Program into Adrenyx Biosciences

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 9, 2026-- Spruce Biosciences, Inc. (Nasdaq: SPRB), a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for neurological disorders with significant unmet medical need, today reported financial results for the third quarter ended September 30, 2026, and provided corporate updates.

"We are executing with discipline as we complete the final steps toward our planned BLA submission for TA-ERT in December, which we believe will be a defining milestone for Spruce and for the children and families living with MPS IIIB," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. "Our pre-BLA meetings with the FDA in the second quarter provided alignment on the content and format of the BLA, and we remain on track to complete our second Process Performance Qualification ("PPQ") batch and initiate our TrAnsform confirmatory study as planned in December."

"We have also taken deliberate steps to strengthen our balance sheet and sharpen our strategic focus," continued Dr. Szwarcberg. "Our amended Avenue Loan Agreement expands our near-term access to debt capital and extends our interest-only period, giving us added financial flexibility as we move through BLA review and prepare for a potential U.S. commercial launch. At the same time, the separation of CRHX-101 (formerly SPR-202) into Adrenyx Biosciences creates a dedicated company with its own financing, allowing us to concentrate our capital and focus our team entirely on TA-ERT, while enabling our shareholders to retain a direct stake in the potential of CRHX-101 through the planned stock distribution. We believe these actions position us to unlock value for our shareholders while we work to bring the first FDA-approved therapy to families with MPS IIIB."

TA-ERT Program Updates

- **BLA submission for TA-ERT for the treatment of MPS IIIB remains on track for December 2026:** Spruce anticipates submitting a BLA in December 2026 seeking accelerated approval of TA-ERT for the treatment of mucopolysaccharidosis type IIIB ("MPS IIIB"), or Sanfilippo Syndrome Type B, based on reduction of cerebrospinal fluid heparan sulfate non-reducing end ("CSF HS-NRE") as a reasonably likely surrogate endpoint of clinical benefit. If approved, TA-ERT may be eligible for a rare pediatric disease priority review voucher. There is currently no FDA-approved therapy for the treatment of MPS IIIB, and disease management consists of limited supportive care.
- **U.S. TA-ERT Expanded Access Program ("EAP") initiated in November 2026:** The open-label, single-arm EAP designed to provide TA-ERT to children in the United States with attenuated and severe MPS IIIB who are not eligible to enroll in the TrAnsform confirmatory study was initiated in November 2026 and is expected to enroll approximately 10 participants. The EAP is being partially funded by the $5.5 million strategic investment from Cure Sanfilippo Foundation and the National MPS Society completed in August 2026. In August 2026, Spruce also launched MPS3BStudy.com, a resource for families and caregivers of children with MPS IIIB to learn about the EAP and the TrAnsform confirmatory study and to register to receive updates as U.S. sites activate and enrollment begins. More information about the EAP can be found at ClinicalTrials.gov.
- **Second PPQ batch on track for December 2026:** Spruce completed the first PPQ batch in July 2026, which will be included in the BLA, and expects to complete the second PPQ batch in December 2026, for submission ahead of the anticipated U.S. Food and Drug Administration ("FDA") mid-cycle review.
- **TrAnsform confirmatory study on track to initiate in December 2026:** The planned TrAnsform confirmatory study 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. The study is expected to enroll approximately 14 participants, with the primary objective of evaluating the effect of TA-ERT on cognition. As a condition of potential FDA accelerated approval of TA-ERT, the FDA requested that Spruce initiate the TrAnsform confirmatory study while the planned BLA submission for TA-ERT is under review. More information about the TrAnsform confirmatory study can be found at ClinicalTrials.gov.
- **MPS IIIB natural history data presented at the 55th Child Neurology Society Annual Meeting:** In October 2026, data from Study 250-902, a prospective, multicenter, multinational, noninterventional, longitudinal natural history study of pediatric participants with severe, non-attenuated MPS IIIB, were presented in a poster titled: "*In-depth analyses of cognition, motor, communication, and adaptive natural history disease course in participants with MPS IIIB*."

Amendment to Avenue Loan Agreement

On November 6, 2026, Spruce entered into an amendment (the “Avenue Amendment”) to its loan and security agreement (the “Avenue Loan Agreement”) with Avenue Capital Management II, L.P. and Avenue Venture Opportunities Fund II, L.P. (together, “Avenue”), which, among other things, (i) increased the amount available under Tranche 2 to up to $15.0 million, which may be drawn between January 1, 2027 and March 31, 2027, subject to the satisfaction of certain conditions; (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 Avenue’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 and, thereafter, through October 31, 2028, in each case subject to the satisfaction of certain conditions.

Separation of CRHX-101 Program into Adrenyx Biosciences

On November 6, 2026, Spruce separated the company’s CRHX-101 (formerly SPR-202) program, an anti-corticotropin-releasing hormone monoclonal antibody, into Adrenyx Biosciences, Inc. (“Adrenyx”), a newly formed wholly-owned subsidiary of Spruce (the “Separation”), and Spruce and Adrenyx entered into a separation and distribution agreement and a transition services agreement. Pursuant to these agreements, Spruce contributed to Adrenyx assets and liabilities relating to the CRHX-101 program effective as of November 6, 2026. Spruce currently intends to distribute all of the outstanding shares of Adrenyx common stock to Spruce stockholders on a pro rata basis (the “Distribution”), in a transaction that is intended to result in two independent public companies. Spruce agreed to provide specified services to Adrenyx for a period of up to 12 months following the completion of the Distribution, subject to extension, compensated by Adrenyx at Spruce’s cost without markup. The transaction is intended to enable each of Spruce and 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 aggregate principal amount was issued at the initial closing on November 6, 2026. Issuance of the remaining notes in subsequent closings is subject to certain terms and conditions set forth in the secured convertible note purchase agreement, including consent of the investor. 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, and Spruce is not permitted to use any such proceeds to fund its own operations.

Spruce’s board of directors has not yet approved the Distribution or set a record date for the Distribution. Prior to the Distribution, Adrenyx will operate as a controlled subsidiary of Spruce. 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 (with up to $50 million funded by the convertible notes investor, inclusive of their note funding), subject to the satisfaction or waiver of certain conditions set forth in the separation and distribution agreement, including the approval of the Distribution by Spruce’s board of directors, the effectiveness of a registration statement to be filed by Adrenyx with the U.S. Securities and Exchange Commission (“SEC”), and approval of the listing of Adrenyx common stock on Nasdaq. Approval by Spruce stockholders is not required as a condition to the consummation of the Distribution. The Distribution is expected to be a taxable transaction for U.S. federal income tax purposes. There can be no assurance that the Distribution, any subsequent closing of Adrenyx notes or the private placement will be completed on the anticipated timeline, on the anticipated terms, or at all.

Third Quarter 2026 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of September 30, 2026 were $87.7 million, compared to $48.9 million as of December 31, 2025. Spruce believes that its cash and cash equivalents as of September 30, 2026 will be sufficient to fund its planned operations and debt obligations into the second half of 2027.
- **Research and Development (“R&D”) Expenses:** R&D expenses were $18.1 million for the third quarter of 2026, compared to $5.0 million for the third quarter of 2025, and $37.9 million for the first nine months of 2026, compared to $15.4 million for the first nine months of 2025. The increases were primarily attributable to increased expenses to advance TA-ERT, including manufacturing and clinical development, partially offset by lower one-time product acquisition costs and the discontinuation of the tildacerfont congenital adrenal hyperplasia development program.
- **General and Administrative (“G&A”) Expenses:** G&A expenses were $5.8 million for the third quarter of 2026, compared to $3.2 million for the third quarter of 2025, and $14.6 million for the first nine months of 2026, compared to $10.0 million for the first nine months of 2025. The increases were primarily due to increased personnel-related costs and professional fees to support the company’s growth, pre-launch activities and the Separation and Distribution.
- **Total Operating Expenses:** Total operating expenses were $24.0 million for the third quarter of 2026, compared to $8.2 million for the third quarter of 2025, and $52.5 million for the first nine months of 2026, compared to $25.4 million for the first nine months of 2025. Operating expenses include non-cash stock-based compensation expense of $1.1 million and $2.7 million for the three and nine months ended September 30, 2026, respectively.
- **Net Loss:** Net loss was $24.0 million, or $(8.51) per basic and diluted share, for the third quarter of 2026, compared to $8.2 million, or $(14.58) per basic and diluted share, for the third quarter of 2025. Net loss was $52.5 million, or $(23.71) per basic and diluted share, for the first nine months of 2026, compared to $24.3 million, or $(41.25) per basic and diluted share, for the first nine months of 2025.

About Spruce Biosciences

Spruce Biosciences is a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for neurological disorders with significant unmet medical need. Spruce’s lead product candidate, tralesinidase alfa enzyme replacement therapy (“TA-ERT”), is in late-stage development for the treatment of mucopolysaccharidosis type IIIB (“MPS IIIB”), or Sanfilippo Syndrome Type B, a devastating pediatric neurodegenerative disorder for which there are no FDA-approved therapies. TA-ERT has received Breakthrough Therapy Designation, Rare Pediatric Disease Designation, Fast Track Designation and Orphan Drug Designation from the FDA, as well as Orphan Drug Designation in the European

Union. To learn more, visit www.sprucebio.com and follow us on X, LinkedIn, Facebook and YouTube.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the expected timing of a planned BLA submission for TA-ERT for the treatment of MPS IIIB and the pathway to potential accelerated approval, including potential eligibility for a rare pediatric disease priority review voucher; the expected timing of completion of the second PPQ batch and subsequent submission of the related data; the expected timing, enrollment and conduct of the TrAnsform confirmatory study and the TA-ERT Expanded Access Program; the planned Distribution of Adrenyx common stock to Spruce stockholders, including the anticipated timing, structure, terms, conditions, tax treatment and benefits thereof; the anticipated financing of Adrenyx, including potential additional note issuances and the anticipated private placement of Adrenyx equity securities; the anticipated listing of Adrenyx common stock on Nasdaq; Adrenyx’s ability to pursue its strategic priorities; the availability of additional borrowings under, and potential extensions of the interest-only period of, the amended Avenue Loan Agreement; Spruce’s expectations regarding the sufficiency of its cash and cash equivalents to fund its planned operations and debt obligations into the second half of 2027; Spruce’s plans to advance TA-ERT through potential FDA approval and commercialization, if approved, including a potential U.S. commercial launch; and expectations regarding Spruce’s product candidate, strategy and regulatory matters. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as “anticipate,” “will,” “potential,” “plan,” “expect,” “believe,” “intend” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Spruce’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with Spruce’s business in general, Spruce’s need for substantial additional capital and its ability to continue as a going concern, risks related to the Separation and the Distribution, the impact of geopolitical and macroeconomic events, and the other risks described in Spruce’s filings with the U.S. Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management’s assumptions and estimates as of such date. Spruce undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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		
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

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

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