Spruce Biosciences Reports Full Year 2025 Financial Results and Provides Corporate Updates

March 9, 2026

Following Positive Type B Meetings with the FDA, BLA Submission for TA-ERT for the Treatment of Sanfilippo Syndrome Type B (MPS IIIB) on Track for the Fourth Quarter of 2026

Appoints Dale Hooks as Chief Commercial Officer, Strengthening the Company's Commercial Capabilities in Preparation for a Potential Launch of TA-ERT

Secured up to $50 Million in Growth Capital from Avenue Capital Group

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 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 year ended December 31, 2025 and provided corporate updates.

"2025 was a very productive year, and our team continues to execute and drive towards key milestones with our tralesinidase alfa enzyme replacement therapy (TA-ERT) program, especially our planned biologics license application (BLA) submission in the fourth quarter of this year and potential commercial launch in MPS IIIB," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. "Our recent productive interactions with the FDA have provided clear next steps that strengthen our conviction in the development of TA-ERT for patients and families living with MPS IIIB, for which currently there are no approved therapies. Our appointment of Dale Hooks as Chief Commercial Officer further reflects our conviction and commitment to building our capabilities and commercial infrastructure, as we position ourselves to capitalize on the next chapter of growth at Spruce."

Recent Corporate Updates

- ***Held Positive Type B Meetings with the FDA.*** In February 2026, the company announced the successful completion of two Type B meetings with the FDA regarding its planned upcoming BLA submission for TA-ERT for the treatment of MPS IIIB. The FDA confirmed that the integrated study data from interventional clinical studies of TA-ERT and the available natural history data could potentially serve as an adequate and well-controlled study for purposes of the FDA's review of the effects of TA-ERT on cerebral spinal fluid heparan sulfate non-reducing end, which could serve as a reasonably likely surrogate endpoint of clinical benefit supporting an accelerated approval. The BLA submission for TA-ERT is anticipated in the fourth quarter of 2026.

- ***Appointed Dale Hooks, an Accomplished Rare Disease Commercial Leader, as Chief Commercial Officer.*** Today, the company announced the appointment of Dale Hooks as Chief Commercial Officer, who brings over three decades of biopharmaceutical marketing and commercialization expertise to drive the potential commercial launch of TA-ERT.

- ***Secured Up to $50 million in Growth Capital from Avenue Capital.*** In January 2026, the company entered into a loan facility for up to $50 million in growth capital to support the continued advancement and potential commercial launch of TA-ERT. The loan facility has a 42-month term and includes an initial tranche of $15 million, which was fully funded in January 2026, and three additional tranches totaling up to $35 million, subject to the satisfaction of certain terms and conditions of the loan and security agreement.

- ***Presented Long-term Data of TA-ERT at the 22nd Annual WORLDSymposium™.*** In February 2026, data from two different analyses were presented highlighting TA-ERT as potentially the first disease-modifying treatment option for MPS IIIB. One presentation showed that long-term administration of TA-ERT resulted in rapid and durable reduction of heparan sulfate and preserved cognitive and non-cognitive clinical outcomes in patients with MPS IIIB relative to natural history patients. The second presentation included analyses of two siblings diagnosed with MPS IIIB showing that, in an age-matched comparison, one sibling treated with TA-ERT appeared to display higher cognitive, language, and motor functioning relative to the untreated sibling at a similar age. For more information, the two poster presentations can be found on the Spruce Biosciences website at https://investors.sprucebio.com/news-and-events/presentations.

- ***Added Regulatory and Clinical Development Expertise to the Executive Leadership Team.*** In February 2026, the company appointed Daven Mody, Pharm.D., as Senior Vice President, Regulatory and Quality, and Bruno Gagnon, B.Pharm., M.Sc., as Senior Vice President, Clinical Development Operations.

- ***Reauthorization of the Rare Pediatric Disease Priority Review Voucher (PRV) Program.*** In February 2026, the PRV program was reauthorized through September 30, 2029. This five-year extension restores a key incentive to develop therapies for rare pediatric diseases, allowing companies to receive a fast-track review voucher for approved drugs.

TA-ERT has secured Rare Pediatric Disease Designation and is eligible for a PRV, if approved by the FDA.

- ***Appointed Keli Walbert, a Proven Pharmaceutical Commercial Leader, to the Board of Directors.*** In December 2025, the company appointed Keli Walbert to its Board of Directors. Ms. Walbert has decades of commercial leadership experience and a proven track record of successful product launches in rare diseases.

Full Year 2025 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of December 31, 2025 were $48.9 million, which excludes the receipt of $15.0 million in gross proceeds under the loan facility with Avenue Capital. The company expects its cash and cash equivalents to fund its current operating plan into early 2027, beyond the anticipated BLA submission for TA-ERT.
- **Research and Development (R&D) Expenses:** R&D expenses for the year ended December 31, 2025 were $19.5 million compared to $46.4 million for the same period in 2024. The decrease in R&D expenses was primarily related to the cessation of development activities of tildacerfont for the treatment of congenital adrenal hyperplasia (CAH), offset by development activities related to TA-ERT for the treatment of MPS IIIB and the acquisition of SPR202, an anti-corticotropin releasing hormone monoclonal antibody for the treatment of CAH.
- **General and Administrative (G&A) Expenses:** G&A expenses for the year ended December 31, 2025 were $17.0 million compared to $14.6 million for the same period in 2024, primarily driven by increased professional service fees, offset by a decrease in stock-based compensation expense.
- **Total Operating Expenses:** Total operating expenses for the year ended December 31, 2025 were $36.5 million compared to $61.1 million for the same period in 2024. Operating expenses include non-cash stock-based compensation expenses of $2.6 million for the year ended December 31, 2025 compared to $5.3 million for the same period in 2024.

  Net Loss: Net loss for the year ended December 31, 2025 was $39.0 million compared to $53.0 million for the same period in 2024.

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. 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 ability to seek accelerated approval of TA-ERT for MPS IIIB based on existing clinical data; the content, timing and likelihood of regulatory filings and approvals for TA-ERT, including advancing this program through a BLA submission and potential FDA approval; the potentially transformative clinical impact for TA-ERT; TA-ERT’s eligibility for a PRV; and TA-ERT’s potential to be the first disease-modifying therapy to treat MPS IIIB. 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,” “could,” “potential,” “on track,” “expect,” 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, 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 BIOSCIENCES, INC.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31,	
	2025	**2024**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 48,906	$ 38,753
Prepaid expenses	353	3,177
Other current assets	2,853	2,276
Total current assets	52,112	44,206
Right-of-use assets	666	934
Other assets	243	69
Total assets	$ 53,021	$ 45,209
LIABILITIES AND STOCKHOLDERS’ EQUITY		

Current liabilities:		
Accounts payable	$ 943	$ 1,295
Accrued expenses and other current liabilities	9,143	12,329
Term loan, current portion	—	1,622
Total current liabilities	10,086	15,246
Lease liabilities, net of current portion	419	736
Term loan, net of current portion	—	124
Other liabilities	—	282
Total liabilities	10,505	16,388
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of December 31, 2025 and 2024	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of December 31, 2025 and 2024; 1,372,043 and 563,042 shares issued and outstanding as of December 31, 2025 and 2024, respectively	—	—
Additional paid-in capital	331,750	279,089
Accumulated deficit	(289,234)	(250,268)
Total stockholders' equity	42,516	28,821
Total liabilities and stockholders' equity	$ 53,021	$ 45,209

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

	Year Ended December 31,	
	2025	**2024**
Collaboration revenue	$ —	$ 4,911
Operating expenses:		
Research and development	19,522	46,418
General and administrative	16,991	14,644
Total operating expenses	36,513	61,062
Loss from operations	(36,513)	(56,151)
Interest expense	(90)	(307)
Change in fair value of warrant liability	(3,500)	—
Interest and other income, net	1,137	3,422
Net loss and comprehensive loss	(38,966)	(53,036)
Net loss per share, basic and diluted	$ (50.83)	$ (96.40)
Weighted-average shares of common stock outstanding, basic and diluted	766,598	550,146

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