



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

May 13, 2026

Long-Term TA-ERT Data Presented at the 22nd Annual WORLDSymposium™ Highlight Rapid and Durable Reduction of Heparan Sulfate and Stabilization of Cognitive Function in Patients with MPS IIIB

Strengthened Leadership Team Across Commercial, Clinical Development, and Regulatory Functions to Support BLA Submission and Pre-Launch Readiness

Closed Underwritten Public Offering for \$69.0 Million in Gross Proceeds, Extending Cash Runway into the Second Half of 2027 and Beyond Anticipated Potential FDA Approval of TA-ERT

Entered into Loan and Security Agreement with Avenue Capital for up to \$50.0 Million in Term Loans to Strengthen Financial Flexibility Ahead of Potential U.S. Commercial Launch

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 13, 2026-- [Spruce Biosciences, Inc.](https://www.sprucebio.com) (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 first quarter ended March 31, 2026 and provided corporate updates.

"We are very pleased with the meaningful progress we continue to make in advancing TA-ERT toward our planned biologics license application submission in the fourth quarter of 2026. This would mark a transformative milestone for Spruce and, more importantly, for the children living with MPS IIIB," said Javier Swarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. "In April, our balance sheet was meaningfully strengthened with the closing of our \$69.0 million underwritten public offering, which was in addition to our \$50.0 million term loan facility signed with Avenue Capital in January, and we are now well positioned to support TA-ERT through key regulatory milestones and to prepare for a potential commercial launch in the United States next year. I want to thank our entire team at Spruce for their tremendous efforts and am also grateful for the continued support from our Board, shareholders, and, most importantly, from the families and patients living with MPS IIIB. We look forward to making a meaningful difference in patients' lives."

TA-ERT Program Updates

- **Continued progress toward BLA submission for TA-ERT for the treatment of MPS IIIB:** Spruce continues to advance manufacturing readiness, regulatory interactions, and commercial planning to support an anticipated BLA submission in the fourth quarter of 2026. There is currently no FDA-approved therapy for the treatment of MPS IIIB, and disease management consists of limited palliative care.
- **Long-term TA-ERT data presented at the 22nd Annual WORLDSymposium™:** At the February 2026 22nd Annual WORLDSymposium™, Spruce shared long-term clinical data supporting TA-ERT as a potential first disease-modifying treatment option for patients with MPS IIIB.

In a platform presentation on February 5, 2026, titled "Long-term administration of tralesenidase alfa enzyme replacement therapy (TA-ERT) results in profound and durable reduction of heparan sulfate (HS) and stabilization of cognitive function and cortical gray matter volume (CGMV) in patients with Sanfilippo Syndrome Type B (MPS IIIB)," Nicole Muschol, M.D., of the International Center for Lysosomal Disorders at the University Medical Center Hamburg-Eppendorf, presented data demonstrating that long-term administration of TA-ERT resulted in rapid and durable reductions in cerebrospinal fluid heparan sulfate, with stabilization of cognitive function and cortical gray matter volume relative to natural history.

- **Confirmatory study and expanded access:** Spruce continues to advance plans for a confirmatory study in patients with MPS IIIB and expanded access program to support continued patient access prior to and following potential approval.

Building Out Commercial Leadership Team and Capabilities

To prepare for a potential U.S. commercial launch of TA-ERT, if approved, Spruce continued to build out its rare disease commercial organization with three senior appointments:

- **Dale Hooks, Chief Commercial Officer:** Mr. Hooks joined Spruce as Chief Commercial Officer in March 2026, bringing nearly 35 years of pharmaceutical marketing and sales experience and commercial leadership across 21 new product launches. He previously served as Chief Commercial Officer of Applied Therapeutics, and earlier as Vice President, Global Commercial Operations at Reata Pharmaceuticals, where he helped lead one of the most successful rare disease launches in U.S. history.
- **Brian Walls, Vice President, Market Access:** Mr. Walls brings more than 20 years of biopharmaceutical commercial leadership experience and has contributed to more than 18 product launches across rare, ultra-rare, oncology, neurology, and metabolic disease indications. Most recently, he served as Vice President, Market Access at Applied Therapeutics,

where he architected the U.S. commercialization access platform for ultra-rare neurology assets.

- **Darren Johnson, Vice President, Commercial Operations:** Mr. Johnson brings nearly two decades of biopharmaceutical commercial leadership experience in market planning, analytics, and operations, with expertise in rare disease launch readiness. He previously served as Senior Director, Global Commercial Analytics at BioMarin Pharmaceutical, where he led commercial analytics and operations for a global rare disease business with product sales in 72 countries. Earlier in his career, he held positions of increasing responsibility at Genentech, most recently as Group Manager, Forecasting & Business Analysis.

Strengthening Clinical Development Capabilities

In February 2026, Spruce expanded its leadership team with two senior appointments to deepen the company's clinical development, regulatory, and quality capabilities in support of the planned TA-ERT BLA submission and potential FDA approval:

- **Bruno Gagnon, B.Pharm., M.Sc., Senior Vice President, Clinical Development Operations:** Mr. Gagnon brings more than 30 years of experience leading clinical operations for global drug development programs. He most recently served as Senior Vice President, Global Clinical Operations at Opthea, where he oversaw clinical execution for a Phase 3 wet age-related macular degeneration program, and previously led development operations at Eidos Therapeutics, a BridgeBio Pharma affiliate, where he played a key role in advancing acoramidis (ATTRUBY®) for the treatment of TTR amyloidosis toward regulatory approval. Earlier, Mr. Gagnon served as Vice President of Clinical Operations at BioMarin Pharmaceutical, directing rare disease clinical programs and global trial execution across multiple development-stage compounds.
- **Daven Mody, Pharm.D., Senior Vice President, Regulatory and Quality:** Dr. Mody brings more than 25 years of regulatory affairs experience guiding global development programs across multiple therapeutic areas, including rare diseases. He most recently held senior regulatory affairs and quality leadership roles at Lassen Therapeutics, Ocelot Bio, and Blade Therapeutics, where he led investigational programs across ophthalmologic, hepatic, pulmonary, and oncology indications and helped secure multiple orphan drug and fast track designations. Earlier in his career, Dr. Mody served as Head of Regulatory Affairs at Theravance Biopharma and Impax Laboratories, where he led efforts in the first-round U.S. and E.U. approvals of YUPELRI® for COPD and RYTARY® for Parkinson's Disease.

Other Corporate Updates

- **Closed Underwritten Public Offering:** On April 22, 2026, Spruce closed its previously announced underwritten public offering of 1,150,000 shares of common stock at a public offering price of \$50.00 per share and pre-funded warrants to purchase up to 50,000 shares of common stock at a public offering price of \$49.99 per pre-funded warrant. The underwriters' 30-day option to purchase up to 180,000 additional shares of common stock was exercised in full. Aggregate gross proceeds to Spruce from the offering were approximately \$69.0 million, before deducting underwriting discounts and commissions and estimated offering expenses payable by the company.
- **Term Loan Facility with Avenue Capital:** On January 7, 2026, Spruce entered into a Loan and Security Agreement with Avenue Capital Management II, L.P., providing for term loans of up to \$50.0 million across four tranches. Tranche 1 of \$15.0 million was funded shortly after closing, and the remaining tranches are subject to the achievement of specified regulatory and commercial milestones related to TA-ERT, among other conditions. The Avenue facility does not contain any minimum cash requirement or other financial covenants.
- **At-the-Market Sales Agreement:** In March 2026, Spruce entered into an Open Market Sales AgreementSM (Sales Agreement) with Jefferies, pursuant to which the company may issue and sell, from time to time, shares of common stock having an aggregate offering price of up to \$75.0 million under its effective shelf registration statement. As of March 31, 2026, no shares of common stock had been issued under the Sales Agreement.

First Quarter 2026 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of March 31, 2026 were \$54.1 million, compared to \$48.9 million as of December 31, 2025. Spruce believes that its cash and cash equivalents as of March 31, 2026, together with the net proceeds from its April 2026 underwritten public offering of common stock and pre-funded warrants, will be sufficient to fund its planned operations and debt obligations into the second half of 2027.
- **Research and Development (R&D) Expenses:** R&D expenses for the three months ended March 31, 2026 were \$7.6 million, compared to \$10.8 million for the same period in 2025. The decrease was primarily attributable to one-time product acquisition costs of \$5.7 million related to SPR202 and the discontinuation of the tildacerfont congenital adrenal hyperplasia development program of \$1.9 million, partially offset by increased expenses to advance TA-ERT.
- **General and Administrative (G&A) Expenses:** G&A expenses for the three months ended March 31, 2026 were \$4.4 million, compared to \$3.7 million for the same period in 2025. The increase was primarily attributable to higher professional fees and personnel-related costs.
- **Total Operating Expenses:** Total operating expenses for the three months ended March 31, 2026 were \$12.0 million, compared to \$14.5 million for the same period in 2025. Operating expenses include non-cash stock-based compensation

expense of \$0.7 million and \$0.5 million for the three months ended March 31, 2026 and 2025, respectively.

- **Net Loss:** Net loss for the three months ended March 31, 2026 was \$12.3 million, or \$(8.94) per basic and diluted share, compared to a net loss of \$14.0 million, or \$(23.95) per basic and diluted share, for the same period in 2025.

April 30, 2026 Financial Update

Spruce also reported cash and cash equivalents were approximately \$107.3 million as of April 30, 2026.

This estimate of the company's cash and cash equivalents as of April 30, 2026 is preliminary, has not been audited and is subject to change upon completion of the company's financial statement closing procedures. Additional information and disclosure would be required for a more complete understanding of the company's financial position and results of operations as of April 30, 2026. Accordingly, the unaudited preliminary cash and cash equivalents balance set forth above reflects Spruce's preliminary estimate with respect to such information, based on information currently available to management, and may vary from its actual financial position as of April 30, 2026. The information presented herein should not be considered a substitute for the financial information the company files with the U.S. Securities and Exchange Commission. The company has no intention or obligation to update preliminary estimates of its cash and cash equivalents set forth above.

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, tralesenidase alfa enzyme replacement therapy (TA-ERT), is in late-stage development for the treatment of mucopolysaccharidoses 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 Spruce on [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 design, results, conduct, progress and timing of Spruce's clinical and preclinical development of TA-ERT and other product candidates, including plans for a confirmatory study and expanded access program; Spruce's expectations regarding the timing of a planned BLA submission for TA-ERT for the treatment of MPS IIIB, including manufacturing readiness activities in support thereof; Spruce's preliminary estimate of its cash and cash equivalents as of April 30, 2026; Spruce's expectations regarding the sufficiency of its cash and cash equivalents and the net proceeds from its April 2026 underwritten public offering and its term loan facility with Avenue Capital to fund its planned operations and debt obligations; Spruce's plans to advance TA-ERT through potential FDA approval and commercialization, if approved; the contributions and impact of recently appointed members of Spruce's leadership team; the potential receipt of additional tranches under its term loan facility with Avenue Capital; potential issuances under Spruce's at-the-market Sales Agreement with Jefferies; and 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," "could," "will," "potential," "suggest," "plan," "expect," "believe," "prepare," "look forward" 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 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 BALANCE SHEETS

(unaudited)

(in thousands, except share and per share amounts)

	March 31, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 54,080	\$ 48,906
Prepaid expenses	864	353
Other current assets	88	2,853
Total current assets	55,032	52,112
Right-of-use assets	595	666
Other assets	539	243
Total assets	\$ 56,166	\$ 53,021
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,683	\$ 943
Accrued expenses and other current liabilities	8,101	9,143
Debt, current portion	1,000	—
Total current liabilities	11,784	10,086

Lease liabilities, net of current portion	332	419
Debt, net of current portion	5,464	—
Warrant liability	3,938	—
Total liabilities	<u>21,518</u>	<u>10,505</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of March 31, 2026 and December 31, 2025	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized as of March 31, 2026 and December 31, 2025; 1,372,278 and 1,372,043 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	336,148	331,750
Accumulated deficit	(301,500)	(289,234)
Total stockholders' equity	<u>34,648</u>	<u>42,516</u>
Total liabilities and stockholders' equity	<u>\$ 56,166</u>	<u>\$ 53,021</u>

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

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

View source version on [businesswire.com](https://www.businesswire.com/news/home/20260513782733/en/): <https://www.businesswire.com/news/home/20260513782733/en/>

Media

Carolyn Hawley
Inizio Evoke Comms
Carolyn.Hawley@inizioevoke.com
media@sprucebio.com

Investors

Monique Kosse
Gilmartin Group
Monique@GilmartinIR.com
investors@sprucebio.com

Source: Spruce Biosciences, Inc.