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

August 12, 2026

Biologics License Application (BLA) for TA-ERT for the Treatment of MPS IIIB Anticipated in the Fourth Quarter of 2026

TrAnsform Confirmatory Study Required for Potential FDA Accelerated Approval of TA-ERT Expected to Initiate in the Fourth Quarter of 2026

Strengthened Leadership Team with the Appointments of Adrian Quartel, M.D., FFPM, as Chief Medical Officer and Jessica Cohen Pfeffer, M.D., as Vice President, Clinical Development

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Aug. 12, 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 second quarter ended June 30, 2026, and provided corporate updates.

“The second quarter was a period of significant execution as we advanced TA-ERT toward our planned BLA submission in the fourth quarter, which would be a transformative 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. “As we prepare for the submission, we are also preparing to initiate our TrAnsform confirmatory study in the fourth quarter of 2026. We are honored and grateful that Cure Sanfilippo Foundation and the National MPS Society have made a combined $5.5 million strategic investment to help broaden patient access to TA-ERT. We believe we are well positioned to advance TA-ERT through key regulatory milestones and prepare for a potential U.S. commercial launch next year.”

TA-ERT Program Updates

- **BLA submission for TA-ERT for the treatment of MPS IIIB anticipated in the fourth quarter of 2026:** Spruce continues to advance manufacturing readiness, regulatory interactions and commercial planning to support an anticipated BLA submission in the fourth quarter of 2026, seeking accelerated approval based on cerebrospinal fluid heparan sulfate non-reducing end (CSF HS-NRE) as a reasonably likely surrogate endpoint of clinical benefit. There is currently no FDA-approved therapy for the treatment of MPS IIIB, and disease management consists of limited palliative care.
- **TrAnsform confirmatory study required for potential FDA accelerated approval of TA-ERT expected to initiate in the fourth quarter of 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 the company 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.

Strengthening Clinical Development and Medical Leadership

During and subsequent to the quarter, Spruce further strengthened its clinical development and medical leadership with two senior appointments to support the planned TA-ERT BLA submission, potential FDA approval and commercial readiness:

- **Adrian Quartel, M.D., FFPM, Chief Medical Officer:** Dr. Quartel was appointed Chief Medical Officer effective July 27, 2026. He brings more than 25 years of international pharmaceutical experience across clinical development, pharmacovigilance and medical affairs, with a track record of advancing and launching enzyme replacement therapies for rare diseases. He joins Spruce from Zevra Therapeutics, where he served as Chief Medical Officer, and previously served as Chief Medical Officer of Acer Therapeutics and of Adamas Pharmaceuticals. Earlier, as Group Vice President of Global Medical Affairs at BioMarin Pharmaceutical, he helped lead the launch of six treatments for rare diseases and genetic disorders, including the enzyme replacement therapies NAGLAZYME®, VIMIZIM® and Brineura® (cerliponase alfa).
- **Jessica Cohen Pfeffer, M.D., Vice President, Clinical Development:** Dr. Cohen Pfeffer was appointed Vice President, Clinical Development effective August 3, 2026. She brings more than a decade of biopharmaceutical experience across clinical development, product portfolio development and medical affairs, including a track record of supporting global regulatory approvals for enzyme replacement therapies for rare pediatric neurodegenerative disorders. She joins Spruce from BioMarin Pharmaceutical, where she most recently served as Executive Medical Director and clinical sciences lead for Brineura® (cerliponase alfa).

Strategic Investment from the Patient Advocacy Community

Today, Spruce separately announced that Cure Sanfilippo Foundation and the National MPS Society have made a combined $5.5 million strategic

investment in Spruce. The proceeds will be used to partially fund the TA-ERT Expanded Access Program (EAP), helping to broaden patient access to investigational TA-ERT for the treatment of MPS IIIB. The planned open-label, single-arm EAP is 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. The EAP is expected to enroll approximately 10 participants across U.S. sites, with TA-ERT administered weekly via an ICV delivery device. The EAP is expected to initiate in the fourth quarter of 2026. More information about the EAP can be found at ClinicalTrials.gov. Additional information regarding the strategic investment is available in a separate press release available in the "News" section of the company's website.

Second Quarter 2026 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of June 30, 2026 were $96.3 million, compared to $48.9 million as of December 31, 2025. Spruce believes that its cash and cash equivalents as of June 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 $12.2 million for the second quarter of 2026 and $19.7 million for the first six months of 2026, compared to $10.4 million for the first six months of 2025. The increase was primarily attributable to increased expenses to advance TA-ERT, including manufacturing scale-up 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 $4.3 million for the second quarter of 2026 and $8.8 million for the first six months of 2026, compared to $6.8 million for the first six months of 2025. The increase was primarily due to increased personnel-related costs and professional fees to support the company's growth and pre-launch activities.
- **Total Operating Expenses:** Total operating expenses were $16.5 million for the second quarter of 2026 and $28.5 million for the first six months of 2026, compared to $17.2 million for the first six months of 2025. Operating expenses include non-cash stock-based compensation expense of $0.9 million and $1.6 million for the three and six months ended June 30, 2026, respectively.
- **Net Loss:** Net loss was $16.2 million, or $(6.68) per basic and diluted share, for the second quarter of 2026, and $28.5 million, or $(14.96) per basic and diluted share, for the first six months of 2026, compared to a net loss of $16.1 million, or $(27.36) per basic and diluted share, for the first six 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 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 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; the expected timing, enrollment and conduct of the TrAnsform confirmatory study and the TA-ERT Expanded Access Program; the $5.5 million strategic investment from Cure Sanfilippo Foundation and the National MPS Society, including the expected use of proceeds; 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; the contributions and impact of recently appointed members of Spruce's leadership team; 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," "will," "potential," "plan," "expect," "believe" 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)

	June 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 96,295	$ 48,906
Prepaid expenses	4,625	353

Other current assets	234	2,853
Total current assets	101,154	52,112
Right-of-use assets	523	666
Other assets	1,175	243
Total assets	$ 102,852	$ 53,021
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,209	$ 943
Accrued expenses and other current liabilities	7,254	9,143
Debt, current portion	2,500	—
Total current liabilities	10,963	10,086
Lease liabilities, net of current portion	245	419
Debt, net of current portion	4,591	—
Warrant liability	3,323	—
Total liabilities	19,122	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 June 30, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of June 30, 2026 and December 31, 2025; 2,752,810 and 1,372,043 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	401,459	331,750
Accumulated deficit	(317,729)	(289,234)
Total stockholders' equity	83,730	42,516
Total liabilities and stockholders' equity	$ 102,852	$ 53,021

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 12,163	$ (430)	$ 19,738	$ 10,407
General and administrative	4,349	3,122	8,761	6,777
Total operating expenses	16,512	2,692	28,499	17,184
Loss from operations	(16,512)	(2,692)	(28,499)	(17,184)
Interest expense	(1,097)	(29)	(1,771)	(65)
Interest and other income, net	765	193	1,251	522
Change in fair value of warrant and conversion option liabilities	615	461	524	619
Net loss and comprehensive loss	(16,229)	(2,067)	(28,495)	(16,108)
Net loss per share, basic and diluted	$ (6.68)	$ (3.50)	$ (14.96)	$ (27.36)
Weighted-average shares of common stock outstanding, basic and diluted	2,431,075	591,137	1,904,505	588,653

View source version on businesswire.com: https://www.businesswire.com/news/home/20260812480178/en/

Media
Heidi Chokeir
Inizio Evoke Comms
heidi.chokeir@inizioevoke.com
media@sprucebio.com

Investors
Monique Kosse

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

Source: Spruce Biosciences, Inc.