Spruce Biosciences Reports First Quarter 2025 Financial Results and Provides Corporate Updates

May 6, 2025

Acquisition of Tralesinidase Alfa Enzyme Replacement Therapy (TA-ERT) for the Treatment of Sanfilippo Syndrome Type B (MPS IIIB)

Biologics License Application (BLA) Submission to U.S. FDA for TA-ERT Expected in 1H 2026

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 6, 2025-- Spruce Biosciences, Inc. (OTC: 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, 2025 and provided corporate updates.

"With no FDA-approved treatments currently available to treat MPS IIIB, TA-ERT has the potential to be a groundbreaking advancement for patients and families impacted by this devastating disease," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce. "Across the landscape, this is an incredibly important and exciting time for patients and families affected by neuropathic MPS diseases. Looking ahead, we remain focused on pursuing accelerated approval of TA-ERT and filing the BLA in the first half of 2026. We also plan to initiate a confirmatory study prior to potential accelerated approval of TA-ERT and enable expanded access programs to ensure that patients have access to therapy."

Corporate Updates

- ***TA-ERT for the Treatment of MPS IIIB.*** Spruce entered into an Asset Purchase Agreement under which the company acquired an exclusive worldwide license agreement for TA-ERT and other enzyme replacement therapy products. TA-ERT is a fusion protein comprised of recombinant human alpha-N-acetylglucosaminidase (rhNAGLU) with modified human insulin-like growth factor 2 via an amino acid linker. TA-ERT is intended as an enzyme replacement therapy for the treatment of patients with MPS IIIB who lack rhNAGLU enzyme activity. In March 2024, in a Type C meeting with the U.S. Food and Drug Administration (FDA), the FDA confirmed that HS-NRE is deemed to be a surrogate biomarker reasonably likely to predict clinical benefit and could serve as a basis for accelerated approval. The FDA also confirmed that the completed clinical and non-clinical studies of TA-ERT were sufficient for a BLA submission and provided guidance around key design elements of a confirmatory trial, which must be initiated prior to potential accelerated approval of TA-ERT. TA-ERT has received Fast Track Designation, Rare Pediatric Disease Designation, and Orphan Drug Designation in the U.S. and EU. Spruce intends to submit the BLA of TA-ERT for the treatment of MPS IIIB in the first half of 2026.
- ***Tildacerfont and Cortibon for the Treatment of Major Depressive Disorder (MDD).*** Spruce entered into a license, development and option agreement (the "HMNC Agreement") with HMNC Holding GmbH ("HMNC"). Under the terms of the HMNC Agreement, HMNC will fund and conduct a Phase 2 proof-of-concept study of tildacerfont, a potent and highly selective, oral, small-molecule antagonist of the CRF_1 receptor, in patients with MDD who will be screened using Cortibon, HMNC's proprietary genetic test. HMNC has initiated the Phase 2 TAMARIND study, which will explore the efficacy of 400mg twice-daily tildacerfont versus placebo in improving depressive symptoms in MDD patients. Topline results from TAMARIND are anticipated in the first half of 2026.

First Quarter 2025 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of March 31, 2025 were $25.6 million. Cash and cash equivalents are expected to allow the company to fund its current operating plan through the end of 2025.
- **Research and Development (R&D) Expenses:** R&D expenses for the three months ended March 31, 2025 were $10.8 million compared to $10.3 million for the same period in 2024. R&D expenses for the three months ended March 31, 2025 include $5.7 million in costs related to the acquisition of SPR202, an anti-corticotrophin releasing hormone monoclonal antibody for the treatment of congenital adrenal hyperplasia.
- **General and Administrative (G&A) Expenses:** G&A expenses for the three months ended March 31, 2025 were $3.7 million compared to $4.3 million for the same period in 2024, primarily driven by a decrease in stock-based compensation expense.
- **Total Operating Expenses:** Total operating expenses for the three months ended March 31, 2025 were $14.5 million compared to $14.6 million for the same period in 2024. Operating expenses include non-cash stock-based compensation expenses of $0.5 million for the three months ended March 31, 2025 compared to $1.6 million for the same period in 2024.
- **Net Loss:** Net loss for the three months ended March 31, 2025 was $14.0 million compared to $11.6 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 anticipated timing and conduct of Spruce’s confirmatory trial for TA-ERT; the timing and likelihood of regulatory filings and approvals for TA-ERT, including the anticipated BLA Submission of TA-ERT for MPS IIIB in the first half of 2026; Spruce’s expectation that topline results from the TAMARIND study will be available in the first half of 2026; and Spruce’s intended focus on serious diseases with significant unmet medical need and clear biology, are forward-looking statements. 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”, “intend”, “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 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, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,615	$ 38,753
Prepaid expenses	2,899	3,177
Other current assets	2,062	2,276
Total current assets	30,576	44,206
Right-of-use assets	869	934
Other assets	204	69
Total assets	$ 31,649	$ 45,209
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities:		
Accounts payable	$ 1,879	$ 1,295
Accrued expenses and other current liabilities	12,442	12,329
Term loan, current portion	1,345	1,622
Total current liabilities	15,666	15,246
Lease liabilities, net of current portion	659	736
Term loan, net of current portion	—	124
Other liabilities	—	282
Total liabilities	16,325	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 March 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of March 31, 2025 and December 31, 2024; 42,231,285 shares issued and outstanding as of March 31, 2025 and December 31, 2024	4	4
Additional paid-in capital	279,629	279,085
Accumulated deficit	(264,309)	(250,268)
Total stockholders’ equity	15,324	28,821
Total liabilities and stockholders’ equity	$ 31,649	$ 45,209

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

	Three Months Ended March 31,	
	2025	2024
Collaboration revenue	$ —	$ 2,002

Operating expenses:		
Research and development	10,837	10,317
General and administrative	3,655	4,318
Total operating expenses	14,492	14,635
Loss from operations	(14,492)	(12,633)
Interest expense	(36)	(97)
Interest and other income, net	487	1,105
Net loss and comprehensive loss	(14,041)	(11,625)
Net loss per share, basic and diluted	$ (0.32)	$ (0.28)
Weighted-average shares of common stock outstanding, basic and diluted	43,944,946	41,096,231

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