Spruce Biosciences Reports Third Quarter 2024 Financial Results and Provides Corporate Updates

November 11, 2024

Topline Data from CAHmelia-204 Study of Tildacerfont in Adult Congenital Adrenal Hyperplasia (CAH) Anticipated in December 2024

Topline Data from CAHptain-205 Study of Tildacerfont in Adult and Pediatric CAH Anticipated in December 2024

Cash Runway Through the End of 2025

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 11, 2024-- Spruce Biosciences, Inc. (Nasdaq: SPRB), a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for endocrine and neurological disorders with significant unmet medical need, today reported financial results for the third quarter ended September 30, 2024 and provided corporate updates.

"We remain on track to report primary efficacy and safety data plus interim data from the open-label extension of the CAHmelia-204 study of tildacerfont in adult CAH patients in December 2024. At the same time, we will also report topline dose-ranging efficacy and safety data from the CAHptain-205 study of tildacerfont in adult and pediatric CAH patients," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce. "It is an honor to continue partnering with the CAH community to open a new chapter in the management of CAH. We recognize the potentially transformative impact of tildacerfont, and we have a strong sense of urgency to deliver on our commitment to CAH patients."

Corporate Updates

***CAHmelia-204 Study of Tildacerfont in Adult CAH*:** CAHmelia-204 is a Phase 2b, randomized, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of tildacerfont in reducing supraphysiologic glucocorticoid (GC) usage, a potentially registrational endpoint, in 90 adults with classic CAH on supraphysiologic doses of GCs with normal or near normal levels of androstenedione (A4) at baseline. In the first part of the clinical trial, patients were randomized to receive 200mg of tildacerfont once-daily (QD) or placebo for 24 weeks. During the second part of the clinical trial, all patients received 200mg of tildacerfont QD for 52 weeks. Throughout the trial, tapering of GCs is guided according to a pre-specified algorithm and continue to physiologic replacement levels, as long as patients remain well controlled based on standard biomarkers and clinical assessments. The primary endpoint of this clinical trial is the absolute change in daily GC dose in hydrocortisone equivalents (HCe) from baseline through week 24.

***CAHptain-205 Study of Tildacerfont in Adult and Pediatric CAH*:** CAHptain-205 is a Phase 2 open-label clinical trial, which utilizes a sequential nine cohort design, to evaluate the safety, efficacy, and pharmacokinetics of tildacerfont in adults and children between two and 17 years of age. Cohorts 1-3 evaluated weight-adjusted doses of tildacerfont between 50mg QD and 200mg QD in pediatric CAH patients between two and 17 years of age, and assessed changes in androgen levels over 12 weeks of treatment as well as the ability to reduce daily GC dose based on A4 normalization. Cohorts 4-9 are evaluating weight-adjusted doses of tildacerfont of 200mg twice-daily (BID) and 400mg BID in adults and children between two and 17 years of age and is assessing changes in androgen levels over four weeks of treatment. An optional open-label extension period will provide additional open-label treatment with tildacerfont to provide long-term safety data for up to two years.

Anticipated Upcoming Milestones

- Topline results from the CAHmelia-204 clinical trial of tildacerfont 200mg QD in adult classic CAH patients on supraphysiologic doses of GCs with normal or near normal levels of A4 anticipated in December 2024
- Topline results from the CAHptain-205 clinical trial of tildacerfont 200mg BID and 400mg BID adult and pediatric cohorts anticipated in December 2024
- End of Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration anticipated in the first half of 2025

Third Quarter 2024 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of September 30, 2024 were $60.1 million. Cash and cash equivalents are expected to allow the company to fund its current operating plan through the end of 2025.
- **Collaboration Revenue:** Collaboration revenue was $0.6 million and $4.2 million for the three and nine months ended September 30, 2024, respectively, compared to $3.1 million and $7.2 million for the same periods in 2023. The collaboration revenue reflects the partial recognition of the $15.0 million upfront payment the company received in April 2023 in connection with the collaboration and license agreement with Kaken Pharmaceutical.
- **Research and Development (R&D) Expenses:** R&D expenses for the three and nine months ended September 30, 2024 were $6.6 million and $25.0 million, respectively, compared to $13.5 million and $38.3 million for the same periods in 2023. The overall decrease in R&D expenses was primarily driven by the decrease in clinical development and manufacturing expenses related to the termination of the CAHmelia-203 study, completion of enrollment in the company's CAHmelia-204 study, and completion of the Phase 2 POWER study in polycystic ovary syndrome, offset by an increase in expenses related to the ongoing CAHptain-205 study.
- **General and Administrative (G&A) Expenses:** G&A expenses for the three and nine months ended September 30, 2024 were $3.5 million and $11.3 million, respectively, compared to $3.2 million and $9.7 million for the same periods in 2023.

- **Total Operating Expenses:** Total operating expenses for the three and nine months ended September 30, 2024 were $10.0 million and $36.3 million, respectively, compared to $16.7 million and $48.0 million for the same periods in 2023. Operating expenses include non-cash stock-based compensation expenses of $1.1 million and $4.4 million for the three and nine months ended September 30, 2024, respectively, compared to $1.1 million and $3.4 million for the same periods in 2023.
- **Net Loss:** Net loss for the three and nine months ended September 30, 2024 was $8.7 million and $29.5 million, respectively, compared to $12.4 million and $38.0 million for the same periods in 2023.

Upcoming Investor Conferences

Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer, will present at the Guggenheim Securities Healthcare Innovation Conference on November 11, 2024, at 3:30 p.m. ET.

Interested parties can access the live webcast here. An archived copy of the webcast will be available on the events section of the company's investor relations website for approximately 90 days.

About Spruce Biosciences

Spruce Biosciences is a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for endocrine and neurological disorders with significant unmet medical need. Spruce is developing its product candidate, tildacerfont, an oral, second-generation CRF_1 receptor antagonist, for the treatment of congenital adrenal hyperplasia (CAH), polycystic ovary syndrome (PCOS) and major depressive disorder (MDD). 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 design, results, conduct, progress and timing of Spruce's clinical trials; Spruce's expectations regarding reporting results of its clinical trials in 2024; Spruce's plans to meet with the FDA to discuss the potential registrational path forward of tildacerfont for adult and pediatric classic CAH; 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," "continue," "will," "potential," "on track," 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)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 60,055	$ 96,339
Prepaid expenses	2,658	3,876
Other current assets	860	1,968
Total current assets	63,573	102,183
Right-of-use assets	998	1,181
Other assets	531	582
Total assets	$ 65,102	$ 103,946
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,799	$ 3,332
Accrued expenses and other current liabilities	7,740	14,600
Term loan, current portion	1,622	1,622
Deferred revenue, current portion	697	4,911
Total current liabilities	11,858	24,465
Lease liabilities, net of current portion	809	1,019
Term loan, net of current portion	524	1,717
Other liabilities	273	236
Total liabilities	13,464	27,437

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, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 41,302,599 and 41,029,832 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	4	4
Additional paid-in capital	278,343	273,737
Accumulated deficit	(226,709)	(197,232)
Total stockholders' equity	51,638	76,509
Total liabilities and stockholders' equity	$ 65,102	$ 103,946

SPRUCE BIOSCIENCES, INC.
CONDENSED 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,	
	2024	2023	2024	2023
Collaboration revenue	$ 602	$ 3,073	$ 4,214	$ 7,202
Operating expenses:				
Research and development	6,554	13,494	24,961	38,332
General and administrative	3,456	3,237	11,330	9,699
Total operating expenses	10,010	16,731	36,291	48,031
Loss from operations	(9,408)	(13,658)	(32,077)	(40,829)
Interest expense	(71)	(119)	(251)	(377)
Interest income and other expense, net	808	1,423	2,851	3,237
Net loss	(8,671)	(12,354)	(29,477)	(37,969)
Other comprehensive gain, net of tax:				
Unrealized gain on available for sale securities	—	52	—	555
Total comprehensive loss	$ (8,671)	$ (12,302)	$ (29,477)	$ (37,414)
Net loss per share, basic and diluted	$ (0.21)	$ (0.30)	$ (0.72)	$ (1.01)
Weighted-average shares of common stock outstanding, basic and diluted	41,302,599	40,710,692	41,187,766	37,751,865

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Media
Katie Beach Oltsik
Inizio Evoke Comms
(937) 232-4889
Katherine.Beach@inizioevoke.com
media@sprucebio.com

Investors
Samir Gharib
President and CFO
Spruce Biosciences, Inc.
investors@sprucebio.com

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