Spruce Biosciences Reports Full Year 2023 Financial Results and Provides Corporate Updates

March 13, 2024

CAHmelia-203 Study of Tildacerfont in Adult Classic Congenital Adrenal Hyperplasia (CAH) with Severe Hyperandrogenemia Did Not Meet Primary Efficacy Endpoint

Positive Data from CAHptain-205 Study of Tildacerfont in Pediatric Classic CAH Supports Further Dose-Ranging Across Additional Dosing Cohorts

Topline Results from CAHmelia-204 Study of Tildacerfont in Adult Classic CAH Evaluating Glucocorticoid (GC) Reduction Anticipated in Third Quarter of 2024

Resource Prioritization and Cost Reductions Extend Cash Runway Through End of 2025

Conference Call Today at 4:30 p.m. ET

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 13, 2024-- Spruce Biosciences, Inc. (Nasdaq: SPRB), a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for rare endocrine disorders with significant unmet medical need, today reported financial results for the year ended December 31, 2023 and provided corporate updates.

"We are grateful to all the patients, families, study team and investigators who supported the CAHmelia-203 clinical trial," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer, Spruce Biosciences. "CAHmelia-203 is the first study of its kind to address a difficult-to-treat CAH patient population with severe and more refractory hyperandrogenemia, which is often attributed to challenging real-life compliance with daily GCs. We garnered important data from this study which will inform ongoing development of tildacerfont in adult classic CAH."

Dr. Szwarcberg added, "Looking ahead to the third quarter of 2024, we are eager to report topline results from CAHmelia-204, which is focused on assessing GC reduction, a potentially registrational endpoint, in a different population of adult CAH patients with relatively controlled A4 levels and historically better adherence to GC therapy. Assuming positive results from CAHmelia-204 and CAHptain-205, we plan to meet with the U.S. Food and Drug Administration (FDA) and comparable foreign regulatory authorities in early 2025 to outline the design of a registrational clinical program in adult and pediatric classic CAH. Finally, we have made the difficult but necessary decision to streamline our operations and implement cost reduction measures, which has extended our cash runway through the end of 2025. I want to thank all of our employees, including those departing Spruce, for their dedication to advancing our mission of bringing forward novel therapies for CAH and other rare endocrine disorders."

Recent Corporate Updates

- ***CAHmelia-203 Study of Tildacerfont in Adult Classic Congenital Adrenal Hyperplasia (CAH) with Severe Hyperandrogenemia Did Not Meet Primary Efficacy Endpoint.*** CAHmelia-203 enrolled 96 subjects with a mean baseline androstenedione (A4) level of 1,151 ng/dL, which is more than five times above the upper limit of normal (ULN). The clinical trial did not achieve the primary efficacy endpoint of the assessment of dose-response for the change in A4 from baseline to week 12. 200mg QD of tildacerfont demonstrated a placebo-adjusted reduction from baseline in A4 of -2.6% with a non-significant p-value at week 12. Compliance with study medication and glucocorticoid (GC) was low with only 50% of patients reporting 80% or greater compliance, resulting in lower-than-expected tildacerfont exposure. Tildacerfont was generally safe and well tolerated at all doses, with no treatment-related serious adverse events (SAEs). Most adverse events were reported as mild to moderate.
- ***Positive Data from CAHptain-205 Study of Tildacerfont in Pediatric Classic CAH Supports Further Dose-Ranging Across Additional Dosing Cohorts.*** CAHptain-205 enrolled 30 children between two and 17 years of age with a mean baseline GC dose of 14 mg/m^2/day and mean baseline A4 level of 372 ng/dL. The study characterized the safety and pharmacokinetic profiles of tildacerfont, as well as changes in androgen levels over 12 weeks of treatment, and the ability to reduce daily GC dose upon A4 normalization. Tildacerfont was generally safe and well tolerated at all dose ranges with no treatment-related SAEs reported. Preliminary pharmacokinetic analysis suggests that tildacerfont is cleared more rapidly in children than in adult CAH patients. 73% of all patients (22 of 30 patients) met the efficacy endpoint of A4 or GC reduction from baseline at 12 weeks of treatment with tildacerfont. 70% of patients with elevated baseline A4 values (16 of 23 patients) demonstrated an A4 reduction at week 4.

Anticipated Upcoming Milestones

- Topline results from the CAHmelia-204 clinical trial in adult classic CAH patients on supraphysiologic doses of glucocorticoids with normal or near normal levels of A4 in the third quarter of 2024
- Topline results from additional dose-ranging in the Phase 2 CAHptain clinical trial in the fourth quarter of 2024
- End of Phase 2 (EOP2) meeting with the U.S. FDA in the first quarter of 2025

Full Year 2023 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of December 31, 2023 were $96.3 million. The company currently has over $81 million in cash and cash equivalents. Resource prioritization and cost reductions, including termination of the CAHmelia-203 clinical trial and a reduction in force of approximately 21%, extend cash runway through the end of 2025, including beyond anticipated topline results from CAHmelia-204 and additional dose-ranging data from CAHptain-205.
- **Collaboration Revenue:** Collaboration revenue for the year ended December 31, 2023 was $10.1 million compared to nil in 2022, reflecting the partial recognition of the $15.0 million upfront payment received from Kaken Pharmaceutical ("Kaken") in connection with the company's strategic collaboration with Kaken to develop and commercialize tildacerfont for the treatment of classic CAH in Japan.
- **Research and Development (R&D) Expenses:** R&D expenses for the year ended December 31, 2023 were $49.4 million compared to $35.2 million in 2022. The overall increase in R&D expenses was primarily related to progressing clinical development of tildacerfont in adult classic CAH, pediatric classic CAH and polycystic ovary syndrome (PCOS).
- **General and Administrative (G&A) Expenses:** G&A expenses for the year ended December 31, 2023 were $12.7 million compared to $12.1 million in 2022.
- **Total Operating Expenses:** Total operating expenses for the year ended December 31, 2023 were $62.1 million compared to $47.3 million in 2022. Non-cash stock-based compensation expense for the year ended December 31, 2023 was $4.6 million compared to $3.6 million in 2022.
- **Net Loss:** Net loss for the year ended December 31, 2023 was $47.9 million compared to $46.2 million in 2022.

Conference Call Details

Spruce's management team and key study investigators will host a conference call today at 4:30 p.m. ET to discuss the topline results of the CAHmelia-203 and CAHptain-205 clinical studies. Analysts and investors can participate in the conference call by registering here or dialing (866) 777-2509.

An archived copy of the call 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 rare endocrine disorders with significant unmet medical need. Spruce is initially developing its wholly-owned product candidate, tildacerfont, as the potential first non-steroidal, once-daily therapy for patients suffering from classic congenital adrenal hyperplasia (CAH) and other endocrine disorders. 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; tildacerfont's potential to be a novel treatment option that improves long-term health outcomes for patients with CAH; Spruce's expectations regarding reporting results of its clinical trials in 2024; Spruce's plans to meet with the FDA and comparable foreign regulatory authorities to discuss the potential registrational path forward of tildacerfont for adult and pediatric classic CAH; the impact of cost savings initiatives and the length of Spruce's anticipated cash runway; 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" 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.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31,	
	2023	**2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 96,339	$ 24,487
Short-term investments	—	54,590
Prepaid expenses	3,876	3,320
Other current assets	1,968	1,211
Total current assets	102,183	83,608
Right-of-use assets	1,181	1,400

Other assets	582	640
Total assets	$ 103,946	$ 85,648
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,332	$ 1,426
Accrued expenses and other current liabilities	14,600	9,399
Term loan, current portion	1,622	1,622
Deferred revenue	4,911	—
Total current liabilities	24,465	12,447
Lease liabilities, net of current portion	1,019	1,261
Term loan, net of current portion	1,717	3,293
Other liabilities	236	161
Total liabilities	27,437	17,162
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, 2023 and 2022	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of December 31, 2023 and 2022; 41,029,832 and 23,601,004 shares issued and outstanding as of December 31, 2023 and 2022, respectively	4	3
Additional paid-in capital	273,737	218,354
Accumulated other comprehensive loss	—	(558)
Accumulated deficit	(197,232)	(149,313)
Total stockholders' equity	76,509	68,486
Total liabilities and stockholders' equity	$ 103,946	$ 85,648

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

	Year Ended December 31,	
	2023	**2022**
Collaboration revenue	$ 10,089	$ —
Operating expenses:		
Research and development	49,432	35,198
General and administrative	12,650	12,085
Total operating expenses	62,082	47,283
Loss from operations	(51,993)	(47,283)
Interest expense	(483)	(420)
Interest and other income, net	4,557	1,523
Net loss	(47,919)	(46,180)
Other comprehensive gain (loss), net of tax:		
Unrealized gain (loss) on available for sale securities	558	(374)
Total comprehensive loss	$ (47,361)	$ (46,554)
Net loss per share, basic and diluted	$ (1.24)	$ (1.96)
Weighted-average shares of common stock outstanding, basic and diluted	38,510,220	23,527,116

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