Spruce Biosciences Reports First Quarter 2023 Financial Results and Provides Corporate Updates

May 15, 2023

CAHmelia Program in Adult Classic Congenital Adrenal Hyperplasia (CAH) Achieves 50% Enrollment in CAHmelia-204 and Approaches 75% Enrollment in CAHmelia-203

Enrollment in P.O.W.E.R. Study for Polycystic Ovary Syndrome (PCOS) Complete – Topline Results Anticipated in Q3 2023

Cohort 1 for Phase 2 CAHptain Study in Pediatric Classic CAH Fully Enrolled

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May 15, 2023-- 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 quarter ended March 31, 2023 and provided corporate updates.

"I am pleased by the meaningful progress Spruce made across our clinical and business objectives in the first quarter of 2023. Patient enrollment in our CAHmelia program in adult classic CAH continues to progress, as we achieved 50% enrollment in our CAHmelia-204 study and are approaching 75% enrollment in our CAHmelia-203 study. Cohort 1 in our CAHptain study for pediatric classic CAH is fully enrolled with enrollment in cohort 2 currently underway. Additionally, we have completed enrollment in our P.O.W.E.R study for PCOS and will be reporting topline data in the third quarter," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. "As we continue to build our seasoned leadership team for the pivotal year ahead, I am also delighted to welcome Mo Noursalehi, Ph.D., as our Senior Vice President of Biometrics. With his deep clinical development background, Dr. Noursalehi will be a vital asset in helping Spruce achieve its mission of improving treatment options for patients with CAH and other rare endocrine disorders."

Recent Corporate Updates

- **CAHmelia Program in Adult Classic CAH Progresses Enrollment:** Enrollment in the company's CAHmelia-204 clinical trial achieved 50% enrollment. CAHmelia-204 is a randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of tildacerfont in reducing supraphysiologic glucocorticoid use in adult patients with classic CAH. Additionally, enrollment in the company's CAHmelia-203 clinical trial is approaching 75% enrollment. CAHmelia-203 is a randomized, double-blind, placebo-controlled, dose-ranging study evaluating the safety and efficacy of tildacerfont in reducing androstenedione (A4) levels in adult patients with classic CAH while on their current glucocorticoid regimen.
- **Enrollment in P.O.W.E.R. Study for PCOS has Completed – Topline Results Anticipated in 3Q 2023**: The P.O.W.E.R. study, a Phase 2 trial evaluating the efficacy, safety and tolerability of tildacerfont in women with PCOS and elevated adrenal androgens assessed by elevated dehydroepiandrosterone sulfate (DHEAS) levels, has completed enrollment with 27 female subjects. Adrenal androgen excess in PCOS may result from an altered adrenal responsivity to adrenocorticotropic hormone (ACTH). In women whose PCOS is caused by elevated adrenal androgens, tildacerfont may provide a therapeutic option to treat the underlying cause of disease through reductions of ACTH. Topline results are anticipated in the third quarter of 2023.
- **Cohort 1 for CAHptain Study in Pediatric Classic CAH has Fully Enrolled**: Cohort 1 of the CAHptain study has fully enrolled and enrollment for cohort 2 is underway. CAHptain is a Phase 2 open-label clinical trial that utilizes a sequential 3 cohort design (cohorts 1 and 2 comprising of adolescent patients 11 to 17 years of age, and cohort 3 comprising of children 2 to 10 years of age) to evaluate the safety, pharmacokinetics (PK), and exploratory pharmacodynamics (PD) of tildacerfont in children and adolescents with classic CAH. There is a significant medical need to bring androgen-lowering and glucocorticoid-sparing therapies to pediatric classic CAH patients to reduce the risk of premature puberty and the adverse effects of glucocorticoids, including stunted growth resulting in short stature as adults. Spruce remains on track to report topline data from adolescents (cohorts 1 and 2) in the second half of 2023.
- **Appointment of Mo Noursalehi, Ph.D., as Senior Vice President of Biometrics:** As Senior Vice President (SVP) of Biometrics, Mo Noursalehi, Ph.D., oversees clinical biometrics. Dr. Noursalehi is a seasoned industry executive with nearly three decades of experience building program plans and contributing to the development of clinical development strategies in roles of increasing responsibility across biotech and global pharmaceutical companies. He joins Spruce from Global Blood Therapeutics (GBT), recently acquired by Pfizer, where he served as Vice President, Clinical Development and Medical Affairs Biometrics. Prior to GBT, Dr. Noursalehi held various roles at Audentes Therapeutics, Exelixis Pharmaceuticals, Astex Pharmaceuticals, GPC Biotech, Tercica, Abbott Laboratories, and Novartis Pharmaceuticals. He holds a Master of Sciences in Biostatistics from the University of California, Los Angeles Fielding School of Public Health and a Ph.D. in Probability and Applied Statistics from the University of Kansas.
- **Abstract Presented at Pediatric Endocrine Society (PES) 2023 Annual Meeting**: An accepted abstract titled, *Clinical Trials in CAH: So Many Starting, but Not So Many Finishing*, was presented at the PES 2023 Annual Meeting by Mitchell Geffner, M.D., Co-Director of the Congenital Adrenal Hyperplasia Comprehensive Care Clinic and Professor of Pediatrics,

Keck School of Medicine of University of Southern California. The presentation demonstrated findings which underscored an outpacing of CAH clinical trial options to patient participation, highlighting the need for flexible and accessible protocols as well as creative strategies to maximize study recruitment and retention. The abstract was authored by Will Charlton, M.D., M.A.S., Spruce's Chief Medical Officer, P.J. Ramtin, Spruce's SVP of Business Operations and Patient Engagement and Dr. Geffner.

- **Completed Private Placement Financing of $53.6 Million with Top-Tier Healthcare Investors**: In February 2023, the company entered into a definitive securities purchase agreement for a private placement that resulted in gross proceeds of $53.6 million, before deducting commissions and offering expenses.
- **Strategic Partnership and Exclusive Licensing Agreement with Kaken Pharmaceutical:** In January 2023, Spruce and Kaken entered into an exclusive license agreement for the development and commercialization of Spruce's product candidate, tildacerfont, for the treatment of CAH in Japan. Under the terms of the agreement, Spruce received an upfront payment of $15.0 million from Kaken in April 2023 and will be eligible to receive additional payments upon the achievement of future development and commercial milestones, as well as tiered double-digit royalties on net sales in Japan. Kaken will be responsible for the clinical development and commercialization of tildacerfont in Japan, and Spruce will retain all rights to tildacerfont in all other geographies.

Anticipated Upcoming Milestones

- Topline results from the Phase 2 P.O.W.E.R. clinical trial in PCOS in the third quarter of 2023
- Topline data from adolescents (cohorts 1 and 2) of the Phase 2 CAHptain clinical trial in pediatric classic CAH in the second half of 2023
- Topline results from the CAHmelia-203 clinical trial in adult classic CAH patients with highly elevated levels of A4 in the second half of 2023
- 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 second half of 2024

First Quarter 2023 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of March 31, 2023 were $118.6 million. Cash, cash equivalents and investments as of March 31, 2023, together with the $15.0 million upfront payment received by the company under the license agreement with Kaken in April 2023, are expected to allow the company to fund operating and capital expenditures into the first half of 2025.
- **Collaboration Revenue:** Collaboration revenue for the quarter ended March 31, 2023 was $2.0 million compared to nil for the same period in 2022. The increase in collaboration revenue reflects the partial recognition of the $15.0 million upfront payment the company received in connection with the collaboration and license agreement with Kaken Pharmaceutical.
- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended March 31, 2023 were $11.7 million compared to $8.5 million for the same period 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 PCOS.
- **General and Administrative (G&A) Expenses:** G&A expenses for the quarter ended March 31, 2023 were $3.5 million compared to $3.2 million for the same period in 2022.
- **Total Operating Expenses:** Total operating expenses for the quarter ended March 31, 2023 were $15.2 million compared to $11.7 million for the same period in 2022.
- **Net Loss:** Net loss for the quarter ended March 31, 2023 was $12.8 million compared to $11.8 million for the same period in 2022.

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 therapy for patients suffering from classic congenital adrenal hyperplasia (CAH). Spruce is also developing tildacerfont for women suffering from polycystic ovary syndrome (PCOS) with primary adrenal androgen excess. To learn more, visit www.sprucebiosciences.com and follow us on Twitter @Spruce_Bio, 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 enrollment, results, conduct, progress and timing of Spruce's clinical trials; the receipt and presentation of topline data from the same; research and development plans; Spruce's planned operations, including its expectations regarding operating and capital expenditures being funded into the first half of 2025, responsibilities of Spruce and Kaken pursuant to the exclusive license agreement, and the ability of tildacerfont to provide a therapeutic option to treat the underlying cause of disease through reductions of ACTH. 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", "expect", "may," "will", "potential" 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, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 73,926	$ 24,487
Short-term investments	44,659	54,590
Accounts receivable	15,000	—
Prepaid expenses	3,398	3,320
Other current assets	253	1,211
Total current assets	137,236	83,608
Right-of-use assets	1,353	1,400
Other assets	525	640
Total assets	$ 139,114	$ 85,648
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,448	$ 1,426
Accrued expenses and other current liabilities	8,720	9,399
Term loan, current portion	1,622	1,622
Deferred revenue, current portion	9,205	—
Total current liabilities	22,995	12,447
Lease liabilities, net of current portion	1,209	1,261
Term loan, net of current portion	2,901	3,293
Deferred revenue, net of current portion	3,831	—
Other liabilities	181	161
Total liabilities	31,117	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 March 31, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of March 31, 2023 and December 31, 2022; 39,746,116 and 23,601,004 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	4	3
Additional paid-in capital	270,285	218,354
Accumulated other comprehensive loss	(188)	(558)
Accumulated deficit	(162,104)	(149,313)
Total stockholders' equity	107,997	68,486
Total liabilities and stockholders' equity	$ 139,114	$ 85,648

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

	Three Months Ended March 31,	
	2023	2022
Collaboration revenue	$ 1,964	$ —
Operating expenses:		
Research and development	11,712	8,508
General and administrative	3,451	3,225
Total operating expenses	15,163	11,733
Loss from operations	(13,199)	(11,733)
Interest expense	(131)	(87)

Interest and other income, net	539	58
Net loss	(12,791)	(11,762)
Other comprehensive gain (loss), net of tax:		
Unrealized gain (loss) on available for sale securities	370	(509)
Total comprehensive loss	$ (12,421)	$ (12,271)
Net loss per share, basic and diluted	$ (0.40)	$ (0.50)
Weighted-average shares of common stock outstanding, basic and diluted	31,900,160	23,492,295

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