Spruce Biosciences Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 11, 2022

25% Enrollment Achieved in CAHmelia-203 Study for Adult Classic CAH; On Track to Report Topline Data in 2H 2023

Debt Facility with Silicon Valley Bank Amended to Provide Up to $10 Million Credit Line in 2022

Tildacerfont Patent Portfolio Estate Expanded with Key Method of Use Patents

Libbie Mansell, Ph.D., M.B.A., R.A.C., Appointed Chief Regulatory and Quality Officer

SAN FRANCISCO--(BUSINESS WIRE)--May 11, 2022-- 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 first quarter ended March 31, 2022 and provided corporate updates.

"Throughout the first quarter of 2022, we continued to drive our clinical and business objectives forward, with key progress made in our lead program for adults with classic congenital adrenal hyperplasia (CAH), expansion of our executive leadership team, and through potential access to non-dilutive sources of capital. We were pleased to achieve the recent milestone of 25% enrollment in our CAHmelia-203 study for adult classic CAH, which keeps us on track to meet topline data readout for the study in the second half of 2023," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. "The enhanced protocols we rolled-out for the CAHmelia-203 and 204 studies have been well-received by study investigators across our global trial sites and have streamlined screening activities. We look forward to continuing this momentum and providing further enrollment updates over the course of the year."

Recent Corporate & Pipeline Updates

- **25% Enrollment Achieved in CAHmelia-203 Study for Adult Classic CAH:** Spruce Biosciences recently achieved 25% enrollment in the company's CAHmelia-203 clinical study and is on track to report topline data in the second half of 2023. CAHmelia-203 is a randomized, double-blind, placebo-controlled, dose-ranging study evaluating the safety and efficacy of tildacerfont in adult patients with classic CAH and is designed to enroll approximately 72 patients with high levels of androstenedione (A4) on their current glucocorticoid regimen. Study sites are now enrolling under the amended protocol, which is anticipated to accelerate patient enrollment.

- **Enrollment in CAHmelia-204 Progressing Under Amended Protocol:** CAHmelia-204 is a randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of tildacerfont in adult patients with classic CAH. The study is designed to enroll approximately 90 patients on supraphysiologic doses of glucocorticoids at or above 30 mg/d hydrocortisone equivalent with normal or near normal levels of A4. Study sites are now enrolling under the amended protocol, which removed the glucocorticoid conversion requirement. Enrollment is progressing as planned and the company plans to share enrollment updates over the course of the year.

- **Debt Facility with Silicon Valley Bank (SVB) Amended to Provide $10 Million Credit Line in 2022:** Spruce Biosciences has amended its debt facility with SVB to provide a credit line of up to $10 million ("Tranche 2") in 2022, subject to the satisfaction of certain financial and operating conditions. The amendment also reduces the current variable interest rate on the outstanding debt of $5 million by 50 basis points and on Tranche 2 by 250 basis points. Additionally, subject to potential drawdowns under Tranche 2 occurring, the interest-only period for outstanding term debt will be extended from December 31, 2022 to June 30, 2023. No warrants were issued in connection with the amended debt facility.

- **Tildacerfont Patent Portfolio Estate Expanded with Key Method of Use Patents:** Spruce Biosciences continues to expand its patent portfolio for its wholly-owned product candidate tildacerfont to supplement its issued composition of matter patent and market exclusivity afforded by orphan drug designation in the United States and Europe for CAH, if approved. In April 2022, the United States Patent and Trademark Office issued U.S. Patent Number 11,304,950 titled "Methods of treating testicular and ovarian adrenal rest tumors," and U.S. Patent Number 11,311,549 titled "Corticotropin release factor receptor antagonists." The newly issued patents cover broad claims regarding the use of a CRF-1 receptor antagonist for the treatment of adrenal rest tumors and use of tildacerfont to reduce androstenedione in patients with CAH. These patents expand existing patent exclusivity through 2038.

- **Libbie Mansell, Ph.D., M.B.A., R.A.C., Appointed Chief Regulatory and Quality Officer**: In April 2022, Libbie Mansell, Ph.D., M.B.A., R.A.C. was appointed Chief Regulatory and Quality Officer of Spruce Biosciences, and will lead the company's global regulatory affairs and quality strategy. Dr. Mansell is a seasoned regulatory affairs professional, with over 30 years of industry experience in serious and rare diseases. She joins Spruce from Asklepios BioPharmaceutical

(AskBio), where she served as Senior Vice President of Regulatory Affairs. Dr. Mansell's appointment follows the March 2022 appointment of Will Charlton, M.D., M.A.S., as Chief Medical Officer.

Upcoming Corporate Access Events

- **RBC Capital Markets Global Healthcare Conference**
  Date: May 17-18, 2022
  Format: Fireside chat (May 17 at 10:00 a.m. ET) and 1x1 meetings

- **H.C. Wainwright Global Investment Conference**
  Date: May 23-26, 2022
  Format: Company presentation (May 25 at 4:00 p.m. ET) and 1x1 meetings

Upcoming Medical Conferences

- **24th European Congress of Endocrinology (ECE 2022)**
  Date: May 21-24, 2022

- **104th Annual Meeting of the Endocrine Society (ENDO 2022)**
  Date: June 11-14, 2022

Anticipated Upcoming Milestones

- Completion of enrollment from the Phase 2 proof of concept clinical trial in PCOS by the end of 2022 and topline results in the first half of 2023
- Topline safety results from cohort 1 of the Phase 2 pediatric classic CAH clinical trial in the first half of 2023
- Topline results from the CAHmelia-203 clinical trial in adult classic CAH patients with elevated levels of A4 (labeled as in poor disease control) 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 (labeled as in good disease control) in the second half of 2024

First Quarter 2022 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of March 31, 2022, were $108.9 million.
- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended March 31, 2022 were $8.5 million compared to $6.7 million for the same period in 2021. The overall increase in R&D expenses was primarily related progressing clinical development of tildacerfont in adult classic CAH and the initiation of clinical programs in pediatric classic CAH and polycystic ovary syndrome.
- **General and Administrative (G&A) Expenses:** G&A expenses for the quarter ended March 31, 2022 were $3.2 million compared to $3.1 million for the same period in 2021.
- **Total Operating Expenses:** Total operating expenses for the quarter ended March 31, 2022 were $11.7 million, compared to $9.8 million for the same period in 2021. Stock-based compensation expense for the quarters ended March 31, 2022 and 2021 was $1.1 million and $1.1 million, respectively. When excluding depreciation and stock-based compensation expenses, non-GAAP total operating expenses for the quarters ended March 31, 2022 and 2021 were $10.6 million and $8.7 million, respectively.
- **Net Loss:** Net loss for the quarter ended March 31, 2022 was $11.8 million compared to $9.9 million for the same period in 2021.

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). Classic CAH is a serious and life-threatening disease with no known novel therapies approved in approximately 50 years. 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 and announcements regarding the same, and the funding of Spruce’s operations. 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 “expect,” “anticipate”, “will”, “believe”, “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 the COVID-19 pandemic, 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.

Use of Non-GAAP Financial Measures

Spruce has presented certain non-GAAP financial measures in this release. This release and the reconciliation table included herein include non-GAAP total operating expenses, which excludes depreciation and stock-based compensation. Spruce excludes depreciation and stock-based compensation because management believes the exclusion of these items is helpful to investors to evaluate Spruce's recurring operational performance. Spruce management uses this non-GAAP financial measure to monitor and evaluate its operating results and trends on an on-going basis, and internally for operating, budgeting and financial planning purposes. This non-GAAP financial measure should be considered in addition to results prepared in accordance with GAAP but should not be considered a substitute for or superior to GAAP results.

SPRUCE BIOSCIENCES, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share amounts)

	March 31, 2022	December 31, 2021
ASSETS	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 23,343	$ 42,748
Short-term investments	68,005	46,221
Prepaid expenses	3,423	2,530
Other current assets	325	396
Total current assets	95,096	91,895
Restricted cash	216	216
Right-of-use assets, net	1,397	1,479
Long-term investments	17,601	32,459
Other assets	678	437
Total assets	$ 114,988	$ 126,486
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities:		
Accounts payable	$ 1,109	$ 2,823
Term loan, current portion	405	—
Accrued expenses and other current liabilities	6,457	4,613
Accrued compensation and benefits	998	1,435
Total current liabilities	8,969	8,871
Term loan, net of current portion	4,485	4,878
Lease liability, net of current portion	1,196	1,293
Other liabilities	95	73
Total liabilities	14,745	15,115
Stockholders’ equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of March 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value, 200,000,000 shares authorized, 23,492,873 and 23,491,881 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	3	3
Additional paid-in capital	215,828	214,685
Accumulated other comprehensive loss	(693)	(184)
Accumulated deficit	(114,895)	(103,133)
Total stockholders’ equity	100,243	111,371
Total liabilities and stockholders’ equity	$ 114,988	$ 126,486

SPRUCE BIOSCIENCES, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 8,508	$ 6,714
General and administrative	3,225	3,103
Total operating expenses	11,733	9,817
Loss from operations	(11,733)	(9,817)
Interest expense	(87)	(89)
Other income, net	58	19
Net loss	$ (11,762)	$ (9,887)
Unrealized loss on available for sale securities	(509)	—
Comprehensive loss	$ (12,271)	$ (9,887)
Net loss per share, basic and diluted	$ (0.50)	$ (0.42)
Weighted-average shares of common stock outstanding, basic and diluted	23,492,295	23,283,658

SPRUCE BIOSCIENCES, INC.
Reconciliation of Total Operating Expenses to Non-GAAP Total Operating Expenses
(unaudited)
(in thousands)

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Total operating expenses	$ 11,733	$ 9,817
Adjustments:		
Depreciation	9	4
Stock-based compensation	1,141	1,120
Non-GAAP total operating expenses	$ 10,583	$ 8,693

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