Spruce Biosciences Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Updates

March 14, 2022

Topline Safety Data from Cohort 1 of Phase 2 Pediatric Classic CAH Study Expected by 1H 2023

Will Charlton, M.D., M.A.S., Appointed Chief Medical Officer

SAN FRANCISCO--(BUSINESS WIRE)--Mar. 14, 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 fourth quarter and full year ended December 31, 2021 and provided a corporate update.

“Over the last quarter, we have made notable progress in our efforts to advance new treatment options for people living with rare endocrine disorders and to maximize the potential of tildacerfont as a therapeutic to treat people living with classic congenital adrenal hyperplasia (CAH) and polycystic ovary syndrome (PCOS),” said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. “We are expanding the number of study sites globally and rolling out updated protocols for the CAHmelia-203 and CAHmelia-204 clinical trials in adult classic CAH, which we expect will accelerate patient enrollment. We were also pleased to initiate our Phase 2 clinical trials in patients with pediatric classic CAH and PCOS and expect topline results from both studies by the first half of 2023.”

Corporate Updates

- **Topline Safety Data from Cohort 1 of Phase 2 Pediatric Classic CAH Study Expected by 1H 2023:** Spruce is investigating tildacerfont for the treatment of classic CAH in children and recently initiated a Phase 2 clinical trial. There is a significant unmet 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. The Phase 2 open-label clinical trial will utilize a sequential 3 cohort design to evaluate the safety and pharmacokinetics of tildacerfont in children six to 17 years of age with classic CAH.
- **Will Charlton, M.D., M.A.S., Appointed Chief Medical Officer**: In March 2022, Will Charlton, M.D., M.A.S, was appointed Chief Medical Officer of Spruce Biosciences, and will lead the company’s clinical development and global drug development strategy. Dr. Charlton is a board-certified pediatric endocrinologist with two decades of experience as a clinician and industry executive building successful programs across clinical development, medical affairs and drug safety. He joins Spruce from 89bio, Inc., where he served as Vice President, Clinical Development, and was responsible for clinical development, pharmacology and pharmacovigilance across multiple therapeutic areas.

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 by the first half of 2023
- Topline safety results from cohort 1 of the Phase 2 pediatric classic CAH clinical trial by the first half of 2023
- Topline results from the Phase 2 CAHmelia-203 clinical trial in adult classic CAH patients with poor disease control by the second half of 2023
- Topline results from the Phase 2 CAHmelia-204 clinical trial in adult classic CAH patients with good disease control by the second half of 2024

Fourth Quarter and Full Year 2021 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of December 31, 2021, were $121.4 million, which management anticipates funds the company into the second quarter of 2024.
- **Research and Development (R&D) Expenses:** R&D expenses for the fourth quarter and full year ended December 31, 2021 were $6.3 million and $30.7 million, respectively, compared to $5.8 million and $23.9 million for the same periods in 2020, respectively. The overall increase in R&D expenses was primarily related to the advancement of tildacerfont into late-stage clinical development.
- **General and Administrative (G&A) Expenses:** G&A expenses for the fourth quarter and full year ended December 31, 2021 were $2.9 million and $11.4 million, respectively, compared to $2.5 million and $5.6 million for the same periods in 2020, respectively. The overall increase in G&A expenses was primarily driven by an increase in costs related to operation as a public company.
- **Total Operating Expenses:** Total operating expenses for the fourth quarter and full year ended December 31, 2021 were $9.1 million and $42.1 million, respectively, compared to $8.3 million and $29.4 million for the same periods in 2020,

respectively. Stock-based compensation expense for the three and twelve months ended December 31, 2021 was $0.8 million and $4.0 million, respectively. When excluding depreciation and stock-based compensation expenses, total operating expenses for the three months and full year ended December 31, 2021 were $8.3 million and $38.1 million, respectively.

- **Net Loss:** Net loss for the fourth quarter and full year ended December 31, 2021 was $9.2 million and $42.3 million, respectively, compared to $8.3 million and $29.5 million for the same periods in 2020, respectively.

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 a rare form of 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 results, conduct, progress and timing of Spruce’s clinical trials and announcements regarding the same. 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,” “plans,” “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 tables included herein include non-GAAP total operating expenses and non-GAAP G&A expenses, both of which exclude 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 these non-GAAP financial measures to monitor and evaluate its operating results and trends on an on-going basis, and internally for operating, budgeting and financial planning purposes. The non-GAAP financial measures 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.
BALANCE SHEETS
(in thousands, except share amounts)

	December 31,	
	2021	**2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 42,748	$ 157,150
Short-term investments	46,221	—
Prepaid expenses	2,530	2,971
Other current assets	396	276
Total current assets	91,895	160,397
Restricted cash	216	216
Right-of-use assets	1,479	1,793
Long-term investments	32,459	—
Other assets	437	477
Total assets	$ 126,486	$ 162,883
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities:		
Accounts payable	$ 2,823	$ 3,628
Term loan, current portion	—	2,554
Accrued expenses and other current liabilities	4,613	2,496
Accrued compensation and benefits	1,435	1,085
Total current liabilities	8,871	9,763
Term loan, net of current portion	4,878	1,922
Lease liability, net of current portion	1,293	1,653

Other liabilities	73	118
Total liabilities	15,115	13,456
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares and 0 shares authorized as of December 31, 2021 and 2020, respectively; 0 shares issued and outstanding as of December 31, 2021 and 2020	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of December 31, 2021 and 2020, respectively; 23,491,881 shares and 23,260,399 shares issued and outstanding as of December 31, 2021 and 2020, respectively	3	2
Additional paid-in capital	214,685	210,266
Accumulated other comprehensive loss	(184)	—
Accumulated deficit	(103,133)	(60,841)
Total stockholders' equity	111,371	149,427
Total liabilities and stockholders' equity	$ 126,486	$ 162,883

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 6,258	$ 5,814	$ 30,698	$ 23,854
General and administrative	2,877	2,521	11,368	5,562
Total operating expenses	9,135	8,335	42,066	29,416
Loss from operations	(9,135)	(8,335)	(42,066)	(29,416)
Interest expense	(88)	(78)	(345)	(323)
Other income, net	39	75	119	200
Net loss	$ (9,184)	$ (8,338)	$ (42,292)	$ (29,539)
Net loss per share, basic and diluted	$ (0.39)	$ (0.39)	$ (1.81)	$ (4.93)
Weighted-average shares of common stock outstanding, basic and diluted	23,453,793	21,542,045	23,361,416	5,991,213

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
Total operating expenses	$ 9,135	$ 8,335	$ 42,066	$ 29,416
Adjustments:				
Depreciation	8	3	22	4
Stock-based compensation	797	410	3,958	754
Non-GAAP total operating expenses	$ 8,330	$ 7,922	$ 38,086	$ 28,658

Reconciliation of G&A Expenses to Non-GAAP G&A Expenses
(unaudited)
(in thousands)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Operating expenses:				
G&A expenses	$ 2,877	$ 2,521	$ 11,368	$ 5,562
Adjustments:				
Depreciation	6	3	20	4
Stock-based compensation	616	221	2,913	428

Non-GAAP G&A expenses	$ 2,255	$ 2,297	$ 8,435	$ 5,130

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