Spruce Biosciences Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Recent Corporate Updates

March 22, 2021

Late-Stage CAHmelia Program in Adult Classic CAH Advancing with Majority of Study Sites Active

CAHmelia Program Enhanced Following Discussions with FDA - Primary Data Expected in 2022

Amended Debt Facility with SVB Provides Access Up to Additional $25 Million in Non-Dilutive Financing

New Drug Application (NDA) Filing for Tildacerfont in Adult Classic CAH Targeted for 2023

SAN FRANCISCO--(BUSINESS WIRE)--Mar. 22, 2021-- 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, 2020 and provided a corporate update.

"2020 was a transformative year for Spruce Biosciences, as we firmly established our company as an emerging leader in the development of groundbreaking therapies for rare endocrine disorders," said Richard King, Chief Executive Officer, Spruce Biosciences. "The initiation of our CAHmelia program in adult classic congenital adrenal hyperplasia (CAH) moves us one step closer to changing the treatment paradigm for patients living with this chronic and potentially life-threatening disease. Following the completion of our upsized IPO in October 2020, we are also preparing to expand the utility of tildacerfont through studies in children with classic CAH and in women living with a rare form of polycystic ovary syndrome (PCOS), with Phase 2 programs in both indications on track to initiate in the second half of 2021. We also remain focused on clinical study execution: we have the majority of our CAHmelia study sites now active across 2 continents and are encouraged by the level of patient interest registered with our study investigators and at CAHstudy.com."

King continued, "Following discussions with U.S. Food and Drug Administration, we have decided to increase the open label extension period for CAHmelia-203 by 18 weeks and for CAHmelia-204 by 24 weeks. In addition, we have increased the size of CAHmelia-204 from 60 patients to 90 patients. We believe that these changes will result in a more robust data package. With these program enhancements, together with the impact of the ongoing COVID-19 pandemic, we now expect primary data from CAHmelia-203 in the first half of 2022 and CAHmelia-204 in the second half of 2022. Assuming positive study outcomes, we continue to target an NDA filing for tildacerfont in adult classic CAH in 2023."

Recent Operating Highlights

- **Presentation of Phase 1 and 2 Data of Tildacerfont at Endocrine's Society's 2021 Annual Meeting (ENDO 2021):** In March 2021, data from the company's Phase 1 and 2 programs of tildacerfont in classic CAH were presented at ENDO 2021. The presentation highlighted several datasets, including data from the company's SPR001-202 study, which demonstrated the ability of tildacerfont to reduce and normalize key disease biomarkers over a 12-week period. Normalization of highly elevated hormones in classic CAH patients over a 12-week study and without increases to daily steroid doses has not been reported to date with any other investigational product candidate.

- **Submission of Pediatric Investigation Plan (PIP) to the European Medicines Agency (EMA):** Spruce has submitted a PIP to the Pediatric Committee of the EMA regarding a registrational program in pediatric classic CAH.

- **Patent Issuance Extends Tildacerfont Exclusivity Through 2038:** In December 2020, the United States Patent and Trademark Office issued US Patent Number 10,849,908 titled "Corticotrophin releasing factor antagonists." This newly issued patent covers broad claims regarding the use of a CRF1 receptor antagonist for the treatment of CAH, builds on existing composition of matter patents, and further extends exclusivity through 2038.

- **Addition to Russell 2000®, 3000®, and Microcap® Indexes:** In December 2020, the company was added to the Russell 2000®, 3000®, and Microcap® indexes as part of Russell's quarterly additions of selected initial public offering (IPOs). The additions increase overall awareness and visibility of the company within the investment community and may broaden its institutional shareholder base.

- **Amended Debt Facility with Silicon Valley Bank (SVB) Provides Access to $25 Million in Non-Dilutive Financing:** The company has amended its debt facility with SVB to increase the aggregate principal amount of the term loan commitment by SVB from $4.5 million to $30 million. The amendment refinances and delays repayment of principal of the existing $4.5 million term loan to 2023 and provides access up to $25 million in additional non-dilutive financing for general corporate purposes.

- **Cash and Cash Equivalents of $157.2 Million at 2020 Year End:** Following the IPO in October 2020, the company is

well capitalized to advance its pipeline through major milestones, including primary data readout from its late-stage CAHmelia program and Phase 2 programs in pediatric classic CAH and a rare form of PCOS.

Anticipated Upcoming Milestones

- Filing of an Investigational New Drug (IND) application in the first half of 2021 in PCOS
- Initiation of a Phase 2 proof-of-concept clinical trial in the second half of 2021 in PCOS
- Initiation of a Phase 2 clinical program in pediatric classic CAH in the second half of 2021

Financial Highlights

- **Cash and Cash Equivalents:** Cash and cash equivalents as of December 31, 2020, were $157.2 million.

- **Research and Development (R&D) Expenses:** R&D expenses for the fourth quarter and full year ended December 31, 2020 were $5.8 million and $23.9 million compared to $2.8 million and $10.8 million for the same periods in 2019, 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, 2020 were $2.5 million and $5.6 million, compared to $0.3 million and $2.3 million for the same periods in 2019, respectively. The overall increase in G&A expenses was primarily driven by an increase in costs related to operation as a public company.

- **Net Loss:** Net loss for the fourth quarter and full year ended December 31, 2020 was $8.3 million and $29.5 million, compared to $3.2 million and $13.1 million for the same periods in 2019, 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 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, representing 3-5% of females with PCOS (estimated to be 150,000 to 200,000 patients in the United States). To learn more, visit www.sprucebiosciences.com and follow us on Twitter @Spruce_Bio, LinkedIn and Facebook.

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, the regulatory approval path for tildacerfont, the strength of Spruce’s balance sheet and the adequacy of Spruce’s cash position. 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 “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.

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

	December 31,	
	2020	**2019**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 157,150	$ 3,924
Prepaid expenses	2,971	215
Other current assets	276	513
Total current assets	160,397	4,652
Restricted cash	216	—
Right-of-use assets	1,793	—
Other assets	477	40

Total assets	$ 162,883	$ 4,692
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 3,628	$ 1,878
Term loan, current portion	2,554	1,252
Accrued expenses and other current liabilities	2,496	265
Accrued compensation and benefits	1,085	908
Total current liabilities	9,763	4,303
Term loan, net of current portion	1,922	3,193
Lease liability, net of current portion	1,653	—
Other liabilities	118	20
Total liabilities	13,456	7,516
Series A redeemable convertible preferred stock, $0.0001 par value; 0 shares and 28,000,000 shares authorized, issued and outstanding as of December 31, 2020 and 2019, respectively; liquidation preference of $0 and $28,000 as of December 31, 2020 and 2019, respectively	—	27,813
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares and 0 shares authorized as of December 31, 2020 and 2019, respectively; 0 shares issued and outstanding as of December 31, 2020 and 2019	—	—
Common stock, $0.0001 par value; 200,000,000 shares and 41,000,000 shares authorized as of December 31, 2020 and 2019, respectively; 23,260,399 shares and 764,408 shares issued and outstanding as of December 31, 2020 and 2019, respectively	2	1
Additional paid-in capital	210,266	664
Accumulated deficit	(60,841)	(31,302)
Total stockholders' equity (deficit)	149,427	(30,637)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 162,883	$ 4,692

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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 5,813	$ 2,847	$ 23,854	$ 10,817
General and administrative	2,521	286	5,562	2,290
Total operating expenses	8,334	3,133	29,416	13,107
Loss from operations	(8,334)	(3,133)	(29,416)	(13,107)
Interest expense	(79)	(60)	(323)	(65)
Other income, net	75	12	200	84
Net loss	$ (8,338)	$ (3,181)	$ (29,539)	$ (13,088)
Net loss per share, basic and diluted	$ (0.39)	$ (4.16)	$ (4.93)	$ (17.12)
Weighted-average shares of common stock outstanding, basic and diluted	21,542,045	764,408	5,991,213	764,408

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