



## Spruce Biosciences Reports Third Quarter 2021 Financial Results and Provides Corporate Updates

November 15, 2021

*Planned Initiation of Phase 2 Programs in Pediatric Classic CAH and Polycystic Ovary Syndrome*

*Late-Stage CAHmelia Program in Adult Classic CAH Expanded to Sites in Australia and Canada*

*Cash, Cash Equivalents and Investments of \$131.3 Million as of September 30, 2021*

SAN FRANCISCO--(BUSINESS WIRE)--Nov. 15, 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 third quarter ended September 30, 2021 and provided a corporate update.

"We continue to make progress in advancing tildacerfont for the treatment of patients with rare endocrine disorders with the planned initiation of a Phase 2 clinical trial for children with classic congenital adrenal hyperplasia (CAH), as well as a proof-of-concept clinical trial for women with a rare form of polycystic ovary syndrome (PCOS)," said Mike Grey, Executive Chairman of Spruce Biosciences, who has taken on the role of Interim Chief Executive Officer following the retirement of Richard King as separately announced today. "While we have recently seen an encouraging upward trend in the pace of site activation and patient enrollment across our CAHmelia studies in adults with classic CAH, the continued variability of the impact of the COVID-19 pandemic across sites throughout the United States and Europe has impacted enrollment and we now expect to report topline results from the CAHmelia-203 study in 2023."

### **Corporate & Pipeline Updates in Q3 2021**

- **Update on Expected Timeline for Topline Data from the CAHmelia Program in Adult Classic CAH:** Due to the continued impact of the COVID-19 pandemic on the pace of patient enrollment and site activation in the company's CAHmelia program, Spruce now expects to report topline results from CAHmelia-203 in 2023. Spruce will provide an update on timing expectations for topline results from the CAHmelia-204 study in the coming months, following the completion of a full assessment of the pandemic's impact on projected enrollment.
- **Phase 2 CAHmelia Program in Adult Classic CAH Expanded to Sites in Australia and Canada:** Spruce has expanded the CAHmelia program in adult classic CAH beyond the United States and Europe to include sites in Australia and Canada in response to patient and investigator interest. The additional sites also provide more robust recruitment capabilities to accelerate enrollment and offset any additional disruption related to the ongoing COVID-19 pandemic.
- **Inaugural Research and Development Day Highlighted Tildacerfont in CAH:** In August, Spruce hosted its [inaugural virtual research and development day](#) highlighting the potential value of tildacerfont in treating adult and pediatric classic CAH. Management was joined by leading endocrinologists, Richard Auchus, MD, PhD, Professor of Internal Medicine and Pharmacology at the University of Michigan, and Paul Thornton, MD, Medical Director, Endocrine and Diabetes Program, Cook Children's Medical Center.
- **Planned Initiation of Phase 2 Clinical Trial in Pediatric Classic CAH on Track:** The Phase 2 open-label clinical trial will utilize a sequential 3 cohort design to evaluate the safety, pharmacokinetics, and exploratory pharmacodynamics of tildacerfont in children aged 6 to 17 with classic CAH. Various weight adjusted doses of tildacerfont dosed once daily for a duration of 2 weeks will be evaluated.
- **Planned Initiation of Phase 2 Proof of Concept Clinical Trial in PCOS on Track:** A randomized, placebo-controlled, response-guided, intrasubject dose escalation study will evaluate the safety and efficacy of various tildacerfont dose levels (50 mg, 100 mg, and 200 mg QD) compared to placebo for up to 16 weeks of treatment in subjects with PCOS and elevated adrenal androgens as measured by DHEAS levels at baseline.

### **Third Quarter 2021 Financial Results**

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of September 30, 2021, were \$131.3 million.
- **Research and Development (R&D) Expenses:** R&D expenses for the three and nine months ended September 30, 2021 were \$8.6 million and \$24.4 million, respectively, compared to \$7.8 million and \$18.0 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 three and nine months ended September 30, 2021 were \$2.8 million and \$8.5 million, respectively, compared to \$1.8 million and \$3.0 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 three and nine months ended September 30, 2021 were \$11.4 million and \$32.9 million, respectively, compared to \$9.6 million and \$21.1 million for the same periods in 2020, respectively. Stock-based compensation expense for the three and nine months ended September 30, 2021 was \$1.0 million and \$3.2 million, respectively. When excluding depreciation and stock-based compensation expenses, total operating expenses for the three and nine months ended September 30, 2021 were \$10.4 million and \$29.8 million, respectively.
- **Net Loss:** Net loss for the three and nine months ended September 30, 2021 was \$11.4 million and \$33.1 million, respectively, compared to \$9.6 million and \$21.2 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](http://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.**  
**CONDENSED BALANCE SHEETS**  
(unaudited)  
(in thousands, except share amounts)

	September 30, 2021	December 31, 2020
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 58,363	\$ 157,150
Short-term investments	33,957	—
Prepaid expenses	1,301	2,971
Other current assets	301	276
Total current assets	93,922	160,397
Restricted cash	216	216
Right-of-use assets, net	1,559	1,793
Long-term investments	38,975	—
Other assets	415	477

Total assets	\$	135,087	\$	162,883
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>				
Current liabilities:				
Accounts payable	\$	2,128	\$	3,628
Term loan, current portion		—		2,554
Accrued expenses and other current liabilities		5,924		2,496
Accrued compensation and benefits		1,009		1,085
Total current liabilities		9,061		9,763
Term loan, net of current portion		4,867		1,922
Lease liability, net of current portion		1,388		1,653
Other liabilities		51		118
Total liabilities		15,367		13,456
Stockholders' equity:				
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, and no shares issued and outstanding as of September 30, 2021 and December 31, 2020		—		—
Common stock, \$0.0001 par value, 200,000,000 shares authorized, 23,379,887 and 23,260,399 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively		3		2
Additional paid-in capital		213,682		210,266
Accumulated other comprehensive loss		(16)		—
Accumulated deficit		(93,949)		(60,841)
Total stockholders' equity		119,720		149,427
Total liabilities and stockholders' equity	\$	135,087	\$	162,883

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 8,607	\$ 7,769	\$ 24,440	\$ 18,040
General and administrative	2,793	1,790	8,491	3,041
Total operating expenses	11,400	9,559	32,931	21,081
Loss from operations	(11,400)	(9,559)	(32,931)	(21,081)
Interest expense	(88)	(79)	(257)	(245)
Other income, net	41	51	80	125
Net loss	\$ (11,447)	\$ (9,587)	\$ (33,108)	\$ (21,201)
Unrealized gain/(loss) on available for sale securities	13	-	(16)	-
Comprehensive loss	\$ (11,434)	\$ (9,587)	\$ (33,124)	\$ (21,201)
Net loss per share, basic and diluted	\$ (0.49)	\$ (12.35)	\$ (1.42)	\$ (27.54)
Weighted-average shares of common stock outstanding, basic and diluted	23,367,140	776,159	23,330,399	769,766

**SPRUCE BIOSCIENCES, INC.**

**Reconciliation of Total Operating Expenses to Non-GAAP Total Operating Expenses**  
(unaudited)  
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Total operating expenses	\$ 11,400	\$ 9,559	\$ 32,931	\$ 21,081
Adjustments:				
Depreciation	5	1	14	2
Stock-based compensation	1,031	218	3,161	346
Non-GAAP total operating expenses	\$ 10,364	\$ 9,340	\$ 29,756	\$ 20,733

**Reconciliation of G&A Expenses to Non-GAAP G&A Expenses**

(unaudited)  
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
G&A expenses	\$ 2,793	\$ 1,790	\$ 8,491	\$ 3,041
Adjustments:				
Depreciation	5	1	9	2
Stock-based compensation	777	129	2,297	208
Non-GAAP G&A expenses	<u>\$ 2,011</u>	<u>\$ 1,660</u>	<u>\$ 6,185</u>	<u>\$ 2,831</u>

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