Spruce Biosciences Reports Third Quarter 2022 Financial Results and Provides Corporate Updates

November 10, 2022

CAHmelia-203 Approaching 50% Enrollment; CAHmelia-204 Recently Surpassed 25% Enrollment

Appointment of Saba Sile, M.D., as Vice President of Clinical Development

SAN FRANCISCO--(BUSINESS WIRE)--Nov. 10, 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 third quarter ended September 30, 2022 and provided corporate updates.

"The third quarter of 2022 was one of continuous execution and momentum on multiple fronts. We were pleased to have recently surpassed 25% enrollment in our CAHmelia-204 study and are approaching 50% enrollment in our CAHmelia-203 study," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. "As we continue to advance our late-stage clinical pipeline of therapies for rare endocrine disorders, I am excited to welcome Dr. Saba Sile as our Vice President of Clinical Development. With her extensive background in directing clinical development across multiple rare disease programs, Dr. Sile will play a key role in delivering on the full potential of tildacerfont to bring therapeutic benefit to patients with congenital adrenal hyperplasia (CAH) and other endocrine disorders."

Recent Corporate Update

- **Appointment of Saba Sile, M.D., as Vice President of Clinical Development**: As Vice President of Clinical Development, Dr. Sile will report to Dr. Will Charlton, Chief Medical Officer, and lead global clinical development of tildacerfont. Dr. Sile is a seasoned clinical research and development physician with nearly two decades of experience directing and leading clinical development programs that span across multiple therapeutic areas, including cardiovascular, immunology, and rare disease programs. Dr. Sile joins Spruce from Horizon Therapeutics, where she served as Executive Medical Director of Clinical Development. Prior to Horizon, she held roles of increasing responsibility at Raptor Pharmaceuticals, Gilead Sciences, and BioMarin Pharmaceutical. She earned an M.D. from the University of Pittsburgh School of Medicine and completed Genetics and Nephrology fellowships at Vanderbilt University.

Anticipated Upcoming Milestones

- Topline results from the Phase 2 proof-of-concept clinical trial in polycystic ovary syndrome (PCOS) 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 androstenedione (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

Third Quarter 2022 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and short-term investments as of September 30, 2022, were $90.4 million.
- **Research and Development (R&D) Expenses:** R&D expenses for the three and nine months ended September 30, 2022, were $8.8 million and $26.4 million, respectively, compared to $8.6 million and $24.4 million, respectively, for the same periods in 2021. The overall increase in R&D expenses was primarily related to 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 three and nine months ended September 30, 2022, were $2.8 million and $8.8 million, respectively, compared to $2.8 million and $8.5 million, respectively, for the same periods in 2021.
- **Total Operating Expenses:** Total operating expenses for the three and nine months ended September 30, 2022, were $11.6 million and $35.2 million, respectively, compared to $11.4 million and $32.9 million, respectively, for the same periods in 2021. Stock-based compensation expense for the three and nine months ended September 30, 2022, was $0.8 million and $2.8 million, respectively, compared to $1.0 million and $3.2 million, respectively, for the same periods in 2021. When

excluding depreciation and stock-based compensation expenses, total non-GAAP operating expenses for the three and nine months ended September 30, 2022, were $10.8 million and $32.3 million, respectively, compared to $10.4 million and $29.8 million for the same periods in 2021.

- **Net Loss:** Net loss for the three and nine months ended September 30, 2022 was $11.4 million and $35.0 million, respectively, compared to $11.4 million and $33.1 million, respectively, for the same periods 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; the receipt of topline data from the same; and Dr. Sile’s role as Vice President of Clinical Development. 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”, “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 geopolitical and macroeconomic events, including 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 Measure

This release and the reconciliation tables included herein include non-GAAP total operating expenses, which excludes depreciation and stock-based compensation expenses. Spruce excludes depreciation and stock-based compensation expenses 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
(unaudited)
(in thousands, except share and per share amounts)

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,649	$ 42,748
Short-term investments	68,751	46,221
Prepaid expenses and other current assets	2,786	2,926
Total current assets	93,186	91,895
Restricted cash	216	216
Operating lease right-of-use assets	1,229	1,479
Long-term investments	—	32,459
Other assets	667	437
Total assets	$ 95,298	$ 126,486
LIABILITIES AND STOCKHOLDERS’ EQUITY		
Current liabilities:		
Accounts payable	$ 2,181	$ 2,823
Term loan, current portion	1,216	—
Accrued expenses and other current liabilities	8,604	6,048
Total current liabilities	12,001	8,871
Term loan, net of current portion	3,685	4,878
Operating lease liability, net of current portion	998	1,293
Other liabilities	139	73
Total liabilities	16,823	15,115

Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized and no shares issued or outstanding as of September 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value, 200,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 23,560,250 and 23,491,881 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	3	3
Additional paid-in capital	217,514	214,685
Accumulated other comprehensive loss	(873)	(184)
Accumulated deficit	(138,169)	(103,133)
Total stockholders' equity	78,475	111,371
Total liabilities and stockholders' equity	$ 95,298	$ 126,486

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 8,791	$ 8,607	$ 26,359	$ 24,440
General and administrative	2,766	2,793	8,814	8,491
Total operating expenses	11,557	11,400	35,173	32,931
Loss from operations	(11,557)	(11,400)	(35,173)	(32,931)
Interest expense	(110)	(88)	(291)	(257)
Interest and other income, net	266	41	428	80
Net loss	$ (11,401)	$ (11,447)	$ (35,036)	$ (33,108)
Unrealized (loss) gain on available for sale securities	(28)	13	(689)	(16)
Comprehensive loss	$ (11,429)	$ (11,434)	$ (35,725)	$ (33,124)
Net loss per share, basic and diluted	$ (0.48)	$ (0.49)	$ (1.49)	$ (1.42)
Weighted-average shares of common stock outstanding, basic and diluted	23,560,250	23,367,140	23,515,651	23,330,399

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Total operating expenses	$ 11,557	$ 11,400	$ 35,173	$ 32,931
Adjustments:				
Depreciation	10	5	27	14
Stock-based compensation	783	1,031	2,829	3,161
Total Non-GAAP operating expenses	$ 10,764	$ 10,364	$ 32,317	$ 29,756

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Source: Spruce Biosciences, Inc.