Spruce Biosciences Reports Second Quarter 2021 Financial Results and Provides Corporate Updates

August 10, 2021

Clearance of IND for Treatment of Polycystic Ovary Syndrome

New Patent Broadens Tildacerfont Intellectual Property Estate in Congenital Adrenal Hyperplasia

Publication of Tildacerfont Phase 2 Data in the Journal of Clinical Endocrinology and Metabolism

SAN FRANCISCO--(BUSINESS WIRE)--Aug. 10, 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 second quarter ended June 30, 2021 and provided a corporate update.

"As we continue to progress the execution of the CAHmelia clinical program in adults with classic congenital adrenal hyperplasia (CAH), we were also pleased with the FDA's clearance of our investigational new drug (IND) application for polycystic ovary syndrome (PCOS). This milestone allows us to continue fulfilling our strategy of advancing tildacerfont as a potential treatment for patients with rare endocrine disorders with significant unmet medical need," said Richard King, Chief Executive Officer of Spruce Biosciences. "We believe that tildacerfont may provide a therapeutic option to treat the underlying pathophysiology of disease through reduction of adrenocorticotropic hormone (ACTH) and therefore adrenal hyperandrogenism in this population. With no therapies currently approved in the U.S. to treat hyperandrogenism due to adrenal dysfunction in females with PCOS, the clearance of our IND brings us one step closer to developing a potential new treatment option for these patients."

Corporate & Pipeline Highlights in Q2 2021

- **Clearance of IND for Treatment of Polycystic Ovary Syndrome:** During the second quarter, Spruce completed a meeting with and submitted an IND application to the FDA for the study of tildacerfont, a potent and highly selective, non-steroidal CRF1 receptor antagonist, in females with PCOS. PCOS is a hormonal disorder common among women of reproductive age and is characterized by an overproduction of androgens, which can result in irregular menses, infertility, hirsutism, male pattern baldness and acne. Adrenal androgen excess in PCOS may result from an enhanced adrenal responsivity to ACTH. With clearance of the IND, Spruce remains on track to initiate a Phase 2 proof of concept study later this year.
- **Issuance of Patent Broadens Tildacerfont Intellectual Property Estate in CAH:** The United States Patent and Trademark Office issued U.S. Patent 11,007,201 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 and method of use patents, and broadens tildacerfont's patent exclusivity through 2038.
- **Publication of Tildacerfont Phase 2 Data in the *Journal of Clinical Endocrinology and Metabolism*:** In June 2021, Spruce announced the publication of the results from two Phase 2 clinical trials investigating tildacerfont in adult patients with classic CAH in the *Journal of Clinical Endocrinology and Metabolism*. The results of the trials showed that, in subjects with elevations of ACTH and androstenedione, at baseline, tildacerfont reduced these key hormone biomarkers, with normalization in 60% and 40% of subjects, respectively. Tildacerfont was generally safe and well-tolerated.
- **Cash, Cash Equivalents, and Investments of $139 Million:** Based on Spruce's current operating plan, Spruce believes it is well capitalized to advance its pipeline beyond key milestones, including primary data readout from its CAHmelia trials and Phase 2 programs in pediatric classic CAH and PCOS.

Anticipated Upcoming Milestones

Spruce reaffirms the following previously issued clinical development program milestones:

- Initiation of a Phase 2 proof-of-concept clinical trial in PCOS in the second half of 2021
- Initiation of a Phase 2 clinical trial in pediatric classic CAH in the second half of 2021
- Results from CAHmelia-203 in adult classic CAH patients with poor disease control the first half of 2022
- Results from CAHmelia-204 in adult classic CAH patients with good disease control in the second half of 2022

Spruce now confirms the following clinical development program milestone:

- Results from the Phase 2 proof-of-concept clinical trial in PCOS in the first half of 2023

Second Quarter 2021 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of June 30, 2021, were $139.0 million.

- **Research and Development (R&D) Expenses:** R&D expenses for the three and six months ended June 30, 2021 were $9.1 million and $15.8 million, respectively, compared to $5.7 million and $10.3 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 six months ended June 30, 2021 were $2.6 million and $5.7 million, respectively, compared to $0.7 million and $1.3 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 six months ended June 30, 2021 were $11.7 million and $21.5 million, respectively, compared to $6.4 million and $11.5 million for the same periods in 2020, respectively. Stock-based compensation for the three and six months ended June 30, 2021 was $1.0 million and $2.1 million, respectively. When excluding depreciation and stock-based compensation, total operating expenses for the three and six months ended June 30, 2021 were $10.7 million and $19.4 million, respectively.
- **Net Loss:** Net loss for the three and six months ended June 30, 2021 was $11.8 million and $21.7 million, respectively, compared to $6.4 million and $11.6 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, 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.

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)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 78,278	$ 157,150
Short-term investments	30,945	—
Prepaid expenses	1,799	2,971
Other current assets	347	276
Total current assets	111,369	160,397
Restricted cash	216	216
Right-of-use assets	1,638	1,793
Long-term investments	29,768	—
Other assets	457	477

Total assets	$ 143,448	$ 162,883
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,113	$ 3,628
Term loan, current portion	—	2,554
Accrued expenses and other current liabilities	4,894	2,496
Accrued compensation and benefits	973	1,085
Total current liabilities	6,980	9,763
Term loan, net of current portion	4,855	1,922
Lease liability, net of current portion	1,478	1,653
Other liabilities	29	118
Total liabilities	13,342	13,456
Stockholders' equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized, and no shares issued and outstanding as of June 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value, 200,000,000 shares authorized, 23,370,070 and 23,260,399 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	3	2
Additional paid-in capital	212,634	210,266
Accumulated other comprehensive loss	(29)	—
Accumulated deficit	(82,502)	(60,841)
Total stockholders' equity	130,106	149,427
Total liabilities and stockholders' equity	$ 143,448	$ 162,883

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 9,119	$ 5,662	$ 15,833	$ 10,272
General and administrative	2,595	727	5,698	1,250
Total operating expenses	11,714	6,389	21,531	11,522
Loss from operations	(11,714)	(6,389)	(21,531)	(11,522)
Interest expense	(80)	(92)	(169)	(166)
Other income, net	20	35	39	74
Net loss	$ (11,774)	$ (6,446)	$ (21,661)	$ (11,614)
Unrealized loss on available for sale securities	(29)	-	(29)	-
Comprehensive loss	$ (11,803)	$ (6,446)	$ (21,690)	$ (11,614)
Net loss per share, basic and diluted	$ (0.50)	$ (8.43)	$ (0.93)	$ (15.15)
Weighted-average shares of common stock outstanding, basic and diluted	23,329,756	764,408	23,306,708	766,534

SPRUCE BIOSCIENCES, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Total operating expenses	$ 11,714	$ 6,389	$ 21,531	$ 11,522
Adjustments:				
Depreciation	5	—	9	—
Stock-based compensation	1,010	96	2,130	128
Non-GAAP total operating expenses	$ 10,699	$ 6,293	$ 19,392	$ 11,394

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
G&A expenses	$ 2,595	$ 727	$ 5,698	$ 1,250
Adjustments:				
Depreciation	5	—	9	—
Stock-based compensation	664	57	1,520	79
Non-GAAP G&A expenses	$ 1,926	$ 670	$ 4,169	$ 1,171

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