# Spruce Biosciences Reports Third Quarter 2023 Financial Results and Provides Corporate Updates

November 13, 2023

*Enrollment Completed in CAHptain-205 Study in Pediatric Classic Congenital Adrenal Hyperplasia (CAH)*

*Target Enrollment Completed in CAHmelia-203 Study in Adult Classic CAH*

*CAHmelia-204 Study in Adult Classic CAH on Track to Complete Enrollment in Early Q1 2024*

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Nov. 13, 2023-- 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, 2023 and provided corporate updates.

“Achieving completion of enrollment milestones in the CAHptain-205 and CAHmelia-203 studies underscores the strong execution of our key clinical objectives and the momentum within our adult and pediatric classic CAH programs,” said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. “We continue to make notable progress in our efforts to advance tildacerfont as a potentially novel therapeutic option for people living with CAH and are eager to report topline data from CAHmelia-203 and CAHptain-205 in the first quarter of 2024.”

**Recent Corporate Updates**

- **CAHptain-205 Study in Pediatric Classic CAH Completes Enrollment:** Enrollment in the CAHptain study is complete with 30 patients, surpassing the target enrollment of 20 patients. CAHptain is a Phase 2 open-label clinical trial that utilizes a sequential 3 cohort design (cohorts 1 and 2 comprised of adolescent patients 11 to 17 years of age, and cohort 3 comprised of children 2 to 10 years of age) to evaluate the safety, pharmacokinetics (PK), and exploratory pharmacodynamics (PD) of tildacerfont in children with classic CAH.
- **CAHmelia-203 Study in Adult Classic CAH Completes Target Enrollment:** Target enrollment of 72 patients in the company’s CAHmelia-203 clinical trial is complete. CAHmelia-203 is a randomized, double-blind, placebo-controlled, dose-ranging Phase 2b clinical trial evaluating the safety and efficacy of tildacerfont in adults with classic CAH and highly elevated levels of androstenedione (A4) at baseline while on stable glucocorticoid dosing. Due to substantial patient interest in CAHmelia-203, final enrollment in the study will exceed its original target of 72 patients.
- **CAHmelia-204 Study in Adult Classic CAH on Track to Complete Enrollment in Early Q1 2024:** Enrollment in the CAHmelia-204 clinical trial surpassed 75% enrollment and remains on track to complete enrollment in the early first quarter of 2024. CAHmelia-204 is a randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of tildacerfont in reducing supraphysiologic glucocorticoid use in adult patients with classic CAH.

**Anticipated Upcoming Milestones**

- Completion of enrollment in 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 early first quarter of 2024
- Topline results from the CAHmelia-203 clinical trial in adult classic CAH patients with highly elevated levels of A4 in the first quarter of 2024
- Topline results from all cohorts in the CAHptain-205 clinical trial in pediatric classic CAH patients in the first quarter of 2024
- 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 third quarter of 2024

**Third Quarter 2023 Financial Results**

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of September 30, 2023 were $108.0 million. Cash, cash equivalents and investments are expected to allow the company to fund operating and capital expenditures into the first half of 2025.
- **Collaboration Revenue:** Collaboration revenue for the three and nine months ended September 30, 2023 were $3.1 million and $7.2 million, respectively, compared to nil for the same periods in 2022. The increase in collaboration revenue reflects the partial recognition of the $15.0 million upfront payment the company received in connection with the collaboration and license agreement with Kaken Pharmaceutical.

- **Research and Development (R&D) Expenses:** R&D expenses for the three and nine months ended September 30, 2023 were $13.5 million and $38.3 million, respectively, compared to $8.8 million and $26.4 million for the same periods in 2022. The overall increase in R&D expenses was primarily related to progressing clinical development of tildacerfont in adult classic CAH, pediatric classic CAH and PCOS.

- **General and Administrative (G&A) Expenses:** G&A expenses for the three and nine months ended September 30, 2023 were $3.2 million and $9.7 million, respectively, compared to $2.8 million and $8.8 million for the same periods in 2022.

- **Total Operating Expenses:** Total operating expenses for the three and nine months ended September 30, 2023 were $16.7 million and $48.0 million, respectively, compared to $11.6 million and $35.2 million for the same periods in 2022.

- **Net Loss:** Net loss for the three and nine months ended September 30, 2023 was $12.4 million and $38.0 million, respectively, compared to $11.4 million and $35.0 million for the same periods in 2022.

**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). Spruce is also developing tildacerfont for women suffering from polycystic ovary syndrome (PCOS). To learn more, visit www.sprucebio.com and follow us on Twitter/X @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 and presentation of topline data from the same; research and development plans; and Spruce’s planned operations, including its expectations regarding operating and capital expenditures being funded into the first half of 2025. 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”, “expect”, “may”, “plan”, “will”, “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, 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.**
**CONDENSED BALANCE SHEETS**
**(unaudited)**
**(in thousands, except share and per share amounts)**

| | September 30, 2023 | December 31, 2022 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 98,801 | $ 24,487 |
| Short-term investments | 9,231 | 54,590 |
| Prepaid expenses | 2,687 | 3,320 |
| Other current assets | 419 | 1,211 |
| Total current assets | 111,138 | 83,608 |
| Right-of-use assets | 1,240 | 1,400 |
| Other assets | 607 | 640 |
| Total assets | $ 112,985 | $ 85,648 |
| **LIABILITIES AND STOCKHOLDERS’ EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,152 | $ 1,426 |
| Accrued expenses and other current liabilities | 11,616 | 9,399 |
| Term loan, current portion | 1,622 | 1,622 |
| Deferred revenue, current portion | 7,798 | — |
| Total current liabilities | 24,188 | 12,447 |
| Lease liabilities, net of current portion | 1,083 | 1,261 |
| Term loan, net of current portion | 2,113 | 3,293 |
| Other liabilities | 220 | 161 |

| | | |
|---|---|---|
| Total liabilities | 27,604 | 17,162 |
| 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, 2023 and December 31, 2022 | — | — |
| Common stock, $0.0001 par value; 200,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 40,710,692 and 23,601,004 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively | 4 | 3 |
| Additional paid-in capital | 272,662 | 218,354 |
| Accumulated other comprehensive loss | (3) | (558) |
| Accumulated deficit | (187,282) | (149,313) |
| Total stockholders' equity | 85,381 | 68,486 |
| Total liabilities and stockholders' equity | $ 112,985 | $ 85,648 |

**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, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Collaboration revenue | $ 3,073 | $ — | $ 7,202 | $ — |
| Operating expenses: | | | | |
| Research and development | 13,494 | 8,791 | 38,332 | 26,359 |
| General and administrative | 3,237 | 2,766 | 9,699 | 8,814 |
| Total operating expenses | 16,731 | 11,557 | 48,031 | 35,173 |
| Loss from operations | (13,658) | (11,557) | (40,829) | (35,173) |
| Interest expense | (119) | (110) | (377) | (291) |
| Interest and other income, net | 1,423 | 266 | 3,237 | 428 |
| Net loss | (12,354) | (11,401) | (37,969) | (35,036) |
| Other comprehensive gain (loss), net of tax: | | | | |
| Unrealized gain (loss) on available for sale securities | 52 | (28) | 555 | (689) |
| Total comprehensive loss | $ (12,302) | $ (11,429) | $ (37,414) | $ (35,725) |
| Net loss per share, basic and diluted | $ (0.30) | $ (0.48) | $ (1.01) | $ (1.49) |
| Weighted-average shares of common stock outstanding, basic and diluted | 40,710,692 | 23,560,250 | 37,751,865 | 23,515,651 |

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