UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 4, 2024

Spruce Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39594**	**81-2154263**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
611 Gateway Boulevard, Suite 740 South San Francisco, California		**94080**
(Address of principal executive offices)		**(Zip Code)**

Registrant's telephone number, including area code: (415) 655-4168

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	SPRB	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On January 4, 2024, Spruce Biosciences, Inc. (the "Company") issued a press release providing a corporate update that included updates on its clinical programs, anticipated upcoming milestones, and an estimate that its cash and cash equivalents as of December 31, 2023 were approximately $96 million. This amount is unaudited and preliminary and is subject to completion of financial closing procedures. Additional information and disclosure would be required for a more complete understanding of the Company's financial position and results of operations as of December 31, 2023. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

All of the information furnished in this Item 2.02 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended ("Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On January 5, 2024, the Company issued a press release reporting baseline characteristics of patients enrolled in the Company's Phase 2b CAHmelia-203 and CAHmelia-204 clinical trials of tildacerfont for the treatment of adult classic congenital adrenal hyperplasia ("CAH"). A copy of the press release is furnished as Exhibit 99.2 hereto.

All of the information furnished in this Item 7.01 and Item 9.01 (including Exhibit 99.2) shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act and shall not be incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

As noted in Item 7.01, on January 5, 2024, the Company issued a press release reporting baseline characteristics of patients enrolled in the Company's Phase 2b CAHmelia-203 and CAHmelia-204 clinical trials of tildacerfont for the treatment of adult classic CAH:

CAHmelia Adult Classic CAH Program Baseline Characteristics

Study Characteristics	CAHmelia-203 (N = 96)	CAHmelia-204 (N = 98)[1]
Male/Female (Proportion of Total Subjects)	47% Male 53% Female	47% Male 53% Female
Average Age Age Ranges	32 Years Old (18 – 65 Years Old)	33 Years Old (18 – 64 Years Old)
Average Baseline Glucocorticoid (GC) Dose[2]	27 mg/day (14 mg/m^2/day)	35 mg/day (19 mg/m^2/day)
Average Baseline Androstenedione (A4) Level[3]	1,149 ng/dL	214 ng/dL
Body Mass Index (BMI)	50% Obese (BMI ≥ 30 kg/m^2)	53% Obese (BMI ≥ 30 kg/m^2)

[1] Patients enrolled as of December 20, 2023. Final enrollment is anticipated to be completed in January 2024 and projected between 98 and 100 patients.
[2] In hydrocortisone equivalents (HCe)
[3] Pre-GC dose.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, the results, conduct, progress and timing of the Company's clinical trials. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they prove incorrect or do not fully materialize, could cause the Company's results to differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, risks and uncertainties related to: topline data may not reflect the complete or final results of a particular study or trial, and are subject to change; the Company's ability to advance, obtain regulatory approval of and ultimately commercialize its product candidates; the timing and results of preclinical and clinical trials; the risk that positive results in a clinical trial may not be replicated in subsequent trials or successes in early stage clinical trials may not be predictive of results in later stage trials and preliminary interim data readouts of ongoing trials may show results that change when such trials are completed; the Company's ability to fund development activities and achieve development goals; the Company's ability to protect its intellectual property; the direct and indirect impacts of geopolitical and macroeconomic events on the Company's business; and other risks and uncertainties described under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, its subsequently filed Quarterly Reports on Form 10-Q, and the other documents the Company files from time to time with the U.S. Securities and Exchange Commission ("SEC"). These forward-looking statements speak only as of the date of this Current Report on Form 8-K, and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of Spruce Biosciences, Inc., dated January 4, 2024.
99.2	Press Release of Spruce Biosciences, Inc., dated January 5, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SPRUCE BIOSCIENCES, INC.

Date: January 8, 2024

By: /s/ Samir Gharib
Samir Gharib
President and Chief Financial Officer

Spruce Biosciences Provides Clinical Program Updates and Outlook for 2024

Catalyst-Heavy 2024 with Topline Results from CAHmelia-203 in Adult Classic Congenital Adrenal Hyperplasia (CAH) and CAHptain-205 in Pediatric Classic CAH Anticipated in March 2024

Topline Results from CAHmelia-204 in Adult Classic CAH Anticipated in Q3 2024

Cash Runway Anticipated into the First Half of 2025

South San Francisco, Calif. – Jan. 4, 2024 – 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 provided an update on its clinical programs, upcoming milestones and strategic priorities for advancing tildacerfont for the treatment of adult and pediatric classic congenital adrenal hyperplasia (CAH).

“2023 was a year of exceptional clinical execution across the board, and we were pleased to reach important milestones by completing enrollment in CAHmelia-203 for adult classic CAH and CAHptain-205 for pediatric classic CAH,” said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. “We’re also nearing completion of enrollment in CAHmelia-204 for adult classic CAH and look forward to maintaining this momentum with a catalyst-heavy 2024, and plan to report topline results from CAHmelia-203 and CAHptain-205 in March 2024, along with results from CAHmelia-204 in the third quarter of 2024.”

Dr. Szwarcberg continued, “There is a significant unmet medical need in children and adults with CAH to alleviate the systemic risks and comorbidities associated with hyperandrogenemia and chronic overexposure to glucocorticoids (GCs). Tildacerfont, if approved, has the potential to alter the treatment paradigm by providing a new and potentially novel, once-daily, non-steroidal treatment option that reduces adrenal hormones and alleviates the daily burden of supraphysiologic exposure to GCs. We are committed to unlocking the full therapeutic potential of tildacerfont and delivering a quantifiable and meaningful improvement over today’s standard of care in CAH.”

Anticipated Upcoming Milestones

- Completion of enrollment in CAHmelia-204 clinical trial in adult classic CAH patients on supraphysiologic doses of glucocorticoids with normal or near normal levels of androstenedione (A4) in January 2024
- Topline results from the CAHmelia-203 clinical trial in adult classic CAH patients with highly elevated levels of A4 in March 2024
- Topline results from all cohorts in the CAHptain-205 clinical trial in pediatric classic CAH patients in March 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

Tildacerfont Program Updates

Late-Stage CAHmelia Program in Adult Classic CAH

- **CAHmelia-203 Study in Adult Classic CAH Completes Enrollment:** Enrollment in CAHmelia-203 is complete with 96 patients, surpassing target enrollment of 72 patients. 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 A4 at baseline while on stable glucocorticoid dosing. The primary endpoint of the clinical trial is the percentage change in A4 from baseline at week 12. Topline results from the study are anticipated in March 2024.

- **Enrollment for CAHmelia-204 Study in Adult Classic CAH to be Completed in January 2024:** Enrollment in CAHmelia-204 is anticipated to be completed in January 2024, and will surpass target enrollment of 90 patients. CAHmelia-204 is a randomized, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of tildacerfont in reducing supraphysiologic glucocorticoid usage in adults with classic CAH in patients on supraphysiologic doses of glucocorticoids with normal or near normal levels of A4 at baseline. Based on a statistical analysis of aggregated blinded data, the primary endpoint of this clinical trial is now the absolute change in glucocorticoid dose from baseline at week 24. Topline results from the study are anticipated in the third quarter of 2024.

Pediatric Classic CAH Program

- **CAHptain-205 Study in Pediatric Classic CAH Completes Enrollment:** Enrollment in CAHptain-205 is complete with 30 patients, surpassing target enrollment of 20 patients**.** CAHptain-205 is a Phase 2 open-label clinical trial, which utilizes a sequential three cohort design, to evaluate the safety, efficacy, and pharmacokinetics of tildacerfont in children two to 17 years of age. The primary endpoint of this clinical trial is safety. Additional secondary endpoints include the proportion of subjects who achieve reduction in A4 or daily glucocorticoid dosing at week 12 and the proportion of subjects with elevated A4 at baseline who achieve a reduction in A4 at week 4. Topline results from the study are anticipated in March 2024.

Financial Update

Cash and cash equivalents as of December 31, 2023 were approximately $96 million. Based on the company's current operating plan, operating and capital expenditures are funded into the first half of 2025. Common shares outstanding as of December 31, 2023 were 41.0 million.

These amounts are unaudited and preliminary and are subject to completion of financial closing procedures. Additional information and disclosure would be required for a more complete understanding of the company's financial position and results of operations as of December 31, 2023.

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, once-daily therapy for patients suffering from classic congenital adrenal hyperplasia (CAH) and other endocrine disorders. To learn more, visit www.sprucebio.com and follow us on X, 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 fulfillment of Spruce's strategic business objectives, the advancement of Spruce's drug development pipeline, 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 "plan", "anticipate", "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.

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Spruce Biosciences Reports Baseline Characteristics from CAHmelia-203 and CAHmelia-204 Studies in Adult Classic CAH

Baseline Characteristics Reinforce Study Enrichment Strategy in Adult Classic Congenital Adrenal Hyperplasia (CAH) Program

South San Francisco, Calif. – Jan. 5, 2024 – 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 baseline characteristics of patients enrolled in the CAHmelia-203 and CAHmelia-204 clinical studies of tildacerfont for the treatment of adult classic congenital adrenal hyperplasia (CAH).

"The baseline characteristics of patients enrolled in our CAHmelia-203 and CAHmelia-204 studies reinforce our adult CAH program enrichment strategy and underscore the clinical significance of both hyperandrogenemia and hypercortisolemia within this patient population," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. "In particular, patients in CAHmelia-203, which is assessing the change in androstenedione (A4) from baseline at week 12, enrolled with mean baseline A4 levels nearly six times above the upper limit of normal on a mean baseline daily glucocorticoid (GC) dose of 27 mg hydrocortisone equivalents (HCe)."

Dr. Szwarcberg continued: "By contrast, patients in CAHmelia-204, which is assessing the absolute change in GC dose from baseline at week 24, enrolled with a mean baseline daily GC dose of 35 mg HCe and suppressed levels of A4. Collectively, we are encouraged by these baseline characteristics and look forward to reporting topline results from CAHmelia-203 in March, followed by CAHmelia-204 in the third quarter."

CAHmelia Adult Classic CAH Program Baseline Characteristics

Study Characteristics	CAHmelia-203 (N = 96)	CAHmelia-204 (N = 98)[1]
Male/Female (Proportion of Total Subjects)	47% Male 53% Female	47% Male 53% Female
Average Age Age Ranges	32 Years Old (18 – 65 Years Old)	33 Years Old (18 – 64 Years Old)
Average Baseline Glucocorticoid (GC) Dose[2]	27 mg/day (14 mg/m^2/day)	35 mg/day (19 mg/m^2/day)
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Body Mass Index (BMI)	50% Obese (BMI ≥ 30 kg/m^2)	53% Obese (BMI ≥ 30 kg/m^2)

[1] Patients enrolled as of December 20, 2023. Final enrollment is anticipated to be completed in January 2024 and projected between 98 and 100 patients.

[2] In hydrocortisone equivalents (HCe)

[3] Pre-GC dose.

About Congenital Adrenal Hyperplasia (CAH)

CAH is an autosomal recessive disease, driven by a mutation in the gene that encodes an enzyme necessary for the synthesis of key adrenal hormones. In CAH patients, the body is not able to produce cortisol, leading to serious health consequences. The absence of cortisol alters the normal feedback cycle of the hypothalamic-pituitary-adrenal (HPA) axis and leads to excess secretion of adrenocorticotropic hormone (ACTH), hyperplasia of the adrenal gland, and consequently high levels of adrenal androgen production. As a result, CAH patients suffer from premature puberty, impaired fertility, hirsutism, acne, the development of adrenal rest tumors, and an impaired quality of life, and additionally for females, virilized genitalia and menstrual irregularities. Currently, the only way to downregulate the production of excess androgens in CAH patients is to administer supraphysiologic doses of glucocorticoids, which present specific side effects, including increased risks of developing diabetes, cardiovascular disease, stunted growth, osteoporosis, thin skin, gastrointestinal disorders, and decreased lifespan.

About Tildacerfont

Tildacerfont is a potent and highly selective, non-steroidal, once-daily oral antagonist of the CRF1 receptor, which is the receptor for corticotropin-releasing factor (CRF), a hormone that is secreted by the hypothalamus. The CRF1 receptor is abundantly expressed in the pituitary gland where it is the primary regulator of the HPA axis. By blocking the CRF1 receptor, tildacerfont has the potential to address the uncontrolled cortisol feedback regulatory pathway in CAH, and in turn reduce the production of ACTH in the pituitary, limiting the amount of androgen produced downstream from the adrenal gland. By controlling excess adrenal androgens through an independent mechanism, tildacerfont has the potential to reduce the unwanted clinical symptoms associated with high androgen exposure and could also enable treating physicians to lower the supraphysiologic glucocorticoid doses given to CAH patients to near physiologic levels. Tildacerfont has been evaluated in over 200 subjects across nine completed clinical trials in which it has been generally well tolerated. No drug-related serious adverse events have been reported related to tildacerfont treatment in completed studies.

About CAHmelia-203

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 A4 at baseline while on stable glucocorticoid dosing. This clinical trial enrolled 96 subjects with elevated levels of A4. For the first six weeks, patients will receive blinded placebo to assess their adherence to their existing glucocorticoid therapy. Patients who continue to meet all eligibility criteria at the end of this period will enter a three-part treatment period. During the placebo-controlled treatment period, patients will be randomized in a blinded manner to receive placebo, 50mg, 100mg, or 200mg tildacerfont once daily. Dosing in the placebo-controlled treatment period will continue for 12 weeks. The primary endpoint of the clinical trial is the percentage change in A4 from baseline to week 12 with secondary endpoints including the proportion of patients with levels of 17-OHP and A4 within the target and normal range, respectively, and change in lesion volume of TARTs in men. Following the placebo-controlled treatment period, all patients will receive tildacerfont following a dose-escalation protocol that allows dose increase to 200mg once daily over 12 weeks. Following the 12-week dose-escalation period, all patients will continue receiving tildacerfont at 200mg once daily for an additional 46 weeks. Patients who achieve control of A4 while on supraphysiologic glucocorticoid treatment will have the opportunity to reduce their glucocorticoid dosing in the open-label period according to a pre-specified

algorithm in the protocol. Additional endpoints include clinical outcomes and patient and clinician reported outcomes. For more information about the CAHmelia program, please visit https://www.sprucebio.com/cahmelia.

About CAHmelia-204

CAHmelia-204 is a randomized, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of tildacerfont in reducing supraphysiologic glucocorticoid usage in approximately 90 adults with classic CAH in patients on supraphysiologic doses of glucocorticoids with normal or near normal levels of A4 at baseline. This clinical trial is designed in two parts. In the first part of the clinical trial, patients will be randomized to receive 200mg tildacerfont once daily or placebo for 24 weeks. During the second part of the clinical trial, all patients will receive open-label 200mg tildacerfont once daily for 52 weeks. Throughout the trial, tapering of glucocorticoids will be guided according to a pre-specified algorithm and continue to the lowest level possible (physiologic replacement levels), as long as patients remain well controlled based on standard biomarkers and clinical assessments. The primary endpoint of this clinical trial is the absolute change in daily glucocorticoid dose in hydrocortisone equivalents (HCe) from baseline at week 24. The percent change in glucocorticoid dose from baseline to week 24 will be assessed as a secondary endpoint. Median total cumulative GC dose (HCe) at week 24, change from baseline in insulin resistance at week 24, and percent change from baseline in weight at week 24 and after 52 weeks of tildacerfont treatment will also be assessed as secondary endpoints. Effects on insulin resistance, weight, waist circumference, bone mineral density after 52 weeks of tildacerfont treatment will be assessed as exploratory endpoints. For more information about the CAHmelia program, please visit https://www.sprucebio.com/cahmelia.

About Spruce Biosciences

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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.

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