

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): December 10, 2024

Spruce Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39594
(Commission File Number)

81-2154263
(IRS Employer
Identification No.)

611 Gateway Boulevard, Suite 740
South San Francisco, California
(Address of principal executive offices)

94080
(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 8.01 Other Events.

On December 10, 2024, Spruce Biosciences, Inc. (the “Company”) issued a press release announcing topline results from its CAHmelia-204 study of tildacerfont in adult Congenital Adrenal Hyperplasia (“CAH”) and its CAHptain-205 study of tildacerfont in adult and pediatric CAH.

CAHmelia-204 was a Phase 2b, randomized, double-blind, placebo-controlled clinical trial that evaluated the safety and efficacy of tildacerfont in reducing supraphysiologic glucocorticoid (“GC”) usage in 100 adults with classic CAH on a mean GC dose of 35mg/day of hydrocortisone equivalents (“HCe”) (19mg/m²/day) and mean androstenedione (“A4”) level of 214 ng/dL at baseline.

The clinical trial did not achieve the primary efficacy endpoint of the absolute change in daily GC dose from baseline at week 24. 200mg once-daily (“QD”) of tildacerfont demonstrated a placebo-adjusted reduction from baseline in daily GC dose of 0.7mg HCe (95% CI: -4.3 to 2.9, p=0.7). Approximately 98% of patients were highly compliant with study drug. Tildacerfont was generally safe and well tolerated with no serious adverse events (“SAEs”).

CAHptain-205 was a Phase 2 open-label, 4-week, sequential cohort clinical trial, that evaluated the safety, pharmacodynamics (changes in A4 levels), and pharmacokinetics of QD and twice-daily (“BID”) doses of tildacerfont from 50mg QD to 400mg BID in pediatric and adult patients with CAH. A trend was observed of larger reductions from baseline in A4 levels with higher BID doses of tildacerfont. Tildacerfont was generally safe and well tolerated across all doses with no drug-related SAEs.

The Company plans to evaluate a full range of strategic options in addressing diseases with serious unmet need for patients. In the interim, the CAHmelia-204 and CAHptain-205 clinical trials will be discontinued, and the Company will be winding down its investment in tildacerfont for the treatment of CAH.

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. Such forward-looking statements include statements regarding, among other things, the Company’s plans to evaluate a full range of strategic options, the discontinuance of the CAHmelia-204 and CAHptain-205 clinical trials, and the wind-down of the Company’s investment in tildacerfont for the treatment of CAH. 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 “may” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon the Company’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 the Company’s business in general, the impact of geopolitical and macroeconomic events, 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, 2023, 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. 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.
