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): March 10, 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 March 13, 2024, Spruce Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the full year ended December 31, 2023 and providing corporate updates, including topline results from its CAHmelia-203 study of tildacerfont in adult classic CAH and its CAHptain-205 study of tildacerfont in pediatric classic CAH. 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 (the "Exchange Act"), and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 2.05 Costs Associated with Exit or Disposal Activities

On March 10, 2024, the Board of Directors of the Company (the "Board") approved a plan to implement cost savings initiatives, including termination of the CAHmelia-203 study and a workforce reduction of approximately 21% (the "Realignment Plan"). The Realignment Plan is effective immediately, with a termination date of March 31, 2024 for affected employees. Affected employees will be offered separation benefits, including severance payments and healthcare coverage assistance.

The final costs, charges and expenditures relating to the Realignment Plan will not be known until all related activities have been completed. The Company estimates that it will incur approximately $0.4 million in cash charges in connection with the Realignment Plan, consisting of expenses related to employee severance payments and healthcare coverage assistance and related costs. The Company expects that the majority of these estimated charges will be recorded in the second quarter of 2024 and that the execution of the Realignment Plan will be substantially complete during the second quarter of 2024.

The estimates of the costs, charges and expenditures that the Company expects to incur in connection with the Realignment Plan, and the timing thereof, are preliminary estimates based on the Company's current expectations and are subject to a number of assumptions, and actual amounts and results may differ materially from such estimates. In addition, the Company may incur other costs, charges, expenditures, impairments and other impacts not currently contemplated due to unanticipated events that may occur, including in connection with the implementation of the Realignment Plan.

Item 8.01 Other Information.

On March 13, 2024, the Company announced topline results from its CAHmelia-203 study of tildacerfont in adult classic CAH and its CAHptain-205 study of tildacerfont in pediatric classic CAH. The CAHmelia-203 clinical trial did not achieve the primary efficacy endpoint of the assessment of dose response for the change in androstenedione, or A4, from baseline to week 12. 200mg once-daily of tildacerfont demonstrated a placebo-adjusted reduction from baseline in A4 of -2.6% with a non-significant p value at week 12. Tildacerfont was generally safe and well tolerated at all dose ranges with no treatment-related serious adverse events ("SAEs"). Most adverse events were reported as mild to moderate.

In the CAHptain-205 clinical trial, tildacerfont was generally safe and well tolerated at all dose ranges with no treatment-related SAEs reported. Preliminary pharmacokinetic analysis suggests that tildacerfont is cleared more rapidly in children than in adult CAH patients. 73% of all patients (22 of 30 patients) met the efficacy endpoint of A4 or glucocorticoid ("GC") reduction from baseline at 12 weeks of treatment with tildacerfont. 70% of patients with elevated baseline A4 values (16 of 23 patients) demonstrated an A4 reduction at week 4. The Company plans to continue dose-ranging across additional cohorts to evaluate dose selection to inform its registrational program. The Company anticipates topline results in the fourth quarter of 2024.

The Company expects to report topline results from its CAHmelia-204 study, which is focused on assessing GC reduction in a different population of adult CAH patients with relatively controlled A4 levels, in the third quarter of 2024. Assuming positive results from CAHmelia-204 and CAHptain-205, the Company plans to meet with the U.S. Food and Drug Administration and comparable foreign regulatory authorities to outline the design of a registrational clinical program in adult and pediatric classic CAH.

Cautionary Note Regarding Forward-Looking Statements

This report, including Exhibit 99.1 hereto, contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, among other things, statements regarding the design, results, conduct, progress and timing of the Company's clinical trials; the Company's expectations regarding reporting results of its clinical trials in 2024; the Company's plans to meet with the U.S. Food and Drug Administration and comparable foreign regulatory authorities to outline the design of a registrational clinical program in adult and pediatric classic CAH; expectations related to the Realignment Plan, including estimated costs, charges and expenditures, impairments and the timing and financial impacts thereof, and the expected timing of the implementation and completion of the Realignment Plan and any associated costs, charges, expenditures and impairments; and the Company's product candidate, strategy and regulatory matters. 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”, “expect” 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 the other risks described in the Company’s filings with the U.S. Securities and Exchange Commission. All information in this report, including the exhibits hereto, is current as of the date of this report, and the Company undertakes no duty to update this information unless required by law

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release of Spruce Biosciences, Inc., dated March 13, 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: March 13, 2024

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

Exhibit 99.1

Spruce Biosciences Reports Full Year 2023 Financial Results and Provides Corporate Updates

CAHmelia-203 Study of Tildacerfont in Adult Classic Congenital Adrenal Hyperplasia (CAH) with Severe Hyperandrogenemia Did Not Meet Primary Efficacy Endpoint

Positive Data from CAHptain-205 Study of Tildacerfont in Pediatric Classic CAH Supports Further Dose-Ranging Across Additional Dosing Cohorts

Topline Results from CAHmelia-204 Study of Tildacerfont in Adult Classic CAH Evaluating Glucocorticoid (GC) Reduction Anticipated in Third Quarter of 2024

Resource Prioritization and Cost Reductions Extend Cash Runway Through End of 2025

Conference Call Today at 4:30 p.m. ET

South San Francisco, Calif. – March 13, 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 financial results for the year ended December 31, 2023 and provided corporate updates.

“We are grateful to all the patients, families, study team and investigators who supported the CAHmelia-203 clinical trial,” said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer, Spruce Biosciences. “CAHmelia-203 is the first study of its kind to address a difficult-to-treat CAH patient population with severe and more refractory hyperandrogenemia, which is often attributed to challenging real-life compliance with daily GCs. We garnered important data from this study which will inform ongoing development of tildacerfont in adult classic CAH.”

Dr. Szwarcberg added, “Looking ahead to the third quarter of 2024, we are eager to report topline results from CAHmelia-204, which is focused on assessing GC reduction, a potentially registrational endpoint, in a different population of adult CAH patients with relatively controlled A4 levels and historically better adherence to GC therapy. Assuming positive results from CAHmelia-204 and CAHptain-205, we plan to meet with the U.S. Food and Drug Administration (FDA) and comparable foreign regulatory authorities in early 2025 to outline the design of a registrational clinical program in adult and pediatric classic CAH. Finally, we have made the difficult but necessary decision to streamline our operations and implement cost reduction measures, which has extended our cash runway through the end of 2025. I want to thank all of our employees, including those departing Spruce, for their dedication to advancing our mission of bringing forward novel therapies for CAH and other rare endocrine disorders.”

Recent Corporate Updates

- ***CAHmelia-203 Study of Tildacerfont in Adult Classic Congenital Adrenal Hyperplasia (CAH) with Severe Hyperandrogenemia Did Not Meet Primary Efficacy Endpoint*.** CAHmelia-203 enrolled 96 subjects with a mean baseline androstenedione (A4) level of 1,151 ng/dL, which is more than five times above the upper limit of normal (ULN). The clinical trial did not achieve the primary efficacy endpoint of the assessment of dose-response for the change in A4 from baseline to week 12. 200mg QD of tildacerfont demonstrated a placebo-adjusted reduction from baseline in A4 of -2.6% with a non-significant p-value at week 12. Compliance with study

medication and glucocorticoid (GC) was low with only 50% of patients reporting 80% or greater compliance, resulting in lower-than-expected tildacerfont exposure. Tildacerfont was generally safe and well tolerated at all doses, with no treatment-related serious adverse events (SAEs). Most adverse events were reported as mild to moderate.

- ***Positive Data from CAHptain-205 Study of Tildacerfont in Pediatric Classic CAH Supports Further Dose-Ranging Across Additional Dosing Cohorts.*** CAHptain-205 enrolled 30 children between two and 17 years of age with a mean baseline GC dose of 14 mg/m^2/day and mean baseline A4 level of 372 ng/dL. The study characterized the safety and pharmacokinetic profiles of tildacerfont, as well as changes in androgen levels over 12 weeks of treatment, and the ability to reduce daily GC dose upon A4 normalization. Tildacerfont was generally safe and well tolerated at all dose ranges with no treatment-related SAEs reported. Preliminary pharmacokinetic analysis suggests that tildacerfont is cleared more rapidly in children than in adult CAH patients. 73% of all patients (22 of 30 patients) met the efficacy endpoint of A4 or GC reduction from baseline at 12 weeks of treatment with tildacerfont. 70% of patients with elevated baseline A4 values (16 of 23 patients) demonstrated an A4 reduction at week 4.

Anticipated Upcoming Milestones

- 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
- Topline results from additional dose-ranging in the Phase 2 CAHptain clinical trial in the fourth quarter of 2024
- End of Phase 2 (EOP2) meeting with the U.S. FDA in the first quarter of 2025

Full Year 2023 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of December 31, 2023 were $96.3 million. The company currently has over $81 million in cash and cash equivalents. Resource prioritization and cost reductions, including termination of the CAHmelia-203 clinical trial and a reduction in force of approximately 21%, extend cash runway through the end of 2025, including beyond anticipated topline results from CAHmelia-204 and additional dose-ranging data from CAHptain-205.
- **Collaboration Revenue:** Collaboration revenue for the year ended December 31, 2023 was $10.1 million compared to nil in 2022, reflecting the partial recognition of the $15.0 million upfront payment received from Kaken Pharmaceutical (“Kaken”) in connection with the company’s strategic collaboration with Kaken to develop and commercialize tildacerfont for the treatment of classic CAH in Japan.
- **Research and Development (R&D) Expenses:** R&D expenses for the year ended December 31, 2023 were $49.4 million compared to $35.2 million 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 polycystic ovary syndrome (PCOS).

- **General and Administrative (G&A) Expenses:** G&A expenses for the year ended December 31, 2023 were $12.7 million compared to $12.1 million in 2022.

- **Total Operating Expenses:** Total operating expenses for the year ended December 31, 2023 were $62.1 million compared to $47.3 million in 2022. Non-cash stock-based compensation expense for the year ended December 31, 2023 was $4.6 million compared to $3.6 million in 2022.

- **Net Loss:** Net loss for the year ended December 31, 2023 was $47.9 million compared to $46.2 million in 2022.

Conference Call Details

Spruce's management team and key study investigators will host a conference call today at 4:30 p.m. ET to discuss the topline results of the CAHmelia-203 and CAHptain-205 clinical studies. Analysts and investors can participate in the conference call by registering here or dialing (866) 777-2509.

An archived copy of the call will be available on the events section of the company's investor relations website for approximately 90 days.

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 design, results, conduct, progress and timing of Spruce's clinical trials; tildacerfont's potential to be a novel treatment option that improves long-term health outcomes for patients with CAH; Spruce's expectations regarding reporting results of its clinical trials in 2024; Spruce's plans to meet with the FDA and comparable foreign regulatory authorities to discuss the potential registrational path forward of tildacerfont for adult and pediatric classic CAH; the impact of cost savings initiatives and the length of Spruce's anticipated cash runway; and Spruce's product candidate, strategy and regulatory matters. 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", "potential", "plan" 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.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	December 31,	
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 96,339	$ 24,487
Short-term investments	—	54,590
Prepaid expenses	3,876	3,320
Other current assets	1,968	1,211
Total current assets	102,183	83,608
Right-of-use assets	1,181	1,400
Other assets	582	640
Total assets	$ 103,946	$ 85,648
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,332	$ 1,426
Accrued expenses and other current liabilities	14,600	9,399
Term loan, current portion	1,622	1,622
Deferred revenue	4,911	—
Total current liabilities	24,465	12,447
Lease liabilities, net of current portion	1,019	1,261
Term loan, net of current portion	1,717	3,293
Other liabilities	236	161
Total liabilities	27,437	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 December 31, 2023 and 2022	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of December 31, 2023 and 2022; 41,029,832 and 23,601,004 shares issued and outstanding as of December 31, 2023 and 2022, respectively	4	3
Additional paid-in capital	273,737	218,354
Accumulated other comprehensive loss	—	(558)
Accumulated deficit	(197,232)	(149,313)
Total stockholders' equity	76,509	68,486
Total liabilities and stockholders' equity	$ 103,946	$ 85,648

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

	Year Ended December 31,	
	2023	2022
Collaboration revenue	$ 10,089	$ —
Operating expenses:		
Research and development	49,432	35,198
General and administrative	12,650	12,085
Total operating expenses	62,082	47,283
Loss from operations	(51,993)	(47,283)
Interest expense	(483)	(420)
Interest and other income, net	4,557	1,523
Net loss	(47,919)	(46,180)
Other comprehensive loss, net of tax:		
Unrealized gain (loss) on available for sale securities	558	(374)
Total comprehensive loss	$ (47,361)	$ (46,554)
Net loss per share, basic and diluted	$ (1.24)	$ (1.96)
Weighted-average shares of common stock outstanding, basic and diluted	38,510,220	23,527,116

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