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): May 13, 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 May 13, 2024, Spruce Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2024 and providing corporate updates. 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

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

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

Exhibit 99.1

Spruce Biosciences Reports First Quarter 2024 Financial Results and Provides Corporate Updates

Analyses of Data from CAHmelia-203 in Adult Congenital Adrenal Hyperplasia (CAH) Demonstrate Correlation Between Tildacerfont Response and Baseline Glucocorticoid (GC) Dose and Drug Compliance

Posters Highlighting Baseline Characteristics from the CAHmelia Program in Adult CAH and CAHptain-205 Study in Pediatric CAH Presented at the Pediatric Endocrine Society (PES) 2024 Annual Meeting

Topline Data from the CAHmelia-204 Study in Adult CAH and Additional Dose-Ranging Data from Adults and Children with CAH in CAHptain-205 Anticipated in Q3 2024

South San Francisco, Calif. – May 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 first quarter ended March 31, 2024 and provided corporate updates.

"We are encouraged by key learnings from analyses of data from our CAHmelia-203 clinical trial in adult CAH patients with severe hyperandrogenemia," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer, Spruce Biosciences. "In the open-label portion of the study, tildacerfont demonstrated a maximum mean reduction in adrenocorticotropic hormone (ACTH) of 45%, suggesting pituitary target engagement and direct evidence of its mechanism of action. Additionally, we observed that higher GC doses at baseline as well as higher rates of study drug compliance were associated with larger placebo-adjusted reductions from baseline in androstenedione (A4)."

Dr. Szwarcberg added, "These findings underscore the challenges of treating severe hyperandrogenemia within this patient population and reinforce our belief that tildacerfont may have a greater benefit in CAHmelia-204, which is assessing GC reduction in a controlled and more compliant population of adult CAH patients. We look forward to reporting data from the CAHmelia-204 study in the third quarter of this year."

Analyses of Data from CAHmelia-203 in Adult CAH

- Directionally favorable reductions in ACTH were noted in the blinded and open-label portions of the study with a maximum mean reduction of 45% at week 64 (n = 19).

- Higher GC doses at baseline were associated with a larger placebo-adjusted reductions from baseline in A4 after the initial 12 weeks of treatment with tildacerfont. Patients with a baseline GC dose of 15mg hydrocortisone equivalents (HCe) had a mean placebo-adjusted increase from baseline in A4 of 18% after 12 weeks of treatment with tildacerfont. By contrast, patients with a baseline GC dose of 55mg HCe had a mean placebo-adjusted decrease from baseline in A4 of 27% after 12 weeks of treatment with tildacerfont. Patients in CAHmelia-203 enrolled with a mean baseline A4 level of more than five times above the upper limit of normal on a mean baseline daily GC dose of 27 mg HCe compared to patients in CAHmelia-204 who enrolled with a mean baseline daily GC dose of 37 mg HCe and A4 level near the upper limit of normal.

- Higher rates of study drug compliance were associated with a larger placebo-adjusted reductions from baseline in A4 after 12 weeks of treatment with tildacerfont. Patients with compliance to study drug of 55% had a mean placebo-adjusted increase from baseline in A4 of 14% after 12 weeks of treatment with tildacerfont. By contrast, patients who were fully compliant with study drug had a mean

placebo-adjusted decrease from baseline in A4 up to 14% after 12 weeks of treatment with tildacerfont. Compliance with tildacerfont in the clinical trial was measured through pill counts, corroborated by patient-reported electronic diaries.

Other Corporate Updates

- **Poster Highlighting Baseline Characteristics from the CAHmelia Program in Adult CAH Presented at the PES 2024 Annual Meeting:** Paul Thornton, M.B.B.S., Medical Director of the Endocrine and Diabetes Program at a CAH Center of Excellence, presented baseline characteristics from Spruce's CAHmelia program evaluating tildacerfont in adult CAH, as an illustration of outcomes of current pediatric CAH disease management. Specifically, differences in adult height and weight relative to national and global averages suggest that the current treatment paradigm in pediatric CAH is inadequate to address the long-term goal of optimization of height and weight, which requires maintaining a balance between hyperandrogenemia and GC overexposure throughout childhood. The poster presentation is available on the company's website.

- **Poster Highlighting Baseline Characteristics from the CAHptain-205 Study in Pediatric CAH Presented at the PES 2024 Annual Meeting:** Mimi S. Kim, M.D., Co-Director, Congenital Adrenal Hyperplasia Comprehensive Care Clinic, Children's Hospital Los Angeles presented baseline characteristics from the Phase 2 CAHptain study evaluating tildacerfont in children and adolescents with CAH. The preliminary baseline characteristics of CAHptain highlight that androgen control in children and adolescents with CAH often requires supraphysiologic GC doses. While a majority of participants in CAHptain-205 experienced reductions in both A4 and GC doses, preliminary pharmacokinetic results suggest that tildacerfont clearance is more rapid in children than adults. Further dose-ranging in the study is ongoing. The poster presentation is available on the company's website.

Anticipated Upcoming Milestones

- Topline results from the CAHmelia-204 clinical trial in adult classic CAH patients on supraphysiologic doses of GCs with normal or near normal levels of A4 in the third quarter of 2024

- Topline interim results from additional dose-ranging in the Phase 2 CAHptain clinical trial in the third quarter of 2024

- End of Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) in the first quarter of 2025

Upcoming Investor Conferences

Company management will participate in two upcoming investor conferences taking place in May.

Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer, will participate in a fireside chat at the JMP Securities Life Sciences Conference on May 14, 2024 at 10:30 a.m. ET and in a fireside chat at the RBC Capital Markets Global Healthcare Conference on May 15, 2024 at 8:30 a.m. ET. Company management will also be hosting 1x1 meetings at each conference.

The live webcast for each conference presentation can be accessed on the events section of the company's investor relations website and will be available for replay after the conclusion of the live presentations for approximately 90 days.

First Quarter 2024 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of March 31, 2024 were $81.2 million. Cash and cash equivalents are expected to allow the company to fund its current operating plan through the end of 2025.

- **Collaboration Revenue:** Collaboration revenue was $2.0 million for each of the three months ended March 31, 2024 and 2023. The 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 months ended March 31, 2024 were $10.3 million, compared to $11.7 million for the same period in 2023. The overall decrease in R&D expenses was primarily related to completion of enrollment in the company's CAH programs and completion of its Phase 2 study in polycystic ovary syndrome (PCOS).

- **General and Administrative (G&A) Expenses:** G&A expenses for the three months ended March 31, 2024 were $4.3 million, compared to $3.5 million for the same period in 2023.

- **Total Operating Expenses:** Total operating expenses for the three months ended March 31, 2024 were $14.6 million, compared to $15.2 million for the same period in 2023. Operating expenses include non-cash stock-based compensation expenses of $1.6 million and $1.1 million for the three months ended March 31, 2024 and 2023, respectively.

- **Net Loss:** Net loss for the three months ended March 31, 2024 was $11.6 million, compared to $12.8 million for the same period in 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 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 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 design, results, conduct, progress and timing of Spruce's clinical trials; Spruce's expectations regarding reporting results of its clinical trials in 2024; Spruce's plans to meet with the FDA to discuss the potential registrational path forward of tildacerfont for adult and pediatric classic CAH; upcoming investor conferences; 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”, “suggest”, “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.
CONDENSED BALANCE SHEETS
(unaudited)
(in thousands, except share and per share amounts)

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 81,154	$ 96,339
Prepaid expenses	3,100	3,876
Other current assets	1,611	1,968
Total current assets	85,865	102,183
Right-of-use assets	1,121	1,181
Other assets	553	582
Total assets	$ 87,539	$ 103,946
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,891	$ 3,332
Accrued expenses and other current liabilities	11,973	14,600
Term loan, current portion	1,622	1,622
Deferred revenue	2,908	4,911
Total current liabilities	18,394	24,465
Lease liabilities, net of current portion	950	1,019
Term loan, net of current portion	1,321	1,717
Other liabilities	250	236
Total liabilities	20,915	27,437
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 41,154,799 and 41,029,832 shares issued and outstanding as of March 31, 2043 and December 31, 2023, respectively	4	4
Additional paid-in capital	275,477	273,737
Accumulated deficit	(208,857)	(197,232)
Total stockholders' equity	66,624	76,509
Total liabilities and stockholders' equity	$ 87,539	$ 103,946

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

	Three Months Ended March 31,	
	2024	2023
Collaboration revenue	$ 2,002	$ 1,964
Operating expenses:		
Research and development	10,317	11,712
General and administrative	4,318	3,451
Total operating expenses	14,635	15,163
Loss from operations	(12,633)	(13,199)
Interest expense	(96)	(131)
Interest income and other expense, net	1,105	539
Net loss	(11,624)	(12,791)
Other comprehensive gain (loss), net of tax:		
Unrealized gain on available for sale securities	—	370
Total comprehensive loss	$ (11,624)	$ (12,421)
Net loss per share, basic and diluted	$ (0.28)	$ (0.40)
Weighted-average shares of common stock outstanding, basic and diluted	41,096,231	31,900,160

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