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): August 12, 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 August 12, 2024, Spruce Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 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 August 12, 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: August 12, 2024

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

Exhibit 99.1

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

Announced Strategic Collaboration with HMNC Brain Health GmbH (HMNC) to Develop Tildacerfont for the Treatment of Major Depressive Disorder (MDD)

Topline Data from CAHmelia-204 Study of Tildacerfont in Adult Congenital Adrenal Hyperplasia (CAH) Anticipated in Q4 2024

Topline Data from CAHptain-205 Study of Tildacerfont in Adult and Pediatric CAH Anticipated in Q4 2024

Cash Runway Through the End of 2025

South San Francisco, Calif. – August 12, 2024 – Spruce Biosciences, Inc. (Nasdaq: SPRB), a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for endocrine and neurological disorders with significant unmet medical need, today reported financial results for the second quarter ended June 30, 2024 and provided corporate updates.

"We remain committed to advancing the development of tildacerfont and opening a new chapter in the management of CAH with a potentially life-changing medicine for patients and their families," said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce. "In the fourth quarter of 2024, we plan to report primary efficacy and safety data through week 24 plus interim data from the open-label extension of the CAHmelia-204 study, which is assessing glucocorticoid (GC) reduction, a potentially registrational endpoint in adult CAH patients on supraphysiologic GC doses with normal or near normal levels of androstenedione (A4)."

Dr. Szwarcberg added, "At the same time, we will also report topline data from CAHptain-205, which will include week 4 efficacy and safety measures on 200mg twice-daily (BID) and 400mg BID doses of tildacerfont in adults, adolescents and children with CAH and elevated levels of A4. Following our analysis of results from the CAHmelia-203 study, which evaluated doses of tildacerfont up to 200mg once-daily (QD) in adults with CAH and highly elevated levels of A4, we believe that tildacerfont has the potential to address severe hyperandrogenemia in CAH at higher doses taken BID. If results from CAHmelia-204 and CAHptain-205 are positive, we intend to meet with the U.S. Food and Drug Administration (FDA) and comparable foreign regulatory authorities to align on the next steps for our CAH program."

Corporate Updates

- **Announced Strategic Collaboration with HMNC to Develop Personalized Treatment for MDD:** Spruce entered into a license, development and option agreement with HMNC to develop Spruce's investigational product candidate, tildacerfont, a second-generation CRF_1 receptor antagonist, with HMNC's companion diagnostic, the proprietary Cortibon Genetic Selection Tool (Cortibon), as a personalized medicine with potential for the treatment of MDD. Under the terms of the agreement, HMNC will fund and conduct a Phase 2 proof-of-concept study of tildacerfont in MDD patients, who will be screened using Cortibon. Spruce has an option to in-license exclusive worldwide rights to Cortibon after completion of the study, if results are positive.
- **Poster Highlighting Final Results from Phase 2 POWER Study of Tildacerfont for the Treatment of Polycystic Ovary Syndrome (PCOS) Presented at ENDO 2024 Annual Meeting:** Ricardo Azziz, M.D., M.B.A., M.P.H., Professor, Obstetrics and Gynecology at University of Alabama at Birmingham School of Medicine, presented final results from the Phase 2 POWER study, which demonstrated the ability of tildacerfont to reduce dehydroepiandrosterone sulfate levels over 12 weeks in women with PCOS. Additionally, an observed increase in serum sex hormone binding globulin demonstrated that tildacerfont may potentially lower levels of free, bioactive sex hormones such as testosterone. Tildacerfont was well-tolerated, with no safety signals observed. The majority of adverse events were mild to moderate, and no serious adverse reactions were reported. The poster presentation is available on the company's website.
- **Poster Highlighting Impact of Geography and Insurance on Healthcare Utilization Preferences of Individuals with CAH Presented at ENDO 2024 Annual Meeting:** Prasanth Surampudi, M.D., Associate Professor, Endocrinology, Diabetes and Metabolism at U.C. Davis School of Medicine, presented findings related to the need for increased partnership between primary care physicians and endocrinologists as well as increased education among CAH patients and advocacy groups of specialty care to improve biochemical outcomes that reduce risks of morbidity and mortality in adult CAH patients. The poster presentation is available on the company's website.

- **Poster Highlighting Pediatric and Adult Endocrinology Practices to Improve Biochemical Outcomes in Adults with CAH Presented at ENDO 2024 Annual Meeting:** Wenyu Huang, M.D., Ph.D., Associate Professor, Division of Endocrinology, Metabolism and Molecular Medicine at Northwestern University Feinberg School of Medicine, and Amir Hamrahian, M.D., Associate Professor of Medicine, Division of Endocrinology, Diabetes and Metabolism at John Hopkins University, presented findings exploring the risks associated with CAH diagnosis and treatment, including health impacts of hyperandrogenemia and serious adverse events with long-term use of supraphysiologic GC doses. The poster presentation is available on the company's website.

Anticipated Upcoming Milestones

- Topline results from the CAHmelia-204 clinical trial of tildacerfont 200mg QD in adult classic CAH patients on supraphysiologic doses of GCs with normal or near normal levels of A4 anticipated in the fourth quarter of 2024
- Topline results from the CAHptain-205 clinical trial of tildacerfont 200mg BID and 400mg BID adult and pediatric cohorts anticipated in the fourth quarter of 2024
- End of Phase 2 (EOP2) meeting with the U.S. FDA anticipated in the first half of 2025

Second Quarter 2024 Financial Results

- **Cash and Cash Equivalents:** Cash and cash equivalents as of June 30, 2024 were $69.7 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 $1.6 million and $3.6 million for the three and six months ended June 30, 2024, respectively, compared to $2.2 million and $4.1 million for the same periods in 2023. The collaboration revenue reflects the partial recognition of the $15.0 million upfront payment the company received in April 2023 in connection with the collaboration and license agreement with Kaken Pharmaceutical.
- **Research and Development (R&D) Expenses:** R&D expenses for the three and six months ended June 30, 2024 were $8.1 million and $18.4 million, respectively, compared to $13.1 million and $24.8 million for the same periods in 2023. The overall decrease in R&D expenses was primarily driven by the decrease in clinical development and manufacturing expenses related to the termination of the CAHmelia-203 study, completion of enrollment in the company's CAHmelia-204 study, and completion of the Phase 2 POWER study in PCOS.
- **General and Administrative (G&A) Expenses:** G&A expenses for the three and six months ended June 30, 2024 were $3.6 million and $7.9 million, respectively, compared to $3.0 million and $6.5 million for the same periods in 2023.
- **Total Operating Expenses:** Total operating expenses for the three and six months ended June 30, 2024 were $11.6 million and $26.3 million, respectively, compared to $16.1 million and $31.3 million for the same periods in 2023. Operating expenses include non-cash stock-based compensation expenses of $1.7 million and $3.2 million for the three and six months ended June 30, 2024, respectively, compared to $1.2 million and $2.3 million for the same periods in 2023.
- **Net Loss:** Net loss for the three and six months ended June 30, 2024 was $9.2 million and $20.8 million, respectively, compared to $12.8 million and $25.6 million for the same periods in 2023.

About Spruce Biosciences

Spruce Biosciences is a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for endocrine and neurological disorders with significant unmet medical need. Spruce is developing its product candidate, tildacerfont, an oral, second-generation CRF_1 receptor antagonist, for the treatment of congenital adrenal hyperplasia (CAH), polycystic ovary syndrome (PCOS) and major depressive disorder (MDD). 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; 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; 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”, “intend” 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)

	June 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 69,683	$ 96,339
Prepaid expenses	2,698	3,876
Other current assets	1,531	1,968
Total current assets	73,912	102,183
Right-of-use assets	1,060	1,181
Other assets	547	582
Total assets	$ 75,519	$ 103,946
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 682	$ 3,332
Accrued expenses and other current liabilities	10,683	14,600
Term loan, current portion	1,622	1,622
Deferred revenue, current portion	1,298	4,911
Total current liabilities	14,285	24,465
Lease liabilities, net of current portion	880	1,019
Term loan, net of current portion	923	1,717
Other liabilities	262	236
Total liabilities	16,350	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 June 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 41,302,599 and 41,029,832 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	4	4
Additional paid-in capital	277,203	273,737
Accumulated deficit	(218,038)	(197,232)
Total stockholders' equity	59,169	76,509
Total liabilities and stockholders' equity	$ 75,519	$ 103,946

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Collaboration revenue	$ 1,610	$ 2,165	$ 3,612	$ 4,129
Operating expenses:				
Research and development	8,090	13,126	18,407	24,838
General and administrative	3,556	3,011	7,874	6,462
Total operating expenses	11,646	16,137	26,281	31,300
Loss from operations	(10,036)	(13,972)	(22,669)	(27,171)
Interest expense	(83)	(127)	(180)	(258)
Interest income and other expense, net	938	1,275	2,043	1,814
Net loss	(9,181)	(12,824)	(20,806)	(25,615)
Other comprehensive gain, net of tax:				
Unrealized gain on available for sale securities	—	133	—	503
Total comprehensive loss	$ (9,181)	$ (12,691)	$ (20,806)	$ (25,112)
Net loss per share, basic and diluted	$ (0.22)	$ (0.32)	$ (0.51)	$ (0.71)
Weighted-average shares of common stock outstanding, basic and diluted	41,163,209	40,547,925	41,129,719	36,247,931

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