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 14, 2023

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** **(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 2.02 Results of Operations and Financial Condition.

On August 14, 2023, Spruce Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2023 and providing corporate updates that included interim results from the Company's Phase 2 POWER proof-of-concept clinical trial evaluating its product candidate tildacerfont for the treatment of polycystic ovary syndrome ("PCOS"). 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 8.01 Other Events.

As noted in Item 2.02, on August 14, 2023, the Company issued a press release providing corporate updates that included interim results from the Company's Phase 2 POWER proof-of-concept clinical trial evaluating its product candidate tildacerfont for the treatment of PCOS. The POWER clinical trial is a randomized, placebo-controlled, dose-escalation trial to evaluate the safety and efficacy of tildacerfont titrated to 200 mg QD compared to placebo at 12 weeks of treatment in subjects with PCOS and elevated adrenal androgens as measured by dehydroepiandrosterone sulfate ("DHEAS") levels at baseline. The Company conducted an analysis of interim data from 20 patients (13 on tildacerfont and 7 on placebo) through the 12-week treatment period for the POWER clinical trial. The study enrolled 27 patients in total. The interim data from the POWER clinical trial support target engagement and suggest that DHEAS may be reduced with tildacerfont treatment in women suffering from PCOS. Tildacerfont was well-tolerated, with a safety profile that is consistent with past studies. Most adverse events were classified as mild-moderate, balanced between treatment arms, unrelated to study drug and single event occurrences. No serious adverse reactions or dose toxicities were observed, and there was no evidence of adrenal insufficiency. Final data from the POWER clinical trial will be presented at a future medical conference.

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 enrollment, results, conduct, progress and timing of the Company's clinical trials; the receipt and presentation of topline data from the same; research and development plans; the Company's planned operations, including its expectations regarding operating and capital expenditures being funded into the first half of 2025; the implications of the interim data from the POWER study; tildacerfont's potential to become a first-in-class therapy for PCOS; the Company's expectations to further engage regulatory authorities regarding tildacerfont; and the ability of tildacerfont to provide a therapeutic option to treat the underlying cause of disease through reductions of ACTH. 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", "expect", "may," "plan," "will", "potential" 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, the risk that interim data from the POWER study will differ from final data once available, along with 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, 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. 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 August 14, 2023
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 14, 2023

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

Spruce Biosciences Reports Second Quarter 2023 Financial Results and Provides Corporate Updates

Spruce Reports Interim Data from Phase 2 POWER Proof-of-Concept Study in Polycystic Ovary Syndrome (PCOS)

CAHmelia Program in Adult Classic Congenital Adrenal Hyperplasia (CAH) Surpasses 75% Enrollment in CAHmelia-203 and Approaches 75% Enrollment in CAHmelia-204

Screening Underway for Cohort 3 in CAHptain Study for Pediatric Classic CAH

South San Francisco, Calif. – August 14, 2023 – 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 second quarter ended June 30, 2023 and provided corporate updates.

“Our goal with the POWER study is to assess the ability of tildacerfont to reduce dehydroepiandrosterone sulfate (DHEAS) in women with PCOS, and the interim results support target engagement and suggest that DHEAS may be reduced with tildacerfont treatment” said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. “With a significant unmet medical need for new PCOS treatments and no FDA-approved therapies today, we are eager to analyze and present the full data set at an upcoming medical conference.”

Dr. Szwarcberg continued, “As we approach key topline data readouts, we continue to make meaningful progress across our adult and pediatric CAH programs. In our CAHmelia program in adult classic CAH, we’ve surpassed 75% enrollment in the CAHmelia-203 study and are approaching 75% enrollment in the CAHmelia-204 study. Cohort 2 in our CAHptain study for pediatric classic CAH is nearly fully enrolled, with screening in cohort 3 currently underway. Finally, as we continue building our seasoned leadership team for the pivotal year ahead, I am delighted to welcome Heidi Petersen, M.P.H., as our Senior Vice President of Regulatory and Quality. With more than 25 years of life sciences industry experience managing complex drug development programs, Ms. Petersen will be vital as we advance tildacerfont towards a potential registrational submission for classic CAH.”

Recent Corporate Updates

- **Spruce Biosciences Reports Interim Data from Phase 2 POWER Proof-of-Concept Study in Polycystic Ovary Syndrome (PCOS):** The company conducted an analysis of interim data from 20 patients (13 on tildacerfont and 7 on placebo) through the 12-week treatment period for the Phase 2 dose-escalation, proof-of-concept study. As previously announced, the study enrolled 27 patients in total. The interim data from the study support target engagement and suggest that DHEAS may be reduced with tildacerfont treatment in women suffering from PCOS. Tildacerfont was well-tolerated, with a safety profile that is consistent with past studies. Most adverse events were classified as mild-moderate, balanced between treatment arms, unrelated to study drug and single event occurrences. No serious adverse reactions or dose toxicities were observed, and there was no evidence of adrenal insufficiency. Final data from the proof-of-concept study will be presented at a future medical conference.

- **Progress in Enrollment of CAHmelia Program in Adult Classic CAH:** Enrollment in the company’s CAHmelia-203 clinical trial surpassed 75% enrollment. CAHmelia-203 is a randomized, double-blind, placebo-controlled, dose-ranging study evaluating the safety and efficacy of tildacerfont in reducing androstenedione (A4) levels in adult patients with classic CAH while on their current glucocorticoid regimen. Additionally, enrollment in the company’s CAHmelia-204 clinical trial is approaching 75% enrollment. CAHmelia-204 is a randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of tildacerfont in reducing supraphysiologic glucocorticoid use in adult patients with classic CAH.

- **Screening for Cohort 3 in CAHptain Study for Pediatric Classic CAH Underway**: Enrollment for Cohort 2 of the CAHptain study is nearly complete and screening for Cohort 3 is underway. Patients in Cohort 1 have completed

12 weeks of treatment and have entered the extension portion of the study. CAHptain is a Phase 2 open-label clinical trial that utilizes a sequential 3 cohort design (cohorts 1 and 2 comprised of adolescent patients 11 to 17 years of age, and cohort 3 comprised of children 2 to 10 years of age) to evaluate the safety, pharmacokinetics (PK), and exploratory pharmacodynamics (PD) of tildacerfont in children with classic CAH.

- **Appointment of Heidi Petersen, M.P.H., as Senior Vice President of Regulatory and Quality:** As Senior Vice President of Regulatory and Quality, Heidi Petersen, will be responsible for leading the company's global regulatory affairs and quality strategy. Ms. Petersen is a seasoned industry executive with nearly three decades of experience overseeing global development of biologics and small molecule investigational products in immuno-oncology, infectious disease, and rare disease indications. Prior to joining Spruce, Ms. Petersen was Senior Vice President of Regulatory Affairs at Mereo BioPharma. Ms. Petersen earned a Master of Public Health from Columbia University.

Anticipated Upcoming Milestones

- Topline data from adolescents (cohorts 1 and 2) of the Phase 2 CAHptain clinical trial in pediatric classic CAH in the second half of 2023
- Topline results from the CAHmelia-203 clinical trial in adult classic CAH patients with highly elevated levels of A4 in the second half of 2023
- 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 second half of 2024

Second Quarter 2023 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of June 30, 2023 were $120.5 million. Cash, cash equivalents and investments are expected to allow the company to fund operating and capital expenditures into the first half of 2025.
- **Collaboration Revenue:** Collaboration revenue for the three and six months ended June 30, 2023 were $2.2 million and $4.1 million, respectively, compared to nil for the same periods in 2022. The increase in 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 and six months ended June 30, 2023 were $13.1 million and $24.8 million, respectively, compared to $9.1 million and $17.6 million for the same periods 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 PCOS.
- **General and Administrative (G&A) Expenses:** G&A expenses for the three and six months ended June 30, 2023 were $3.0 million and $6.5 million, respectively, compared to $2.8 million and $6.0 million for the same periods in 2022.
- **Total Operating Expenses:** Total operating expenses for the three and six months ended June 30, 2023 were $16.1 million and $31.3 million, respectively, compared to $11.9 million and $23.6 million for the same periods in 2022.
- **Net Loss:** Net loss for the three and six months ended June 30, 2023 was $12.8 million and $25.6 million, respectively, compared to $11.9 million and $23.6 million for the same periods in 2022.

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). Spruce is also developing tildacerfont for women suffering from polycystic ovary syndrome (PCOS). To learn more, visit www.sprucebiosciences.com and follow us on Twitter @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 enrollment, results, conduct, progress and timing of Spruce’s clinical trials; the receipt and presentation of topline data from the same; research and development plans; Spruce’s planned operations, including its expectations regarding operating and capital expenditures being funded into the first half of 2025; the implications of the interim data from the POWER study; tildacerfont’s potential to become a first-in-class therapy for PCOS; Spruce’s expectations to further engage regulatory authorities regarding tildacerfont; and the ability of tildacerfont to provide a therapeutic option to treat the underlying cause of disease through reductions of ACTH. 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”, “expect”, “may”, “plan”, “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, the risk that interim data from the POWER study will differ from final data once available, along with 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, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 97,482	$ 24,487
Short-term investments	23,041	54,590
Prepaid expenses	3,400	3,320
Other current assets	206	1,211
Total current assets	124,129	83,608
Right-of-use assets	1,297	1,400
Other assets	536	640
Total assets	$ 125,962	$ 85,648
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 945	$ 1,426
Accrued expenses and other current liabilities	12,107	9,399
Term loan, current portion	1,622	1,622
Deferred revenue, current portion	8,060	—
Total current liabilities	22,734	12,447
Lease liabilities, net of current portion	1,147	1,261
Term loan, net of current portion	2,507	3,293
Deferred revenue, net of current portion	2,811	—
Other liabilities	202	161
Total liabilities	29,401	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 June 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 40,710,692 and 23,601,004 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	4	3
Additional paid-in capital	271,540	218,354
Accumulated other comprehensive loss	(55)	(558)
Accumulated deficit	(174,928)	(149,313)
Total stockholders' equity	96,561	68,486
Total liabilities and stockholders' equity	$ 125,962	$ 85,648

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,	
	2023	2022	2023	2022
Collaboration revenue	$ 2,165	$ —	$ 4,129	$ —
Operating expenses:				
Research and development	13,126	9,060	24,838	17,568
General and administrative	3,011	2,822	6,462	6,048
Total operating expenses	16,137	11,882	31,300	23,616
Loss from operations	(13,972)	(11,882)	(27,171)	(23,616)
Interest expense	(127)	(94)	(258)	(181)
Interest and other income, net	1,275	104	1,814	162
Net loss	(12,824)	(11,872)	(25,615)	(23,635)
Other comprehensive gain (loss), net of tax:				
Unrealized gain (loss) on available for sale securities	133	(152)	503	(661)
Total comprehensive loss	$ (12,691)	$ (12,024)	$ (25,112)	$ (24,296)
Net loss per share, basic and diluted	$ (0.32)	$ (0.51)	$ (0.71)	$ (1.01)
Weighted-average shares of common stock outstanding, basic and diluted	40,547,925	23,493,613	36,247,931	23,492,960

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