

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): November 13, 2023

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 2.02 Results of Operations and Financial Condition.

On November 13, 2023, Spruce Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2023 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 November 13, 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: November 13, 2023

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

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

Enrollment Completed in CAHptain-205 Study in Pediatric Classic Congenital Adrenal Hyperplasia (CAH)

Target Enrollment Completed in CAHmelia-203 Study in Adult Classic CAH

CAHmelia-204 Study in Adult Classic CAH on Track to Complete Enrollment in Early Q1 2024

South San Francisco, Calif. – November 13, 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 third quarter ended September 30, 2023 and provided corporate updates.

“Achieving completion of enrollment milestones in the CAHptain-205 and CAHmelia-203 studies underscores the strong execution of our key clinical objectives and the momentum within our adult and pediatric classic CAH programs,” said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. “We continue to make notable progress in our efforts to advance tildacerfont as a potentially novel therapeutic option for people living with CAH and are eager to report topline data from CAHmelia-203 and CAHptain-205 in the first quarter of 2024.”

Recent Corporate Updates

- **CAHptain-205 Study in Pediatric Classic CAH Completes Enrollment:** Enrollment in the CAHptain study is complete with 30 patients, surpassing the target enrollment of 20 patients. 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.
- **CAHmelia-203 Study in Adult Classic CAH Completes Target Enrollment:** Target enrollment of 72 patients in the company's CAHmelia-203 clinical trial is complete. CAHmelia-203 is a randomized, double-blind, placebo-controlled, dose-ranging Phase 2b clinical trial evaluating the safety and efficacy of tildacerfont in adults with classic CAH and highly elevated levels of androstenedione (A4) at baseline while on stable glucocorticoid dosing. Due to substantial patient interest in CAHmelia-203, final enrollment in the study will exceed its original target of 72 patients.
- **CAHmelia-204 Study in Adult Classic CAH on Track to Complete Enrollment in Early Q1 2024:** Enrollment in the CAHmelia-204 clinical trial surpassed 75% enrollment and remains on track to complete enrollment in the early first quarter of 2024. 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.

Anticipated Upcoming Milestones

- Completion of enrollment in 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 early first quarter of 2024
 - Topline results from the CAHmelia-203 clinical trial in adult classic CAH patients with highly elevated levels of A4 in the first quarter of 2024
 - Topline results from all cohorts in the CAHptain-205 clinical trial in pediatric classic CAH patients in the first quarter of 2024
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- 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

Third Quarter 2023 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of September 30, 2023 were \$108.0 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 nine months ended September 30, 2023 were \$3.1 million and \$7.2 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 nine months ended September 30, 2023 were \$13.5 million and \$38.3 million, respectively, compared to \$8.8 million and \$26.4 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 nine months ended September 30, 2023 were \$3.2 million and \$9.7 million, respectively, compared to \$2.8 million and \$8.8 million for the same periods in 2022.
- **Total Operating Expenses:** Total operating expenses for the three and nine months ended September 30, 2023 were \$16.7 million and \$48.0 million, respectively, compared to \$11.6 million and \$35.2 million for the same periods in 2022.
- **Net Loss:** Net loss for the three and nine months ended September 30, 2023 was \$12.4 million and \$38.0 million, respectively, compared to \$11.4 million and \$35.0 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.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 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; and Spruce’s planned operations, including its expectations regarding operating and capital expenditures being funded into the first half of 2025. 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, 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)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 98,801	\$ 24,487
Short-term investments	9,231	54,590
Prepaid expenses	2,687	3,320
Other current assets	419	1,211
Total current assets	111,138	83,608
Right-of-use assets	1,240	1,400
Other assets	607	640
Total assets	<u>\$ 112,985</u>	<u>\$ 85,648</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,152	\$ 1,426
Accrued expenses and other current liabilities	11,616	9,399
Term loan, current portion	1,622	1,622
Deferred revenue, current portion	7,798	—
Total current liabilities	24,188	12,447
Lease liabilities, net of current portion	1,083	1,261
Term loan, net of current portion	2,113	3,293
Other liabilities	220	161
Total liabilities	27,604	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 September 30, 2023 and December 31, 2022	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 40,710,692 and 23,601,004 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	4	3
Additional paid-in capital	272,662	218,354
Accumulated other comprehensive loss	(3)	(558)
Accumulated deficit	(187,282)	(149,313)
Total stockholders' equity	85,381	68,486
Total liabilities and stockholders' equity	<u>\$ 112,985</u>	<u>\$ 85,648</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Collaboration revenue	\$ 3,073	\$ —	\$ 7,202	\$ —
Operating expenses:				
Research and development	13,494	8,791	38,332	26,359
General and administrative	3,237	2,766	9,699	8,814
Total operating expenses	<u>16,731</u>	<u>11,557</u>	<u>48,031</u>	<u>35,173</u>
Loss from operations	(13,658)	(11,557)	(40,829)	(35,173)
Interest expense	(119)	(110)	(377)	(291)
Interest and other income, net	1,423	266	3,237	428
Net loss	<u>(12,354)</u>	<u>(11,401)</u>	<u>(37,969)</u>	<u>(35,036)</u>
Other comprehensive gain (loss), net of tax:				
Unrealized gain (loss) on available for sale securities	52	(28)	555	(689)
Total comprehensive loss	<u>\$ (12,302)</u>	<u>\$ (11,429)</u>	<u>\$ (37,414)</u>	<u>\$ (35,725)</u>
Net loss per share, basic and diluted	<u>\$ (0.30)</u>	<u>\$ (0.48)</u>	<u>\$ (1.01)</u>	<u>\$ (1.49)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>40,710,692</u>	<u>23,560,250</u>	<u>37,751,865</u>	<u>23,515,651</u>

Media

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