

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 16, 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 March 16, 2023, Spruce Biosciences, Inc. (the "Company") issued a press release announcing its financial results for the full year ended December 31, 2022 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

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release of Spruce Biosciences, Inc., dated March 16, 2023</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)



## Spruce Biosciences Reports Full Year 2022 Financial Results and Provides Corporate Updates

*CAHmelia-203 in Adult Classic CAH Surpasses 50% Enrollment*

*Private Placement Financing of \$53.6 million in Gross Proceeds with Top-Tier Healthcare Investors*

*Strategic Partnership and Exclusive Licensing Agreement with Kaken Pharmaceutical to Develop and Commercialize Tildacerfont for CAH in Japan*

*Private Placement Proceeds and Kaken Upfront Payment Expected to Extend Cash Runway Into 1H 2025*

**South San Francisco, Calif. – March 16, 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 year ended December 31, 2022 and provided corporate updates.

“In 2022, we made significant progress across the board heading into 2023, which we believe will be a pivotal year for Spruce,” said Javier Szwarcberg, M.D., M.P.H., Chief Executive Officer of Spruce Biosciences. “In 2023, we remain focused on delivering data for a number of our ongoing clinical programs, including topline data from our CAHmelia-203 study in adult classic congenital adrenal hyperplasia (CAH), which surpassed 50% enrollment.”

Dr. Szwarcberg continued, “We’ve had a very strong start to the year. In January, we announced a strategic collaboration and exclusive license agreement with Kaken Pharmaceutical (Kaken) to develop and commercialize tildacerfont for CAH in Japan. In February, we closed a private placement financing with top-tier healthcare investors for gross proceeds of \$53.6 million, which, together with the Kaken upfront payment of \$15.0 million, enables us to fund operating and capital expenditures into the first half of 2025, beyond topline results for CAHmelia-204 which are anticipated in the second half of 2024.”

### Recent Corporate Updates

- **CAHmelia-203 in Adult Classic CAH Surpasses 50% Enrollment:** Spruce surpassed 50% enrollment in the company’s CAHmelia-203 clinical study and is on track to report topline data in the second half of 2023. CAHmelia-203 is a randomized, double-blind, placebo-controlled, dose-ranging study evaluating the safety and efficacy of tildacerfont in adult patients with classic CAH and highly elevated levels of androstenedione (A4) on their current glucocorticoid regimen.
  - **Private Placement Financing of \$53.6 million with Top-Tier Healthcare Investors:** In February 2023, the company entered into a definitive securities purchase agreement for a private placement that resulted in gross proceeds of \$53.6 million, before deducting commissions and offering expenses. The private placement included participation from new and existing investors, including 5am Ventures, Abingworth, Armistice Capital, HealthCap, Novo Holdings A/S, RiverVest Venture Partners, and Rock Springs Capital. The proceeds from the financing, together with the \$15.0 million upfront payment due to the company under the license agreement with Kaken, is expected to allow the company to fund operating and capital expenditures into the first half of 2025.
  - **Strategic Partnership and Exclusive Licensing Agreement with Kaken Pharmaceutical:** In January 2023, Spruce and Kaken entered into an exclusive license agreement for the development and commercialization of Spruce’s product candidate, tildacerfont, for the treatment of CAH in Japan. Under the terms of the agreement, Spruce will receive an upfront payment of \$15.0 million from Kaken and will be eligible to receive additional payments upon the achievement of future development and commercial milestones, as well as tiered double-digit royalties on net sales in Japan. Kaken will be responsible for the clinical development and commercialization of tildacerfont in Japan, and Spruce will retain all rights to tildacerfont in all other geographies.
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## Anticipated Upcoming Milestones

Spruce affirms the following anticipated upcoming milestones:

- Topline results from the Phase 2 P.O.W.E.R. clinical trial in polycystic ovary syndrome (PCOS) in the first half of 2023
- 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

## Full Year 2022 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of December 31, 2022 were \$79.1 million, excluding \$53.6 million in gross proceeds from the February 2023 private placement and the \$15.0 million upfront payment due to the company from Kaken. The company has a banking relationship with Silicon Valley Bank but did not experience any financial losses or operational impact from the recent failure of the bank.
- **Research and Development (R&D) Expenses:** R&D expenses for the year ended December 31, 2022 were \$35.2 million compared to \$30.7 million in 2021. 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 year ended December 31, 2022 were \$12.1 million compared to \$11.4 million in 2021.
- **Total Operating Expenses:** Total operating expenses for the year ended December 31, 2022 were \$47.3 million compared to \$42.1 million in 2021. Stock-based compensation expense for the year ended December 31, 2022 was \$3.6 million compared to \$4.0 million in 2021. When excluding depreciation and stock-based compensation expenses, total non-GAAP operating expenses for the year ended December 31, 2022 were \$43.6 million compared to \$38.1 million in 2021.
- **Net Loss:** Net loss for the year ended December 31, 2022 was \$46.2 million compared to \$42.3 million in 2021.

## 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) with primary adrenal androgen excess. To learn more, visit [www.sprucebiosciences.com](http://www.sprucebiosciences.com) and follow us on Twitter @Spruce\_Bio, LinkedIn, Facebook and YouTube.

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## **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, and responsibilities of Spruce and Kaken pursuant to the exclusive license agreement. 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”, “enable”, “expect”, “will”, “believe”, “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 the COVID-19 pandemic and other 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.

## **Use of Non-GAAP Financial Measures**

Spruce has presented certain non-GAAP financial measures in this release. This release and the reconciliation tables included herein include non-GAAP total operating expenses, which excludes depreciation and stock-based compensation. Spruce excludes depreciation and stock-based compensation because management believes the exclusion of these items is helpful to investors to evaluate Spruce’s recurring operational performance. Spruce management uses this non-GAAP financial measure to monitor and evaluate its operating results and trends on an on-going basis, and internally for operating, budgeting and financial planning purposes. This non-GAAP financial measure should be considered in addition to results prepared in accordance with GAAP but should not be considered a substitute for or superior to GAAP results.

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**SPRUCE BIOSCIENCES, INC.**  
**BALANCE SHEETS**  
(in thousands, except share and per share amounts)

	December 31,	
	2022	2021
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 24,487	\$ 42,748
Short-term investments	54,590	46,221
Prepaid expenses	3,320	2,530
Other current assets	1,211	396
Total current assets	83,608	91,895
Long-term investments	—	32,459
Operating lease right-of-use asset	1,400	1,479
Other assets	640	653
Total assets	<u>\$ 85,648</u>	<u>\$ 126,486</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,426	\$ 2,823
Accrued expenses and other current liabilities	9,399	6,048
Term loan, current portion	1,622	—
Total current liabilities	12,447	8,871
Operating lease liability, net of current portion	1,261	1,293
Term loan, net of current portion	3,293	4,878
Other liabilities	161	73
Total liabilities	<u>17,162</u>	<u>15,115</u>
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, 2022 and 2021	—	—
Common stock, \$0.0001 par value; 200,000,000 shares authorized as of December 31, 2022 and 2021; 23,601,004 and 23,491,881 shares issued and outstanding as of December 31, 2022 and 2021, respectively	3	3
Additional paid-in capital	218,354	214,685
Accumulated other comprehensive loss	(558)	(184)
Accumulated deficit	(149,313)	(103,133)
Total stockholders' equity	68,486	111,371
Total liabilities and stockholders' equity	<u>\$ 85,648</u>	<u>\$ 126,486</u>

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

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 35,198	\$ 30,698
General and administrative	12,085	11,368
Total operating expenses	47,283	42,066
Loss from operations	(47,283)	(42,066)
Interest expense	(420)	(345)
Interest and other income, net	1,523	119
Net loss	(46,180)	(42,292)
Other comprehensive loss, net of tax:		
Unrealized loss on available for sale securities	(374)	(184)
Total comprehensive loss	\$ (46,554)	\$ (42,476)
Net loss per share, basic and diluted	\$ (1.96)	\$ (1.81)
Weighted-average shares of common stock outstanding, basic and diluted	23,527,116	23,361,416



**SPRUCE BIOSCIENCES, INC.**  
**RECONCILIATION OF TOTAL OPERATING EXPENSES TO NON-GAAP TOTAL OPERATING EXPENSES**  
**(unaudited)**  
**(in thousands)**

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Total operating expenses	\$ 47,283	\$ 42,066
Adjustments:		
Depreciation	37	22
Stock-based compensation	3,631	3,958
Non-GAAP total operating expenses	<u>\$ 43,615</u>	<u>\$ 38,086</u>

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**Media**

Will Zasadny

Evoke Canale

(619) 961-8848

[will.zasadny@evokecanale.com](mailto:will.zasadny@evokecanale.com)

[media@sprucebiosciences.com](mailto:media@sprucebiosciences.com)

**Investors**

Xuan Yang

Solebury Strategic Communications

(415) 971-9412

[xyang@soleburystrat.com](mailto:xyang@soleburystrat.com)

[investors@sprucebiosciences.com](mailto:investors@sprucebiosciences.com)

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