

**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 12, 2021

**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.)

**2001 Junipero Serra Boulevard, Suite 640**  
**Daly City, California**  
(Address of principal executive offices)

**94014**  
(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 12, 2021, Spruce Biosciences, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2021 and providing a corporate update. 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 (“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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	<a href="#">Press Release of Spruce Biosciences, Inc., dated May 12, 2021</a>

**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 12, 2021

By: \_\_\_\_\_ /s/ Richard King  
Richard King  
Chief Executive Officer

**Spruce Biosciences Reports First Quarter 2021 Financial Results and Provides Corporate Updates**

*Presentation of Phase 2 Data of Tildacerfont at 23<sup>rd</sup> Annual European Congress of Endocrinology*

*Cash and Cash Equivalents of \$148.6 million*

**San Francisco, Calif. – May 12, 2021** – 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, 2021 and provided a corporate update.

“Throughout the first quarter of 2021, Spruce Biosciences made substantial progress in our efforts to advance new treatment options for people living with rare endocrine disorders and to maximize the potential of tildacerfont as a therapeutic to treat people living with classic congenital adrenal hyperplasia, or CAH, and other diseases impacted by ACTH,” said Richard King, Chief Executive Officer of Spruce Biosciences. “We continue to advance enrollment into our late-stage CAHmelia program in adult classic CAH and remain encouraged with the level of patient interest registered with our study investigators. Looking ahead, we remain on track to initiate our Phase 2 program in children with classic CAH in the second half of this year. In the pediatric classic CAH population, the imbalance between excess adrenal androgens and glucocorticoids can lead to irreversible impacts on childhood development. Tildacerfont has the potential to ease the disease and steroid burden for children, which may enable normal growth progression through childhood and adolescence.”

**Corporate Highlights**

- **Presentation of Phase 2 Data of Tildacerfont at European Society of Endocrinology’s 23<sup>rd</sup> Annual European Congress of Endocrinology (ECE 2021):** On May 24, 2021, Richard Auchus, MD, PhD, Professor of Internal Medicine and Pharmacology, University of Michigan, Ann Arbor, will present data from the company’s Phase 2 program of tildacerfont in classic CAH at [ECE 2021](#). The presentation will highlight data from the company’s SPR001-202 clinical trial, which demonstrated the ability of tildacerfont to reduce and normalize key disease biomarkers over a 12-week period. Normalization of highly elevated hormones in classic CAH patients over a 12-week trial and without increases to daily steroid doses, to the company’s knowledge, has not been publicly reported with any other investigational product candidate to date.
- **Cash and Cash Equivalents of \$148.6 Million:** Based on the company’s current operating plan, the company is well capitalized to advance its pipeline through key milestones, including primary data readout from its CAHmelia studies and initiation of Phase 2 programs in pediatric classic CAH and a rare form of polycystic ovary syndrome (PCOS).

**Anticipated Upcoming Milestones**

- Submission of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration for PCOS in the first half of 2021, and initiation of a Phase 2 proof-of-concept clinical trial in the second half of 2021
  - Initiation of a Phase 2 clinical program in pediatric classic CAH in the second half of 2021
-

- Results from CAHmelia-203 in adult classic CAH patients with poor disease control the first half of 2022
- Results from CAHmelia-204 in adult classic CAH patients with good disease control in the second half of 2022

### **First Quarter 2021 Financial Results**

**Cash and Cash Equivalents:** Cash and cash equivalents as of March 31, 2021, were \$148.6 million.

**Research and Development (R&D) Expenses:** R&D expenses for the first quarter ended March 31, 2021 were \$6.7 million compared to \$4.6 million for the same period in 2020. The overall increase in R&D expenses was primarily related to the advancement of tildacerfont into late-stage clinical development.

**General and Administrative (G&A) Expenses:** G&A expenses for the first quarter ended March 31, 2021 were \$3.1 million compared to \$0.5 million for the same period in 2020. The overall increase in G&A expenses was primarily driven by an increase in costs related to operation as a public company.

**Total Operating Expenses:** Total operating expenses for the quarter ended March 31, 2021 were \$9.8 million compared to \$5.1 million for the same period in 2020. Stock-based compensation for the first quarter ended March 31, 2021 was \$1.1 million. When excluding depreciation and stock-based compensation, total operating expenses for the quarter ended March 31, 2021 were \$8.7 million.

**Net Loss:** Net loss for the three months ended March 31, 2021 was \$9.9 million compared to \$5.1 million for the same period in 2020.

### **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 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). Classic CAH is a serious and life-threatening disease with no known novel therapies approved in approximately 50 years. Spruce is also developing tildacerfont for women suffering from a rare form of polycystic ovary syndrome (PCOS) with primary adrenal androgen excess, representing 3-5% of females with PCOS (estimated to be 150,000 to 200,000 patients in the United States). To learn more, visit [www.sprucebiosciences.com](http://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 results, conduct, progress and timing of Spruce’s clinical trials, the regulatory approval path for tildacerfont, the strength of Spruce’s balance sheet and the adequacy of Spruce’s cash position. 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 “plans”, “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 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 and non-GAAP G&A expenses, both of which exclude 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 these non-GAAP financial measures to monitor and evaluate its operating results and trends on an on-going basis, and internally for operating, budgeting and financial planning purposes. The non-GAAP financial measures 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.

**SPRUCE BIOSCIENCES, INC.**  
**CONDENSED BALANCE SHEETS**  
(unaudited)  
(in thousands, except share amounts)

	March 31, 2021	December 31, 2020
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 148,627	\$ 157,150
Prepaid expenses	2,687	2,971
Other current assets	272	276
Total current assets	151,586	160,397
Restricted cash	216	216
Right-of-use assets	1,716	1,793
Other assets	473	477
Total assets	<u>\$ 153,991</u>	<u>\$ 162,883</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,566	\$ 3,628
Term loan, current portion	—	2,554
Accrued expenses and other current liabilities	3,558	2,496
Accrued compensation and benefits	727	1,085
Total current liabilities	6,851	9,763
Term loan, net of current portion	4,843	1,922
Lease liability, net of current portion	1,566	1,653
Other liabilities	8	118
Total liabilities	<u>13,268</u>	<u>13,456</u>
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, and no shares issued and outstanding as of March 31, 2021 and December 31, 2020	—	—
Common stock, \$0.0001 par value, 200,000,000 shares authorized, 23,301,872 and 23,260,399 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	2	2
Additional paid-in capital	211,449	210,266
Accumulated deficit	(70,728)	(60,841)
Total stockholders' equity	<u>140,723</u>	<u>149,427</u>
Total liabilities and stockholders' equity	<u>\$ 153,991</u>	<u>\$ 162,883</u>

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

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 6,714	\$ 4,610
General and administrative	3,103	523
Total operating expenses	<u>9,817</u>	<u>5,133</u>
Loss from operations	(9,817)	(5,133)
Interest expense	(89)	(74)
Other income, net	19	39
Net loss	<u>\$ (9,887)</u>	<u>\$ (5,168)</u>
Net loss per share, basic and diluted	<u>\$ (0.42)</u>	<u>\$ (6.76)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>23,283,658</u>	<u>764,408</u>



**SPRUCE BIOSCIENCES, INC.**  
**Reconciliation of Total Operating Expenses to Non-GAAP Total Operating Expenses**  
**(unaudited)**  
**(in thousands)**

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Operating expenses:</b>		
Total operating expenses	\$ 9,817	\$ 5,133
<b>Adjustments:</b>		
Depreciation	4	—
Stock-based compensation	1,120	32
Non-GAAP total operating expenses	<u>\$ 8,693</u>	<u>\$ 5,101</u>

**Reconciliation of G&A Expenses to Non-GAAP G&A Expenses**  
**(unaudited)**  
**(in thousands)**

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Operating expenses:</b>		
G&A expenses	\$ 3,103	\$ 523
<b>Adjustments:</b>		
Depreciation	4	—
Stock-based compensation	856	22
Non-GAAP G&A expenses	<u>\$ 2,243</u>	<u>\$ 501</u>

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