

**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 18, 2020

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 November 18, 2020, Spruce Biosciences, Inc. (the “Company”) issued a press release providing a corporate update and announcing its financial results for the quarter ended September 30, 2020. 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	<u>Press Release of Spruce Biosciences, Inc., dated November 18, 2020</u>

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 18, 2020

By: _____
/s/ Richard King
Richard King
Chief Executive Officer

Spruce Biosciences Reports Third Quarter 2020 Financial Results and Provides Corporate Update

- Successful Initiation of Late-Stage CAHmelia Program in Adult Classic CAH-
- FDA and EMA Scientific Advice Support Plans in Pediatric Classic CAH Program-
- IPO Results in Pro Forma Cash and Cash Equivalents of \$168.4 Million-

San Francisco, Calif. – November 18, 2020 – 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, 2020 and provided a corporate update.

Recent Accomplishments and Progress Toward Milestones

- **Successful Initiation of the Late-Stage CAHmelia Program in Adult Classic Congenital Adrenal Hyperplasia (CAH).** CAHmelia-203 will assess the impact of tildacerfont, a CRF-1 receptor antagonist, on biomarker control and reducing clinical effects of disease in adult classic CAH patients with poor disease control. CAHmelia-204 will assess the effect of tildacerfont on glucocorticoid reduction and the clinical impact of that reduction in adult classic CAH patients with good disease control. Spruce believes that its two-study strategy may allow it to observe more clinically meaningful outcomes with fewer total patients studied. Screening activities are underway and substantial patient interest for participation in both studies has been registered at CAHstudy.com.
- **Pediatric Scientific Advice Meetings with FDA and European Medicines Agency (EMA) Completed.** Spruce completed a scientific advice meeting with the EMA regarding its clinical development program of tildacerfont in children with classic CAH between the ages 2 and 17. Spruce plans to submit a Pediatric Investigational Plan (PIP) to the Pediatric Committee of the EMA regarding a Phase 3 registrational program in pediatrics. Scientific advice received from both the EMA and FDA also support Spruce's plans to initiate its planned Phase 2 pediatric clinical trial in the second half of 2021.
- **Successful Completion of Initial Public Offering (IPO).** Spruce closed its IPO in October 2020, resulting in net proceeds of \$96.3 million, after deducting underwriting discounts and commissions of approximately \$7.2 million and before deducting offering related expenses. When including net proceeds from the IPO, pro forma cash and cash equivalents as of September 30, 2020 were \$168.4 million.

"The third quarter has been a transformational period for the company, marked by significant accomplishments. We have successfully initiated CAHmelia-203 and CAHmelia-204, our global late-stage development program in adult classic CAH, despite the challenges resulting from the COVID-19 pandemic," said Richard King, Chief Executive Officer. "With the successful completion of our IPO in October 2020, our strong cash position enables us to fund our CAHmelia program through completion and into applications for approval from regulatory authorities, assuming positive study outcomes. In addition, tildacerfont continues to progress towards evaluation in additional indications, including pediatric classic CAH and a rare form of polycystic ovary syndrome driven by a hyper-responsiveness to elevated levels of adrenocorticotrophic hormone. We are focused on executing our clinical development plans and look forward to providing more updates in the future."

Financial Highlights

Cash and Cash Equivalents: Cash and cash equivalents as of September 30, 2020, were \$72.2 million.

Research and Development (R&D) Expenses: R&D expenses consist primarily of pre-clinical, clinical and manufacturing expenses related to the development of tildacerfont. R&D expenses for the three and nine months ended September 30, 2020 were \$7.8 million and \$18.0 million compared to \$2.1 million and \$8.0 million for the same periods in 2019, respectively. The overall increase in R&D expenses was primarily related to an increase in clinical development, manufacturing, and personnel costs associated with advancement of tildacerfont into late-stage clinical development.

General and Administrative (G&A) Expenses: G&A expenses consist primarily of personnel costs, legal and other professional fees, insurance, and other administrative costs. G&A expenses for the three and nine months ended September 30, 2020 were \$1.8 million and \$3.0 million, compared to \$0.5 million and \$2.0 million for the same periods in 2019, respectively. The overall increase in G&A expenses was primarily driven by an increase in professional fees related to the IPO.

Net Loss: Net loss for the three and nine months ended September 30, 2020 was \$9.6 million and \$21.2 million, compared to \$2.6 million and \$9.9 million for the same periods in 2019, respectively.

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 to offer markedly improved disease control and reduce steroid burden 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.

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”, “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 Measure

To supplement our financial information, which is prepared and presented in accordance with generally accepted accounting principles in the United States of America (GAAP), we use the following non-GAAP financial measure: pro forma cash and cash equivalents, which include the net proceeds from the IPO, after deducting underwriting discounts and commissions and before deducting offering related expenses. Management believes the non-GAAP financial measure is helpful to investors to evaluate the company’s financial position. The 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.

There are a number of limitations related to the use of non-GAAP financial measures. In light of these limitations, we provide specific information regarding the GAAP amounts included or excluded from these non-GAAP financial measures and evaluating these non-GAAP financial measures together with their relevant financial measures in accordance with GAAP.

For more information on these non-GAAP financial measures, please see section titled “Reconciliation of Non-GAAP Measure” included at the end of this release.

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

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 72,158	\$ 3,924
Prepaid expenses	1,233	215
Other current assets	209	513
Total current assets	73,600	4,652
Restricted cash	216	—
Right-of-use assets	1,869	—
Deferred offering costs	2,347	—
Other assets	453	40
Total assets	<u>\$ 78,485</u>	<u>\$ 4,692</u>
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 4,002	\$ 1,878
Term loan, current portion	1,908	1,252
Accrued expenses and other current liabilities	3,469	265
Accrued compensation and benefits	707	908
Total current liabilities	10,086	4,303
Term loan, net of current portion	2,561	3,193
Lease liability, net of current portion	1,738	—
Other liabilities	95	20
Total liabilities	<u>14,480</u>	<u>7,516</u>
Series A redeemable convertible preferred stock, \$0.0001 par value, 28,000,000 shares authorized, issued, and outstanding as of September 30, 2020 and December 31, 2019; liquidation preference of \$28,000 as of September 30, 2020 and December 31, 2019	27,813	27,813
Series B redeemable convertible preferred stock, \$0.0001 par value, 73,333,330 shares authorized, issued, and outstanding as of September 30, 2020 and 0 shares authorized, issued and outstanding as of December 31, 2019; liquidation value of \$88,000 as of September 30, 2020 and \$0 as of December 31, 2019	87,633	—
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value, 130,518,922 and 41,000,000 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 822,022 and 764,408 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	1,061	664
Accumulated deficit	(52,503)	(31,302)
Total stockholders' equity (deficit)	<u>(51,441)</u>	<u>(30,637)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 78,485</u>	<u>\$ 4,692</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 7,769	\$ 2,107	\$ 18,040	\$ 7,969
General and administrative	1,790	457	3,041	2,004
Total operating expenses	<u>9,559</u>	<u>2,564</u>	<u>21,081</u>	<u>9,973</u>
Loss from operations	(9,559)	(2,564)	(21,081)	(9,973)
Interest expense	(79)	(5)	(245)	(5)
Other income, net	51	18	125	72
Net loss	<u>\$ (9,587)</u>	<u>\$ (2,551)</u>	<u>\$ (21,201)</u>	<u>\$ (9,906)</u>
Net loss per share, basic and diluted	<u>\$ (12.35)</u>	<u>\$ (3.34)</u>	<u>\$ (27.54)</u>	<u>\$ (12.96)</u>
Weighted-average shares of common stock outstanding, basic and diluted	<u>776,159</u>	<u>764,408</u>	<u>769,766</u>	<u>764,408</u>

SPRUCE BIOSCIENCES, INC.
RECONCILIATION OF NON-GAAP MEASURE
(unaudited)
(in thousands)

	September 30, 2020
Cash and cash equivalents	\$ 72,158
Adjustments:	
Net IPO proceeds after deducting underwriting discounts and commissions and before deducting offering related expenses	96,255
Pro forma cash and cash equivalents	\$ 168,413

Media

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