

**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 15, 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 November 15, 2021, Spruce Biosciences, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 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.

| Exhibit Number | Description |
|---------------------------|--|
| 99.1 | Press Release of Spruce Biosciences, Inc., dated November 15, 2021 |
| 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 15, 2021

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

Spruce Biosciences Reports Third Quarter 2021 Financial Results and Provides Corporate Updates

Planned Initiation of Phase 2 Programs in Pediatric Classic CAH and Polycystic Ovary Syndrome

Late-Stage CAHmelia Program in Adult Classic CAH Expanded to Sites in Australia and Canada

Cash, Cash Equivalents and Investments of \$131.3 Million as of September 30, 2021

San Francisco, Calif. – November 15, 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 third quarter ended September 30, 2021 and provided a corporate update.

We continue to make progress in advancing tildacerfont for the treatment of patients with rare endocrine disorders with the planned initiation of a Phase 2 clinical trial for children with classic congenital adrenal hyperplasia (CAH), as well as a proof-of-concept clinical trial for women with a rare form of polycystic ovary syndrome (PCOS),” said Mike Grey, Executive Chairman of Spruce Biosciences, who has taken on the role of Interim Chief Executive Officer following the retirement of Richard King as separately announced today. “While we have recently seen an encouraging upward trend in the pace of site activation and patient enrollment across our CAHmelia studies in adults with classic CAH, the continued variability of the impact of the COVID-19 pandemic across sites throughout the United States and Europe has impacted enrollment and we now expect to report topline results from the CAHmelia-203 study in 2023.”

Corporate & Pipeline Updates in Q3 2021

- **Update on Expected Timeline for Topline Data from the CAHmelia Program in Adult Classic CAH:** Due to the continued impact of the COVID-19 pandemic on the pace of patient enrollment and site activation in the company’s CAHmelia program, Spruce now expects to report topline results from CAHmelia-203 in 2023. Spruce will provide an update on timing expectations for topline results from the CAHmelia-204 study in the coming months, following the completion of a full assessment of the pandemic’s impact on projected enrollment.
 - **Phase 2 CAHmelia Program in Adult Classic CAH Expanded to Sites in Australia and Canada:** Spruce has expanded the CAHmelia program in adult classic CAH beyond the United States and Europe to include sites in Australia and Canada in response to patient and investigator interest. The additional sites also provide more robust recruitment capabilities to accelerate enrollment and offset any additional disruption related to the ongoing COVID-19 pandemic.
 - **Inaugural Research and Development Day Highlighted Tildacerfont in CAH:** In August, Spruce hosted its inaugural virtual research and development day highlighting the potential value of tildacerfont in treating adult and pediatric classic CAH. Management was joined by leading endocrinologists, Richard Auchus, MD, PhD, Professor of Internal Medicine and Pharmacology at the University of Michigan, and Paul Thornton, MD, Medical Director, Endocrine and Diabetes Program, Cook Children’s Medical Center.
 - **Planned Initiation of Phase 2 Clinical Trial in Pediatric Classic CAH on Track:** The Phase 2 open-label clinical trial will utilize a sequential 3 cohort design to evaluate the safety, pharmacokinetics, and exploratory pharmacodynamics of tildacerfont in children aged 6 to 17 with classic CAH. Various weight
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adjusted doses of tildacerfont dosed once daily for a duration of 2 weeks will be evaluated.

- **Planned Initiation of Phase 2 Proof of Concept Clinical Trial in PCOS on Track:** A randomized, placebo-controlled, response-guided, intrasubject dose escalation study will evaluate the safety and efficacy of various tildacerfont dose levels (50 mg, 100 mg, and 200 mg QD) compared to placebo for up to 16 weeks of treatment in subjects with PCOS and elevated adrenal androgens as measured by DHEAS levels at baseline.

Third Quarter 2021 Financial Results

- **Cash, Cash Equivalents and Investments:** Cash, cash equivalents and investments as of September 30, 2021, were \$131.3 million.
- **Research and Development (R&D) Expenses:** R&D expenses for the three and nine months ended September 30, 2021 were \$8.6 million and \$24.4 million, respectively, compared to \$7.8 million and \$18.0 million for the same periods in 2020, respectively. 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 three and nine months ended September 30, 2021 were \$2.8 million and \$8.5 million, respectively, compared to \$1.8 million and \$3.0 million for the same periods in 2020, respectively. 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 three and nine months ended September 30, 2021 were \$11.4 million and \$32.9 million, respectively, compared to \$9.6 million and \$21.1 million for the same periods in 2020, respectively. Stock-based compensation expense for the three and nine months ended September 30, 2021 was \$1.0 million and \$3.2 million, respectively. When excluding depreciation and stock-based compensation expenses, total operating expenses for the three and nine months ended September 30, 2021 were \$10.4 million and \$29.8 million, respectively.
- **Net Loss:** Net loss for the three and nine months ended September 30, 2021 was \$11.4 million and \$33.1 million, respectively, compared to \$9.6 million and \$21.2 million for the same periods in 2020, 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 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). 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. 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 results, conduct, progress and timing of Spruce’s clinical trials and announcements regarding the same. 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 “expect,” “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)

| | September 30, 2021 | December 31, 2020 |
|---|-----------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 58,363 | \$ 157,150 |
| Short-term investments | 33,957 | — |
| Prepaid expenses | 1,301 | 2,971 |
| Other current assets | 301 | 276 |
| Total current assets | 93,922 | 160,397 |
| Restricted cash | 216 | 216 |
| Right-of-use assets, net | 1,559 | 1,793 |
| Long-term investments | 38,975 | — |
| Other assets | 415 | 477 |
| Total assets | \$ 135,087 | \$ 162,883 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,128 | \$ 3,628 |
| Term loan, current portion | — | 2,554 |
| Accrued expenses and other current liabilities | 5,924 | 2,496 |
| Accrued compensation and benefits | 1,009 | 1,085 |
| Total current liabilities | 9,061 | 9,763 |
| Term loan, net of current portion | 4,867 | 1,922 |
| Lease liability, net of current portion | 1,388 | 1,653 |
| Other liabilities | 51 | 118 |
| Total liabilities | 15,367 | 13,456 |
| Stockholders' equity: | | |
| Preferred stock, \$0.0001 par value, 10,000,000 shares authorized, and no shares issued and outstanding as of September 30, 2021 and December 31, 2020 | — | — |
| Common stock, \$0.0001 par value, 200,000,000 shares authorized, 23,379,887 and 23,260,399 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively | 3 | 2 |
| Additional paid-in capital | 213,682 | 210,266 |
| Accumulated other comprehensive loss | (16) | — |
| Accumulated deficit | (93,949) | (60,841) |
| Total stockholders' equity | 119,720 | 149,427 |
| Total liabilities and stockholders' equity | \$ 135,087 | \$ 162,883 |

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, | |
|--|-------------------------------------|-------------------|------------------------------------|--------------------|
| | 2021 | 2020 | 2021 | 2020 |
| Operating expenses: | | | | |
| Research and development | \$ 8,607 | \$ 7,769 | \$ 24,440 | \$ 18,040 |
| General and administrative | 2,793 | 1,790 | 8,491 | 3,041 |
| Total operating expenses | <u>11,400</u> | <u>9,559</u> | <u>32,931</u> | <u>21,081</u> |
| Loss from operations | (11,400) | (9,559) | (32,931) | (21,081) |
| Interest expense | (88) | (79) | (257) | (245) |
| Other income, net | 41 | 51 | 80 | 125 |
| Net loss | <u>\$ (11,447)</u> | <u>\$ (9,587)</u> | <u>\$ (33,108)</u> | <u>\$ (21,201)</u> |
| Unrealized gain/(loss) on available for sale securities | 13 | - | (16) | - |
| Comprehensive loss | <u>\$ (11,434)</u> | <u>\$ (9,587)</u> | <u>\$ (33,124)</u> | <u>\$ (21,201)</u> |
| Net loss per share, basic and diluted | <u>\$ (0.49)</u> | <u>\$ (12.35)</u> | <u>\$ (1.42)</u> | <u>\$ (27.54)</u> |
| Weighted-average shares of common stock outstanding, basic and diluted | <u>23,367,140</u> | <u>776,159</u> | <u>23,330,399</u> | <u>769,766</u> |

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

| | <u>Three Months Ended September 30,</u> | | <u>Nine Months Ended September 30,</u> | |
|-----------------------------------|---|-----------------|--|------------------|
| | 2021 | 2020 | 2021 | 2020 |
| Operating expenses: | | | | |
| Total operating expenses | \$ 11,400 | \$ 9,559 | \$ 32,931 | \$ 21,081 |
| Adjustments: | | | | |
| Depreciation | 5 | 1 | 14 | 2 |
| Stock-based compensation | 1,031 | 218 | 3,161 | 346 |
| Non-GAAP total operating expenses | <u>\$ 10,364</u> | <u>\$ 9,340</u> | <u>\$ 29,756</u> | <u>\$ 20,733</u> |

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

| | <u>Three Months Ended September 30,</u> | | <u>Nine Months Ended September 30,</u> | |
|----------------------------|---|-----------------|--|-----------------|
| | 2021 | 2020 | 2021 | 2020 |
| Operating expenses: | | | | |
| G&A expenses | \$ 2,793 | \$ 1,790 | \$ 8,491 | \$ 3,041 |
| Adjustments: | | | | |
| Depreciation | 5 | 1 | 14 | 2 |
| Stock-based compensation | 777 | 129 | 2,297 | 208 |
| Non-GAAP G&A expenses | <u>\$ 2,011</u> | <u>\$ 1,660</u> | <u>\$ 6,180</u> | <u>\$ 2,831</u> |

Media Contact:

Will Zasadny
Canale Communications
(619) 961-8848
will@canalecomm.com
media@sprucebiosciences.com

Investors

Xuan Yang
Solebury Trout
(415) 971-9412
xyang@soleburytrout.com
investors@sprucebiosciences.com