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): January 6, 2021

Spruce Biosciences, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39594**	**81-2154263**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2001 Junipero Serra Boulevard, Suite 640 Daly City, California	**94014**
(Address of Principal Executive Offices)	**(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 January 6, 2021, Spruce Biosciences, Inc. (the "Company") issued a press release providing a corporate update and anticipated milestone for 2021. The Company also reported on a preliminary and unaudited basis its estimated cash and cash equivalents balance and number of outstanding shares as of December 31, 2020. These are preliminary estimates based on currently available information and do not present all necessary information for a complete understanding of the Company's financial condition as of December 31, 2020 or the Company's results of operations for the year ended December 31, 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.

Exhibit Number	Description
99.1	Press Release of Spruce Biosciences, Inc., dated January 6, 2021

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: January 6, 2021

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

Exhibit 99.1

Spruce Biosciences Provides Corporate Update and Outlines Milestones for 2021

- CAHmelia Adult Classic CAH Program Underway in U.S. and Europe-
-Initiation of Phase 2 Pediatric Classic CAH Program Anticipated in Second Half of 2021-
-Initiation of Phase 2 Polycystic Ovary Syndrome Program Anticipated in Second Half of 2021-
-New Patent Issuance Extends Tildacerfont Patent Exclusivity through 2038-

San Francisco, Calif. -- (BUSINESS WIRE) – January 6, 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 need, today provided a corporate update and shared anticipated milestones for 2021.

"Our vision is to deliver groundbreaking therapies to patients living with rare endocrine disorders with significant unmet medical need," said Richard King, Chief Executive Officer of Spruce Biosciences. "As we enter the new year, we are entirely focused on clinical study execution. Our potential registration-enabling CAHmelia program for tildacerfont in adult classic congenital adrenal hyperplasia (CAH) is underway. In parallel, we are preparing to advance tildacerfont into the clinic for the treatment of pediatric classic CAH and a rare form of polycystic ovary syndrome (PCOS)."

Mr. King continued, "Following our initial public offering in October 2020, we have sufficient resources to continue to advance our pipeline through major milestones. This includes the completion of our CAHmelia program and, dependent on trial results and subsequent interaction with regulatory agencies, potential submission of our first new drug application for tildacerfont for adults with classic CAH. At the same time, we expect 2021 to be a year of notable progress as we expand our portfolio of indications. Through this, we hope to deliver on the full potential of tildacerfont to bring therapeutic benefit to patients suffering from endocrine disorders driven by excess secretion of or hyperresponsiveness to adrenocorticotropic hormone (ACTH)."

Potential Registration-Enabling Phase 2 CAHmelia Program in Adult Classic CAH

Spruce Biosciences is focused on advancing tildacerfont in potential registration-enabling programs, dependent on clinical trial results, for the treatment of adult patients with CAH.

Based on analyses of the company's clinical data to date, the company has chosen to target two distinct groups of classic CAH patients with either good disease control or poor disease control. These two groups have differing disease challenges centered on the harmful effects of excessive glucocorticoid usage or excessive adrenal androgen levels respectively, both of which have the potential to be addressed by treatment with tildacerfont, if approved.

The company has initiated CAHmelia-203 in adult CAH patients with poor disease control and CAHmelia-204 in adult CAH patients with good disease control focused on glucocorticoid reduction. Study sites across the United States and Europe for both studies are active.

Phase 2 Program in Pediatric Classic CAH

Spruce Biosciences plans to investigate tildacerfont for the treatment of classic CAH in children. There is an urgent medical need to bring androgen-lowering and glucocorticoid-sparing therapies to pediatric classic CAH patients to reduce the risk of premature puberty and the adverse effects of glucocorticoids, including growth inhibition and short-stature as adults. Feedback received from both the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) has been incorporated into the company's Phase 2 development program.

The company plans to achieve the following milestones in 2021:

- Initiation of a Phase 2 clinical program in children in the second half of 2021; and
- Finalization of a Pediatric Investigational Plan to the Pediatric Committee of the EMA regarding a registrational program in pediatrics.

Phase 2 Program in a Rare Form of PCOS

PCOS is a hormonal disorder common among females of reproductive age typically characterized by elevated levels of androgens, irregular periods, and cysts in the ovaries. While the underlying causes of the disease are unknown, elevated levels of androgens may be due to a hyper-responsiveness to ACTH in a subset of women with PCOS. Tildacerfont has the potential to reduce ACTH and adrenal androgens, thereby reducing overall ACTH hyperresponsiveness. Tildacerfont may provide a therapeutic option for females with this rare form of PCOS, representing 3-5% of females with the disorder[1], which is estimated to be 150,000 to 200,000 patients in the United States.

The company plans to achieve the following milestones in 2021:

- Filing of an Investigational New Drug (IND) application in the first half of 2021; and
- Initiation of a Phase 2 proof-of-concept clinical trial in the second half of 2021.

Intellectual Property

Spruce Biosciences continues to expand its patent portfolio for tildacerfont to supplement its issued composition of matter patent that has an expiry date in 2027, and if tildacerfont is approved, will be eligible for patent term extension of up to 5 years. Upon regulatory approval, tildacerfont is also entitled to market exclusivity afforded by orphan drug designation of tildacerfont in the U.S. and Europe for CAH.

In December 2020, the United States Patent and Trademark Office (USPTO) issued US Patent Number 10,849,908 titled “Corticotrophin releasing factor antagonists.” This newly issued patent covers broad claims regarding the use of a CRF1 receptor antagonist for the treatment of CAH and further extends exclusivity through 2038.

Financial Update

As of December 31, 2020, Spruce Biosciences had unaudited cash and cash equivalents of approximately $157 million. Spruce Biosciences had 23,260,399 shares of common stock outstanding as of December 31, 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 to offer markedly improved disease control and reduce steroid burden for patients suffering from classic 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. 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”, “potential”, “anticipates” 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.

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[1] Rosenfield RL, et al. (2016) Endocrine Reviews; 37(5):467–520.