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 5, 2023

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.)**

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

2001 Junipero Serra Boulevard, Suite 640
Daly City, California 94014
(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 1.01 Entry into a Material Definitive Agreement.

On January 5, 2023, Spruce Biosciences, Inc. (the "Company") entered into a Collaboration and License Agreement (the "Agreement") with Kaken Pharmaceutical Co., LTD. ("Kaken"). Under the terms of the Agreement, the Company granted to Kaken the exclusive right to develop, manufacture and commercialize the Company's product candidate, tildacerfont, for the treatment of congenital adrenal hyperplasia ("CAH") in Japan. Pursuant to the Agreement, Kaken will be responsible for securing and maintaining regulatory approvals necessary to commercialize tildacerfont in Japan. The Company will retain all rights to tildacerfont in all other geographies.

The Company has also granted to Kaken a right of first negotiation with respect to the development, manufacturing and commercialization of tildacerfont for CAH in China (including Hong Kong, Taiwan, and Macau), South Korea and other specified southeastern Asian countries, and for indications other than CAH.

Pursuant to the Agreement, Kaken will make an upfront payment to the Company of $15.0 million. In addition to the upfront payment, the Company is entitled to receive up to an aggregate of approximately $65 million (at current exchange rates) upon the achievement of specified milestones related to the development, regulatory approval and commercialization of tildacerfont in Japan, including the achievement of specified net sales thresholds, if approved. Kaken has agreed to pay the Company a non-creditable, non-refundable specified purchase price for each unit of Company-manufactured product supplied to Kaken for commercial sale. In addition, the Company will also be entitled to receive a royalty for each unit of non-Company manufactured product sold equal to a range of double-digit percentages up to the mid-twenties based on annual net sales of tildacerfont in Japan. Both the purchase price for each unit and the royalty rate are subject to reduction in certain circumstances as specified in the Agreement. Kaken's obligation to pay royalties will continue for ten years after the first commercial sale in Japan or, if later, until the expiration of regulatory exclusivity of tildacerfont or the expiration of the last valid claim of a Company-licensed patent covering tildacerfont in Japan (the "Royalty Term").

The Company has agreed to supply Kaken's clinical drug supply requirements of tildacerfont pursuant to a clinical supply agreement that the parties will enter into within ninety days of the effective date of the Agreement. During the Royalty Term, the Company has agreed to supply Kaken's requirements of tildacerfont pursuant to the Agreement and a commercial supply agreement to be entered into by the parties, though Kaken may procure alternate suppliers. Following the Royalty Term, Kaken at its option may continue to purchase Company-manufactured tildacerfont at a purchase price equal to the Company's manufacturing cost plus a low double-digit administrative fee.

Either party may terminate the Agreement (i) in the event the other party shall have materially breached its obligations thereunder and such default shall have continued for a specified period after written notice thereof or (ii) upon the bankruptcy or insolvency of the other party. In addition, the Company may terminate the Agreement upon prior written notice if Kaken ceases all development or commercialization activities for a specified period of time, subject to certain exceptions, or (ii) challenges the validity, enforceability or scope of any of the patents licensed by the Company to Kaken under the Agreement, subject to certain conditions. Kaken may terminate the Agreement at any time for convenience upon prior written notice provided within a specified period of time to the Company.

Item 2.02 Results of Operations and Financial Condition.

On January 9, 2023, the Company issued a press release providing a corporate update that included updates on its clinical programs and an estimate that its cash, cash equivalents and investments as of December 31, 2022 were approximately $79 million. This amount is unaudited and preliminary and is subject to completion of financial closing procedures. Additional information and disclosure would be required for a more complete understanding of the Company's financial position and results of operations as of December 31, 2022.

All of the information furnished in this Item 2.02 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 8.01 Other Events.

As noted in Item 2.02, on January 9, 2023, the Company issued a press release providing a corporate update that included updates on its clinical programs. The Company is investigating the use of its product candidate tildacerfont for the treatment of CAH in children. The Company's Phase 2 open-label clinical trial utilizes a sequential three cohort design (cohorts 1 and 2 comprising of adolescent patients 11 to 17 years of age, and cohort 3 comprising of children two to 10 years of age) to evaluate the safety, pharmacokinetics ("PK"), and exploratory pharmacodynamics ("PD") of tildacerfont in children two to 17 years of age with classic CAH. The Company announced it has implemented the following key protocol changes to enhance the study design and gather additional data to inform future clinical development:

- Increasing the Study Length, Lowering Age Eligibility, and Adding an Open-Label Extension to Make the Trial More Accessible to Patients and Families
    - The Company amended the study length from a two-week PK and exploratory PD study to a 12-week study. The Company plans to also offer a two-year open-label extension to the 12-week study. These changes are designed to enable patients to retain access to the study drug for up to two years following completion of the study, and provide for observation of clinical outcomes, such as bone age and predicted adult height.
    - The Company is lowering the minimum age requirement from six years to two years of age. Given the significant growth and development that occurs in children between the ages of two years and five years of age, this change is designed to provide important data on the impact of reductions in androgen levels and glucocorticoids ("GC") in younger children.
- Increasing the Amount of Data That Can Be Extrapolated from Program
    - The following additional data will be collected to inform a potential Phase 3 registrational clinical trial, while allowing for observation of key clinical outcomes:
        - two weeks of pediatric tildacerfont PK exposure data at two weight adjusted doses (50mg and 200mg) to inform a dose for the Phase 3 registrational program;
        - four weeks of PD data to potentially show reduction in androstenedione (A4) and establish dose-response (day 1-28);
        - A4 reduction data and GC reduction based on a protocol-specified algorithm (day 28-90); and
        - sub-chronic safety data at 12 weeks.

Forward Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, the Company's expectations regarding a Phase 3 registrational clinical trial of tildacerfont in patients with CAH. These forward-looking statements involve risks and uncertainties, as well as assumptions, which, if they prove incorrect or do not fully materialize, could cause the Company's results to differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, risks and uncertainties related to: topline data may not reflect the complete or final results of a particular study or trial, and are subject to change; the Company's ability to advance, obtain regulatory approval of and ultimately commercialize its product candidates; the timing and results of preclinical and clinical trials; the risk that positive results in a clinical trial may not be replicated in subsequent trials or successes in early stage clinical trials may not be predictive of results in later stage trials and preliminary interim data readouts of ongoing trials may show results that change when such trials are completed; the Company's ability to fund development activities and achieve development goals; the Company's ability to protect its intellectual property; the direct and indirect impacts of geopolitical and macroeconomic events on the Company's business; and other risks and uncertainties described under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, its subsequently filed Quarterly Reports on Form 10-Q, and the other documents the Company files from time to time with the U.S. Securities and Exchange Commission ("SEC"). These forward-looking statements speak only as of the date of this Current Report on Form 8-K , and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
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: January 9, 2023

By: /s/ Samir Gharib
Samir Gharib
President and Chief Financial Officer