

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM S-3**

**REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**Spruce Biosciences, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**81-2154263**

(I.R.S. Employer Identification Number)

**Spruce Biosciences, Inc.  
611 Gateway Boulevard, Suite 740  
South San Francisco, California 94080  
(415) 655-4168**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Javier Szwarcberg, M.D., MPH  
Chief Executive Officer  
Spruce Biosciences, Inc.  
611 Gateway Boulevard, Suite 740  
South San Francisco, California 94080  
(415) 655-4168**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

**Copies to:**

**Alexa M. Smith  
Cooley LLP  
10265 Science Center Drive  
San Diego, California 92121  
(858) 550-6000**

**Samir Gharib  
President and Chief Financial Officer  
611 Gateway Boulevard, Suite 740  
South San Francisco, California 94080  
(415) 655-4168**

**From time to time after the effective date of this Registration Statement**  
(Approximate date of commencement of proposed sale to the public)

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer   
Non-accelerated filer

Accelerated filer   
Smaller reporting company   
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 7(a)(2)(B) of the Securities Act.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities or accept an offer to buy these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and it is not soliciting offers to buy these securities in any state where such offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED MARCH 16, 2023**

**PROSPECTUS**



**29,603,000 Shares of Common Stock**

This prospectus relates to the resale from time to time of up to 29,603,000 shares of our common stock by the selling stockholders identified in this prospectus, which consists of (i) 16,116,000 shares of our common stock held by the selling stockholders, (ii) 800,000 shares of our common stock issuable upon the exercise of an outstanding pre-funded warrant to purchase shares of our common stock held by a certain selling stockholder, and (iii) 12,687,000 shares of our common stock issuable upon the exercise of outstanding warrants to purchase shares of our common stock held by the selling stockholders, all of which were issued by us in a private placement on February 16, 2023. We are not selling any shares of common stock under this prospectus and we will not receive any proceeds from the sale by the selling stockholders of the shares offered by this prospectus. We will, however, receive the exercise price of \$0.01 per share of the pre-funded warrant exercised for cash and the exercise price of \$3.96 per share of any of the warrants exercised for cash.

Sales of the shares by the selling stockholders may occur at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices. The selling stockholders may sell shares to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling stockholders, the purchasers of the shares, or both.

We are paying the cost of registering the shares of common stock covered by this prospectus as well as various related expenses. The selling stockholders are responsible for all selling commissions, transfer taxes and other costs related to the offer and sale of their shares.

Our common stock is traded on the Nasdaq Global Select Market under the symbol "SPRB." On March 15, 2023, the last reported sales price of our common stock was \$2.26 per share.

**We are an "emerging growth company" as defined by the Jumpstart Our Business Startups Act of 2012, and as such, have elected to comply with reduced public company reporting requirements for this prospectus and the documents incorporated by reference herein and may elect to comply with reduced public company reporting requirements in future filings.**

*Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" on page 5 of this prospectus as well as those contained in the applicable prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus.*

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

The date of this prospectus is \_\_\_\_\_, 2023.

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## ABOUT THIS PROSPECTUS

This prospectus is a part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or SEC. Under this registration statement, the selling stockholders may sell from time to time in one or more offerings the common stock described in this prospectus.

Neither we nor the selling stockholders have authorized anyone to provide you with information other than the information provided or incorporated by reference in this prospectus and your reliance on any unauthorized information or representation is at your own risk. This prospectus may be used only in jurisdictions where offers and sales of these securities are permitted. You should assume that the information appearing in this prospectus is accurate only as of the date of this prospectus and that any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, or any sale of our common stock. Our business, financial condition and results of operations may have changed since those dates.

A prospectus supplement may add to, update or change the information contained in this prospectus. You should read both this prospectus and any applicable prospectus supplement together with additional information described below under the heading “Where You Can Find More Information.”

In this prospectus, references to “Spruce Biosciences,” “Spruce,” the “Company,” the registrant,” “we,” “us,” and “our” refer to Spruce Biosciences, Inc. The phrase “this prospectus” refers to this prospectus and any applicable prospectus supplement, unless the context requires otherwise.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, any applicable prospectus supplement and the information incorporated by reference in this prospectus and any applicable prospectus supplement contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Private Securities Litigation Reform Act of 1995, as amended, that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, any applicable prospectus supplement and the information incorporated by reference in this prospectus and any applicable prospectus supplement, including statements regarding our future results of operations and financial position, business strategy, research and development costs, the anticipated timing, costs and conduct of our planned clinical trials for tildacerfont, the timing and likelihood of regulatory filings and approvals for tildacerfont, our ability to commercialize tildacerfont, if approved, the pricing and reimbursement of tildacerfont, if approved, the potential benefits of strategic collaborations and our ability to enter into strategic arrangements, timing and likelihood of success, plans and objectives of management for future operations, and future results of anticipated products are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus, any applicable prospectus supplement and the information incorporated by reference in this prospectus and any applicable prospectus supplement are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus or the information incorporated by reference in this prospectus, as applicable, and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus and the documents incorporated by reference herein entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus, any applicable prospectus supplement and the information incorporated by reference in this prospectus and any applicable prospectus supplement. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we undertake no obligation to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks we describe in the reports we will file from time to time with the SEC after the date of this prospectus. See the section titled “Where You Can Find More Information.”

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this prospectus, and while we believe such information provides a reasonable basis for these statements, such information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely on these statements.

## PROSPECTUS SUMMARY

*This summary highlights important features of this offering and the information included or incorporated by reference in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should carefully read this prospectus, any applicable prospectus supplement and the information incorporated by reference in this prospectus and any applicable prospectus supplement before you invest in our common stock.*

### Company Overview

We are a late-stage biopharmaceutical company focused on developing and commercializing novel therapies for rare endocrine disorders with significant unmet medical need. We are initially developing our 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, or CAH. Classic CAH is a serious and life-threatening disease with no known novel therapies approved in approximately 70 years. In a 12-week Phase 2a proof-of-concept clinical trial, tildacerfont-treated adult patients suffering from classic CAH who had elevated adrenal hormones at baseline despite being on standard of care therapy achieved approximately 80% reductions in hormones that are key indicators of poorly controlled disease. Furthermore, over 200 subjects across eight completed clinical trials to date have been administered tildacerfont with no drug-related serious adverse events reported.

We have initiated CAHmelia-203, a placebo-controlled, double-blind Phase 2b clinical trial in adult patients with classic CAH with highly elevated levels of androstenedione (A4) at baseline and anticipate topline results in the second half of 2023. We have also initiated CAHmelia-204, a second Phase 2b clinical trial in adult patients with classic CAH on supraphysiologic doses of glucocorticoids with normal or near normal levels of A4 at baseline focused on glucocorticoid reduction and anticipate topline results in the second half of 2024. Based on post-hoc analyses of our clinical data to date, we have chosen to target two distinct groups of classic CAH patients with either supraphysiologic daily glucocorticoids with normal or near normal levels of A4 at baseline or highly elevated levels of A4 at baseline. A4 is an androgen steroid routinely used as a biomarker of androgen synthesis by the adrenal gland. These two groups, which together make up the entire classic CAH patient population, have differing disease challenges centered on excessive adrenal hormone levels or excessive glucocorticoid usage, both of which have the potential to be addressed by treatment with tildacerfont, if approved. We believe our strategy to study CAH patients in these two enriched sub-populations may enable us to observe clinically meaningful outcomes. Additionally, we believe these two clinical trials will provide sufficient patient exposures for our registrational safety database, which are designed to potentially support registration in the United States and Europe. Assuming positive results from these clinical trials, we plan to meet with the U.S. Food and Drug Administration and certain comparable foreign regulatory authorities to discuss potential registration.

In addition, we are investigating tildacerfont for the treatment of classic CAH in children. We believe there is a significant medical need to provide 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. We have initiated CAHptain, a Phase 2 open-label clinical trial, which will utilize a sequential three cohort design, to evaluate the safety, efficacy, and pharmacokinetics of tildacerfont in children two to 17 years of age with classic CAH. We anticipate topline data from adolescents (cohorts 1 and 2) of the Phase 2 open-label clinical trial in the second half of 2023. We have also submitted a pediatric investigational plan, or PIP, to the Pediatric Committee, or PDCO, of the European Medicines Agency regarding a registrational program in children with classic CAH. PDCO issued an opinion on its agreement with the proposed PIP of tildacerfont for the treatment of CAH which endorsed the clinical program to evaluate the safety, tolerability and efficacy of tildacerfont for the treatment of CAH in patients from one year of age to less than 18 years of age. PDCO also granted a waiver for the treatment of CAH in patients less than one year of age.

Polycystic ovary syndrome, or PCOS, is a hormonal disorder common among females of reproductive age affecting nearly five million females in the United States and approximately 115 million females worldwide. PCOS is characterized by elevated levels of androgens, cysts in the ovaries, and irregular periods. We have identified a subpopulation of patients where elevated levels of adrenal androgens are the cause of disease. We believe that tildacerfont may present a novel mechanism to reduce adrenocorticotrophic hormone, or ACTH, and provide a therapeutic option for females with PCOS and elevated adrenal androgens. By leveraging our existing Phase 1

program, which includes safety, tolerability, and pharmacokinetics of tildacerfont, we have initiated P.O.W.E.R., a Phase 2 proof-of-concept clinical trial. The Phase 2 proof-of-concept clinical trial is a randomized, placebo-controlled, dose escalation trial which will evaluate the safety and efficacy of tildacerfont titrated to 200mg once daily compared to placebo at 12 weeks of treatment in subjects with PCOS and elevated adrenal androgens as measured by dehydroepiandrosterone sulfate levels at baseline. We anticipate topline results from the Phase 2 proof-of-concept clinical trial in the first half of 2023.

Beyond classic CAH and PCOS, we believe tildacerfont has potential utility in a range of diseases where the underlying biology supports a need to reduce excess secretion of or hyperresponsiveness to ACTH. We are committed to leveraging our deep scientific knowledge of the biology of rare endocrine disorders, the benefits of tildacerfont, and our commercial expertise to dramatically transform the lives of individuals living with these devastating disorders.

### **Private Placement**

On February 8, 2023, we entered into a Securities Purchase Agreement, or the Purchase Agreement, with the selling stockholders named in this prospectus, pursuant to which we issued and sold the following securities to the selling stockholders on February 16, 2023: (i) 16,116,000 shares of our common stock, (ii) with respect to a certain selling stockholder, in lieu of shares of common stock, a pre-funded warrant to purchase an aggregate of 800,000 shares of common stock, and (iii) warrants to purchase an aggregate of 12,687,000 shares of common stock, at a purchase price of \$3.17 per share of common stock and accompanying warrant and \$3.16 per pre-funded warrant, in a private placement, or the Private Placement. The total purchase price paid by the selling stockholders at the closing, before deducting commissions to the placement agent and estimated offering expenses, was approximately \$53.6 million, which does not include any exercise price that may be paid upon exercise of the warrants.

The pre-funded warrant has an exercise price equal to \$0.01 per share. The pre-funded warrant is exercisable at any time after its original issuance and will expire on the date that is 60 months from its original issue date on February 16, 2023. Each warrant has an exercise price equal to \$3.96 per share. The warrants are exercisable at any time after their original issuance on February 16, 2023 and will expire on the date that is 60 months from such date. The pre-funded warrant and the warrants provide that a holder of the pre-funded warrant or warrants, as applicable, will not have the right to exercise any portion of its pre-funded warrant or warrants if such holder, together with its affiliates, would beneficially own in excess of a specified initial percentage (4.99% or at such holder's election, 9.99%) of the number of shares of common stock outstanding immediately after giving effect to such exercise, or the Beneficial Ownership Limitation; *provided, however*, that each holder may increase or decrease the Beneficial Ownership Limitation by giving 60 days' notice to us, but not to any percentage in excess of 19.99%.

The shares of common stock issued to the selling stockholders, and the shares of common stock issuable upon exercise of the pre-funded warrant or the warrants, as applicable, were not initially registered under the Securities Act or any state securities laws. We relied on the exemption from the registration requirements afforded by Regulation D under the Securities Act for the Private Placement. In connection with their execution of the Purchase Agreement, each of the selling stockholders represented to us that such selling stockholder is an "accredited investor" as defined in Regulation D of the Securities Act and that the securities purchased by such selling stockholder were being acquired solely for its own account and for investment purposes and not with a present view to its future public sale or distribution.

Under the terms of the Purchase Agreement, we agreed to prepare and file, within 30 days after the closing, a registration statement with the SEC to register for resale the shares of our common stock issued under the Purchase Agreement, the shares of our common stock issuable upon exercise of the pre-funded warrant issued under the Purchase Agreement, and the shares of our common stock issuable upon exercise of the warrants issued under the Purchase Agreement, and to cause the registration statement to become effective within a specified time after the filing of the registration statement.

### **Corporate Information**

We were incorporated in Delaware in April 2016. Our principal executive offices are located at 611 Gateway Boulevard, Suite 740, South San Francisco, California 94080, and our telephone number is (415) 655-4168. Our



corporate website address is [www.sprucebiosciences.com](http://www.sprucebiosciences.com). Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus.

## The Offering

Common stock offered by the selling stockholders	29,603,000 shares, which includes (i) 16,116,000 shares of our common stock held by the selling stockholders, (ii) 800,000 shares of our common stock issuable upon the exercise of an outstanding pre-funded warrant to purchase shares of our common stock held by a certain selling stockholder, and (iii) 12,687,000 shares of our common stock issuable upon the exercise of outstanding warrants to purchase shares of our common stock held by the selling stockholders.
Terms of the offering	Each selling stockholder will determine when and how it will sell the common stock offered in this prospectus, as described in "Plan of Distribution."
Use of proceeds	We will not receive any proceeds from the sale of the shares of common stock covered by this prospectus. We will, however, receive the exercise price of \$0.01 per share of the pre-funded warrant exercised for cash and the exercise price of \$3.96 per share of any of the warrants exercised for cash.
Risk factors	See "Risk Factors" beginning on page 5, for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Nasdaq Global Select Market symbol	SPRB

The selling stockholders named in this prospectus may offer and sell up to 29,603,000 shares of our common stock. Our common stock is currently listed on the Nasdaq Global Select Market under the symbol "SPRB." Shares of our common stock that may be offered under this prospectus will be fully paid and non-assessable. We will not receive any of the proceeds of sales by the selling stockholders of any of the common stock covered by this prospectus. We will, however, receive the exercise price of \$0.01 per share of the pre-funded warrant exercised for cash and the exercise price of \$3.96 per share of any of the warrants exercised for cash. Throughout this prospectus, when we refer to the shares of our common stock being registered on behalf of the selling stockholders for offer and resale, we are referring to the shares of common stock that have been issued to the selling stockholders and the shares of common stock issuable upon exercise of the pre-funded warrant and warrants issued in the Private Placement as described above. When we refer to the selling stockholders in this prospectus, we are referring to the selling stockholders identified in this prospectus and, as applicable, their permitted transferees or other successors-in-interest that may be identified in a supplement to this prospectus or, if required, a post-effective amendment to the registration statement of which this prospectus is a part.

## RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully review the risks and uncertainties described under the heading “Risk Factors” in our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, as filed with the SEC, which are incorporated by reference into this prospectus, as well as in any applicable prospectus supplement, before deciding whether to purchase the common stock being registered pursuant to the registration statement of which this prospectus is a part. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock, and the occurrence of any of these risks might cause you to lose all or part of your investment. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Please also read carefully the section above titled “Special Note Regarding Forward-Looking Statements.”

## USE OF PROCEEDS

We will not receive any of the proceeds from the sale or other disposition of shares of our common stock held by the selling stockholders pursuant to this prospectus. Upon any exercise of the pre-funded warrant or warrants for cash, the applicable selling stockholder would pay us the exercise price set forth in the pre-funded warrant or warrants, as applicable. The cash exercise price of the pre-funded warrant is \$0.01 per share and the cash exercise price of the warrants is \$3.96 per share. We expect to use any such proceeds primarily for our working capital and other corporate and operational purposes. The pre-funded warrant and warrants are only exercisable on a net exercise cashless basis if, at any time following August 16, 2023, there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of, the shares issuable upon exercise of the pre-funded warrant or warrants, as applicable. If the pre-funded warrant or any of the warrants are exercised on a cashless basis, we would not receive any cash payment from the applicable selling stockholder upon any such exercise of the warrants.

We will bear the out-of-pocket costs, expenses and fees incurred in connection with the registration of shares of our common stock to be sold by the selling stockholders pursuant to this prospectus. We are also obligated to pay the reasonable fees and expenses of a single counsel to the selling stockholders in connection with the registration of shares pursuant to this prospectus in an amount not to exceed \$30,000. Other than registration expenses, the selling stockholders will bear underwriting discounts, commissions, placement agent fees or other similar expenses payable with respect to sales of shares of our common stock.

## SELLING STOCKHOLDERS

The selling stockholders may sell some, all or none of their shares. We do not know how long the selling stockholders will hold the shares before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale or other disposition of any of the shares. The shares covered hereby may be offered from time to time by the selling stockholders. As a result, we cannot estimate the number of shares of common stock each of the selling stockholders will beneficially own after termination of sales under this prospectus. In addition, each of the selling stockholders may have sold, transferred or otherwise disposed of all or a portion of its shares of common stock since the date on which it provided information for this table.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to our common stock. Generally, a person “beneficially owns” shares of our common stock if the person has or shares with others the right to vote those shares or to dispose of them, or if the person has the right to acquire voting or disposition rights within 60 days.

The information in the table below and the footnotes thereto regarding shares of common stock to be beneficially owned after the offering assumes the sale of all shares being offered by the selling stockholders under this prospectus. The information in the table below and the footnotes thereto regarding the number of shares being offered by the selling stockholders under this prospectus assumes each selling stockholder has exercised the pre-funded warrant and warrants in full pursuant to cash exercises, subject to the beneficial ownership limitations in the pre-funded warrant and warrants, respectively. The percentage of shares owned prior to and after the offering is based on 39,746,116 shares of common stock outstanding as of March 14, 2023. This information has been obtained from the selling stockholders or in Schedules 13G or 13D and other public documents filed with the SEC. Unless otherwise indicated, the address for the persons and entities listed in the table below is c/o Spruce Biosciences, Inc., 611 Gateway Boulevard, Suite 740, South San Francisco, California 94080.

Name and Address	Before Offering		Number of Shares Offered(1)	After Offering	
	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned		Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Novo Holdings A/S Tuborg Havnevej 19 DK 2900 Hellerup Denmark	6,722,336 (2)	16.91%	3,864,000 (2)	4,514,336 (2)	19.10%
Armistice Capital Master Fund Ltd. c/o Armistice Capital, LLC 510 Madison Avenue, 7th Floor New York, NY 10022	3,928,000 (3)	9.88%	8,274,000 (3)	—	—%
5AM Opportunities II, L.P. c/o 5AM Ventures 501 2nd Street, Suite 350 San Francisco, CA 94107	2,364,000 (4)	5.95%	4,137,000 (4)	—	—%
Abingworth Bioventures VII LP c/o Abingworth LLP 38 Jermyn Street London SW1Y 6DN, U.K.	2,906,518 (5)	7.31%	1,932,000 (5)	1,802,518 (5)	7.63%
HealthCap VIII, L.P. c/o HealthCap VIII GP SA Avenue Villamont 23 - CH 1005 Lausanne, Switzerland	2,977,621 (6)	7.49%	1,652,000 (6)	2,033,621 (6)	8.61%

Name and Address	Before Offering		Number of Shares Offered(1)	After Offering	
	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned		Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Entities affiliated with RiverVest Venture Fund III, L.P. 101 S. Hanley Road, Ste 1850 St. Louis, MO 63105	2,936,281 (7)	7.39%	1,379,000 (7)	2,148,281 (7)	9.09%
Entities affiliated with Rock Springs Management LP 650 South Exeter Street, Suite 1070 Baltimore, MD 21202	2,726,689 (8)	6.86%	1,932,000 (8)	1,622,689 (8)	6.87%
Entities affiliated with AIGH Capital Management, LLC 6006 Berkeley Avenue Baltimore, MD 21209	1,932,000 (9)	4.76%	1,932,000 (9)	—	—%
Alyeska Master Fund, L.P. c/o Maples Corporate Services Limited P.O. Box 309 Ugland House, South Church Street George Town, Grand Cayman, KY1-1104 Cayman Islands, British West Indies	1,750,000 (10)	4.32%	1,750,000 (10)	—	—%
Entities affiliated with Empery Asset Management, LP One Rockefeller Plaza, Suite 1205 New York, NY 10020	1,379,000 (11)	3.42%	1,379,000 (11)	—	—%
CVI Investments, Inc. c/o Heights Capital Management 101 California Street, Suite 3250 San Francisco, CA 94111	826,000 (12)	2.06%	826,000 (12)	—	—%
Entities affiliated With DAFNA Capital Management LLC 10990 Wilshire Blvd Suite 1400 Los Angeles, CA 90024	546,000 (13)	1.37%	546,000 (13)	—	—%

(1) For purposes of this table, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the selling stockholders, including shares of common stock issuable upon exercise of the pre-funded warrant and the warrants, as applicable, issued in the Private Placement.

- (2) Consists of (i) 4,514,336 shares of common stock held prior to the Private Placement by Novo Holdings A/S, or Novo, and (ii) 2,208,000 shares of common stock purchased in the Private Placement by Novo. Novo has the sole power to vote and dispose of the shares, and no individual or other entity is deemed to hold any beneficial ownership in the shares. The number of shares beneficially owned by Novo is limited by beneficial ownership limitations applicable to the exercise of warrants purchased in the Private Placement by Novo, which limit the number of shares such entity can beneficially own after the exercise of warrants to a maximum of 19.99% of our outstanding common stock, unless requisite approval by our stockholders pursuant to the rules and regulations of the Nasdaq Stock Market (or any successor entity) is obtained, as set forth in the warrants. As a result of such limitations, the number of shares beneficially owned does not include up to an aggregate of 1,656,000 shares of common stock issuable upon exercise of warrants purchased in the Private Placement by Novo. The address of Novo is Tuborg Havnevej 19, DK 2900 Hellerup, Denmark.
- (3) Consists of 3,928,000 shares of common stock purchased in the Private Placement by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company, or the Master Fund, and may be deemed to be indirectly beneficially owned by (i) Armistice Capital, LLC, or Armistice, as the investment manager of the Master Fund, and (ii) Steven Boyd, as the Managing Member of Armistice. Armistice and Steven Boyd disclaim beneficial ownership of the reported securities except to the extent of their respective pecuniary interest therein. The number of shares beneficially owned by Armistice and Mr. Boyd is limited by beneficial ownership limitations applicable to the exercise of the pre-funded warrant and warrants purchased in the Private Placement by the Master Fund, which limit the number of shares such entity can beneficially own (i) after the exercise of the pre-funded warrant, to a maximum of 9.99% of our outstanding common stock and (ii) after the exercise of warrants, to a maximum of 4.99% of our outstanding common stock, unless the holder changes such limitations upon written notice to us. As a result of such limitations, the number of shares beneficially owned does not include up to an aggregate of (x) 800,000 shares of common stock issuable upon exercise of the pre-funded warrant purchased in the Private Placement by the Master Fund and (y) 3,546,000 shares of common stock issuable upon exercise of warrants purchased in the Private Placement by the Master Fund. The address of the Master Fund is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.
- (4) Consists of 2,364,000 shares of common stock purchased in the Private Placement by 5AM Opportunities II, L.P., or 5AM Opportunities. 5AM Opportunities II (GP), LLC is the general partner of 5AM Opportunities and may be deemed to have sole investment and voting power over the shares held by 5AM Opportunities. Andrew Schwab and Kush Parmar are the managing members of 5AM Opportunities II (GP), LLC, and may be deemed to share voting and dispositive power over the shares held by 5AM Opportunities. The number of shares beneficially owned by such individuals and entities is limited by beneficial ownership limitations applicable to the exercise of warrants purchased in the Private Placement by 5AM Opportunities, which limit the number of shares such entity can beneficially own after the exercise of warrants to a maximum of 4.99% of our outstanding common stock, unless the holder changes such limitations upon written notice to us. As a result of such limitations, the number of shares beneficially owned does not include up to an aggregate of 1,773,000 shares of common stock issuable upon exercise of warrants purchased in the Private Placement by 5AM Opportunities. The address of 5AM Opportunities is c/o 5AM Ventures, 501 2<sup>nd</sup> Street, Suite 350, San Francisco, CA 94107.

- (5) Consists of (i) 1,792,518 shares of common stock held prior to the Private Placement by Abingworth Bioventures VII LP, or Abingworth VII, (ii) 10,000 shares of common stock issuable upon the exercise of vested stock options held prior to the Private Placement by Bali Muralidhar, a managing partner of Abingworth LLP and (iii) 1,104,000 shares of common stock purchased in the Private Placement by Abingworth VII. The Carlyle Group Inc., which is a publicly traded entity listed on Nasdaq, is the sole shareholder of Carlyle Holdings I GP Inc., which is the sole member of Carlyle Holdings I GP Sub L.L.C., which is the general partner of Carlyle Holdings I L.P., which, with respect to the securities reported herein, is the managing member of CG Subsidiary Holdings L.L.C., which is the managing member of TC Group, L.L.C., which is the managing member of Carlyle Investment Management, L.L.C., which is the sole member of Carlyle Genesis UK LLC, which is the principal member of Abingworth LLP. Abingworth VII has delegated to Abingworth LLP all investment and dispositive power over the securities held of record by Abingworth VII. The shares subject to the options held by Dr. Muralidhar are deemed to be beneficially owned by Abingworth LLP. The number of shares beneficially owned by Abingworth LLP is limited by beneficial ownership limitations applicable to the exercise of warrants purchased in the Private Placement by Abingworth VII, which limit the number of shares such entity can beneficially own after the exercise of warrants to a maximum of 4.99% of our outstanding common stock, unless the holder changes such limitations upon written notice to us. As a result of such limitations, the number of shares beneficially owned does not include up to an aggregate of 828,000 shares of common stock issuable upon exercise of certain warrants purchased in the Private Placement by Abingworth VII. The address of Abingworth VII is c/o Abingworth LLP, 38 Jermyn Street, London SW1Y 6DN, U.K.
- (6) Consists of (i) 2,033,621 shares of common stock held prior to the Private Placement and (ii) 944,000 shares of common stock purchased in the Private Placement, in each case held by HealthCap VIII, L.P. HealthCap VIII GP SA, a Swiss registered L.C.C., or HCSA, is the sole general partner of the fund HealthCap VIII, L.P., or HCLP. HCSA has voting and dispositive power over the shares held by HCLP. HCSA disclaims beneficial ownership of such shares, except to the extent of their pecuniary interest therein. Fabrice Bernhard serves as General Manager of HCSA and each of Dag Richter and Daniel Schafer serves as Director of HCSA. Each of Messrs. Bernhard, Richter and Schafer may be deemed to share voting and investment power with respect to the shares held by HCLP except to the extent of their pecuniary interest therein. The number of shares beneficially owned by such entities is limited by beneficial ownership limitations applicable to the exercise of warrants purchased in the Private Placement by HCLP, which limit the number of shares HCLP can beneficially own after the exercise of warrants to a maximum of 4.99% of our outstanding common stock, unless the holder changes such limitations upon written notice to us. As a result of such limitations, the number of shares beneficially owned does not include up to an aggregate of 708,000 shares of common stock issuable upon exercise of certain warrants purchased in the Private Placement by HCLP. The address of HealthCap VIII, L.P. is c/o HealthCap VIII GP SA Avenue Villamont 23 – CH 1005, Lausanne, Switzerland.



- (7) Consists of (i) 73,199 shares of common stock held prior to the Private Placement by RiverVest Venture Fund III (Ohio), L.P., or RiverVest (Ohio), (ii) 695,905 shares of common stock held prior to the Private Placement by RiverVest Venture Fund IV, L.P., or RiverVest IV, (iii) 1,379,177 shares of common stock held prior to the Private Placement by RiverVest Venture Fund III, L.P., or RiverVest III, (iv) 7,943 shares of common stock purchased in the Private Placement by RiverVest (Ohio), (v) 630,400 shares of common stock purchased in the Private Placement by RiverVest IV and (vi) 149,657 shares of common stock purchased in the Private Placement by RiverVest III. The shares held directly by RiverVest III are indirectly held by RiverVest Venture Partners III, L.P., its general partner, or RiverVest Partners III. The shares held directly by RiverVest (Ohio) are indirectly held by RiverVest Venture Partners III (Ohio), LLC, its general partner, or RiverVest Partners (Ohio) III. RiverVest Partners III is the sole member of RiverVest Partners (Ohio) III. RiverVest Venture Partners III, LLC is the general partner of RiverVest Partners III. The individual managers of RiverVest Ventures Partners III, LLC are Thomas C. Melzer, Jay Schmelter and John P. McKearn, Ph.D. RiverVest Partners III, RiverVest Partners (Ohio) III, RiverVest Venture Partners III, LLC and each of the individual managers share voting and dispositive power with regard to the shares of common stock directly held by RiverVest III and RiverVest (Ohio). Niall O'Donnell, Ph.D., an affiliate of RiverVest III and RiverVest (Ohio), has no voting or investment control over any of the shares held by these entities. The shares held directly by RiverVest IV are indirectly held by RiverVest Venture Partners IV, L.P., its general partner, or RiverVest Partners IV. RiverVest Venture Partners IV, LLC is the general partner of RiverVest Partners IV. The individual managers of RiverVest Ventures Partners IV, LLC are Jay Schmelter, John P. McKearn, Ph.D. and Niall O'Donnell, Ph.D. RiverVest Partners IV, RiverVest Venture Partners IV, LLC and each of the individual managers share voting and dispositive power with regard to the shares directly held by RiverVest IV. The number of shares beneficially owned by such individuals and entities is limited by beneficial ownership limitations applicable to the exercise of warrants purchased in the Private Placement by each of RiverVest (Ohio), RiverVest IV and RiverVest III, which limit the number of shares such entities can each beneficially own after the exercise of warrants to a maximum of 4.99% of our outstanding common stock, unless the holder changes such limitations upon written notice to us. As a result of such limitations, the number of shares beneficially owned does not include up to an aggregate of 591,000 shares of common stock issuable upon exercise of certain warrants purchased in the Private Placement by RiverVest (Ohio), RiverVest IV and RiverVest III. The address of RiverVest (Ohio), RiverVest IV and RiverVest III is 101 S. Hanley Road, Ste 1850, St. Louis, MO 63105.
- (8) Consists of (i) 1,525,000 shares of common stock held prior to the Private Placement by Rock Springs Capital Master Fund LP, or Master Fund, (ii) 97,689 shares of common stock held prior to the Private Placement by Four Pines Master Fund LP, or Four Pines, (iii) 921,209 shares of common stock purchased in the Private Placement by Master Fund and (iv) 182,791 shares of common stock purchased in the Private Placement by Four Pines. Rock Springs Capital Management, LP, or RSCM, serves as the investment manager to each of the Master Fund and Four Pines. Rock Springs Capital LLC, or RSC, is the general partner of RSCM. Each of RSCM and RSC may be deemed to be the indirect beneficial owners of 2,726,689 shares of common stock, and may be deemed to have shared voting and dispositive power with respect to such shares. The number of shares beneficially owned by such entities is limited by beneficial ownership limitations applicable to the exercise of warrants purchased in the Private Placement by each of Master Fund and Four Pines, which limit the number of shares Master Fund and Four Pines can each beneficially own after the exercise of warrants to a maximum of 4.99% of our outstanding common stock, unless the holder changes such limitations upon written notice to us. As a result of such limitations, the number of shares beneficially owned does not include up to an aggregate of 828,000 shares of common stock issuable upon exercise of certain warrants purchased in the Private Placement by Master Fund and Four Pines. The address of RSCM and RSC is 650 South Exeter St., Suite 1070, Baltimore, MD 21202. The address of Master Fund is c/o Walkers Corporate Limited. Cayman Corporate Centre. 27 Hospital Road, George Town, Grand Cayman, KY1-9008, Cayman Islands.

- (9) Consists of (i) 833,376 shares of common stock purchased in the Private Placement and 625,032 shares of common stock issuable upon exercise of warrants purchased in the Private Placement, in each case held by AIGH Investment Partners, L.P., or AIGH LP, (ii) 212,196 shares of common stock purchased in the Private Placement and 159,147 shares of common stock issuable upon exercise of warrants purchased in the Private Placement, in each case held by WVP Emerging Manager Onshore Fund, LLC - AIGH Series, or WVP AIGH and (iii) 58,428 shares of common stock purchased in the Private Placement and 43,821 shares of common stock issuable upon exercise of warrants purchased in the Private Placement, in each case held by WVP Emerging Manager Onshore Fund, LLC - Optimized Equity Series, or WVP OE. Mr. Orin Hirschman is the managing member of AIGH Capital Management, LLC, or AIGH CM, a Maryland limited liability company, which is an advisor with respect to the securities held by AIGH LP, a sub-advisor with respect to the securities held by WVP AIGH and WVP OE. Mr. Hirschman has voting and investment control over the securities indirectly held by AIGH CM and directly held by AIGH IP, WVP AIGH and WVP OE. The address of AIGH IP, WVP AIGH and WVP OE is 6006 Berkeley Avenue, Baltimore, MD 21209.
- (10) Consists of (i) 1,000,000 shares of common stock purchased in the Private Placement and (ii) 750,000 shares of common stock issuable upon the exercise of warrants purchased in the Private Placement. Alyeska Investment Group, L.P., the investment manager of Alyeska Master Fund, L.P., or Alyeska Master, has voting and investment control of the shares held by Alyeska Master. Anand Parekh is the Chief Executive Officer of Alyeska Investment Group, L.P. and may be deemed to be the beneficial owner of such shares. Mr. Parekh, however, disclaims any beneficial ownership of the shares held by Alyeska Master. Alyeska Investment Group, L.P. is located at 77 W. Wacker, Suite 700, Chicago IL 60601.
- (11) Consists of (i) 468,908 shares of common stock purchased in the Private Placement and 351,681 shares of common stock issuable upon exercise of warrants purchased in the Private Placement, in each case held by Empery Asset Master, LTD, (ii) 148,696 shares of common stock purchased in the Private Placement and 111,522 shares of common stock issuable upon exercise of warrants purchased in the Private Placement, in each case held by Empery Tax Efficient, LP and (iii) 170,396 shares of common stock purchased in the Private Placement and 127,797 shares of common stock issuable upon exercise of warrants purchased in the Private Placement, in each case held by Empery Tax Efficient III, LP. Empery Asset Management LP, the authorized agent of Empery Asset Master, LTD, or EAM, has discretionary authority to vote and dispose of the shares held by EAM and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EAM. EAM, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares. Empery Asset Management LP, the authorized agent of Empery Tax Efficient, LP, or ETE, has discretionary authority to vote and dispose of the shares held by ETE and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE. ETE, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares. Empery Asset Management LP, the authorized agent of Empery Tax Efficient III, LP, or ETE III, has discretionary authority to vote and dispose of the shares held by ETE III and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE III. ETE III, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares. The address of EAM, ETE and ETE III is c/o Empery Asset Management, LP, One Rockefeller Plaza, Suite 1205, New York City, NY 10020.
- (12) Consists of (i) 472,000 shares of common stock purchased in the Private Placement and (ii) 354,000 shares of common stock issuable upon the exercise of warrants purchased in the Private Placement. Heights Capital Management, Inc., the authorized agent of CVI Investments, Inc., or CVI, has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc., may also be deemed to have investment discretion and voting power over the shares held by CVI. Mr. Kobinger disclaims any such beneficial ownership of the shares. The address of CVI is c/o Heights Capital Management, 101 California Street, Suite 3250, San Francisco, California, 94111.

- (13) Consists of (i) 234,000 shares of common stock purchased in the Private Placement and 175,500 shares of common stock issuable upon exercise of warrants purchased in the Private Placement, in each case held by DAFNA Lifescience, LP and (ii) 78,000 shares of common stock purchased in the Private Placement and 58,500 shares of common stock issuable upon exercise of the warrants purchased in the Private Placement, in each case held by DAFNA Lifescience Select, LP, or, collectively, the DAFNA Funds. DAFNA Capital Management LLC is the sole general partner of the DAFNA Funds. The Chief Executive Officer and Chief Investment Officer of DAFNA Capital Management LLC are Dr. Nathan Fischel and Dr. Fariba Ghodsian, respectively. These individuals may be deemed to have shared voting and investment power of the shares held by the DAFNA Funds. Each of Dr. Fischel and Dr. Fariba disclaim beneficial ownership of such shares, except to the extent of his or her pecuniary interest therein. The address of the DAFNA Funds is 10990 Wilshire Blvd Suite 1400, Los Angeles, CA 90024.

### **Relationship with Selling Stockholders**

As discussed in greater detail above under the section “Prospectus Summary—Private Placement,” on February 8, 2023, we entered into the Purchase Agreement with the selling stockholders pursuant to which we issued and sold shares of common stock, a pre-funded warrant to purchase shares of common stock and warrants to purchase shares of common stock to the selling stockholders and agreed with the selling stockholders to file a registration statement to enable the resale of the shares of common stock covered by this prospectus. Other than Dr. O’Donnell, who is a member of our board of directors and Managing Director at RiverVest Venture Partners, Dr. Muralidhar, who is a member of our board of directors and Managing Partner of Abingworth LLP, Tiba Aynечи, Ph.D., who is a member of our board of directors and was previously employed as a Senior Partner at Novo Ventures (US) Inc., which provides certain consultancy services to Novo, and Jonas Hansson, a former member of our board of directors who was formerly employed as a partner at HealthCap Advisor AB, an entity affiliated with HCLP, none of the selling stockholders or any persons having control over such selling stockholders has held any position or office with us or our affiliates within the last three years or has had a material relationship with us or any of our predecessors or affiliates within the past three years, other than as a result of the ownership of our shares or other securities.

## PLAN OF DISTRIBUTION

We are registering the shares of common stock issued to the selling stockholders in the Private Placement and the shares of common stock issuable to the selling stockholders upon the exercise of a certain selling stockholder's pre-funded warrant purchased in the Private Placement and upon the exercise of the selling stockholders' warrants purchased in the Private Placement to permit the resale of such shares of common stock by such holders from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register such shares of common stock.

Each selling stockholder, which may include donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of its shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at privately negotiated prices.

A selling stockholder may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its own account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- through agreements between broker-dealers and the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted by applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the pledgees, transferees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into options or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to each such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with its agents from time to time, to reject, in whole or in part, any proposed

purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering.

The selling stockholders also may resell all or a portion of the shares in open market transactions, rather than under this prospectus, in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the common stock or interests therein may be “underwriters” within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act. Selling stockholders who are “underwriters” within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

If underwriters are used in the sale, the shares of common stock will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. In connection with any such underwritten sale of shares of common stock, underwriters may receive compensation from the selling stockholders, for whom they may act as agents, in the form of discounts, concessions or commissions. If the selling stockholders use an underwriter or underwriters to effectuate the sale of shares of common stock, we and/or they will execute an underwriting agreement with those underwriters at the time of sale of those shares of common stock. To the extent required by law, the names of the underwriters will be set forth in a prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes the prospectus supplement and the accompanying prospectus used by the underwriters to sell those securities. The obligations of the underwriters to purchase those shares of common stock will be subject to certain conditions precedent, and unless otherwise specified in a prospectus supplement, the underwriters will be obligated to purchase all the shares of common stock offered by such prospectus supplement if any of such shares of common stock are purchased. Any public offering price and any discounts or concessions allowed or re-allowed or paid to dealers may be changed from time to time.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We are required to pay certain fees and expenses incurred by us incident to the registration of the shares of common stock of the selling stockholders. We are also obligated to pay the reasonable fees and expenses of a single counsel to the selling stockholders in connection with the registration of shares pursuant to this prospectus in an amount not to exceed \$30,000. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act, and the selling stockholders may be entitled to contribution. We may be indemnified by the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act that may arise from any written information furnished to us by the selling stockholders specifically for use in this prospectus, or we may be entitled to contribution.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus forms a part effective until the earlier of (1) February 16, 2026 or (2) the date on which all of the shares may be sold without restriction pursuant to Rule 144 of the Securities Act.

## LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, certain legal matters in connection with the offering and the validity of the securities offered by this prospectus, and any supplement thereto, will be passed upon by Cooley LLP, San Diego, California.

## EXPERTS

The financial statements as of December 31, 2022 and 2021 and for the years then ended incorporated by reference in this prospectus and in the registration statement have been so incorporated in reliance on the report of BDO USA, LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

This prospectus is part of a registration statement we filed with the SEC. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. Neither we nor any selling stockholder, agent, underwriter or dealer has authorized any person to provide you with different information. The selling stockholders are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front page of this prospectus, regardless of the time of delivery of this prospectus or any sale of the securities offered by this prospectus.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC, including our company, Spruce Biosciences, Inc. The address of the SEC website is [www.sec.gov](http://www.sec.gov).

Copies of certain information filed by us with the SEC are also available on our website at [www.sprucebiosciences.com](http://www.sprucebiosciences.com). Information contained in or accessible through our website does not constitute a part of this prospectus and is not incorporated by reference into this prospectus.

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to “incorporate by reference” information that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus, while information that we file later with the SEC will automatically update and supersede the information in this prospectus. We also incorporate by reference into this prospectus the documents listed below and any future filings made by us with the SEC (other than Current Reports or portions thereof furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items and other portions of documents that are furnished, but not filed, pursuant to applicable rules promulgated by the SEC) that are filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the filing and concurrent effectiveness of the registration statement but prior to the termination of all offerings covered by this prospectus:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on [March 16, 2023](#);
- our Current Reports on Form 8-K (other than information furnished rather than filed) filed with the SEC on [January 9, 2023](#) and [February 9, 2023](#); and
- the description of our Common Stock in our registration statement on [Form 8-A](#) filed with the SEC on October 5, 2020, including any amendments or reports filed for the purpose of updating such description.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits which are specifically incorporated by reference into such documents. You should direct any requests for documents by writing us at 611 Gateway Boulevard, Suite 740, South San Francisco, California 94080, Attn: Secretary, or by telephoning us at (415) 655-4168.

Any statement contained herein or in a document incorporated or deemed to be incorporated by reference into this document will be deemed to be modified or superseded for purposes of the document to the extent that a statement contained in this document or any other subsequently filed document that is deemed to be incorporated by reference into this document modifies or supersedes the statement.

## PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 14. Other Expenses of Issuance and Distribution

The following table sets forth the estimated costs and expenses to be incurred by us in connection with the registration of the securities under this registration statement, all of which will be borne by us. All the amounts shown are estimates, except for the SEC registration fee.

SEC Registration Fee	\$	7,471
Legal Fees and Expenses	\$	280,000
Accounting Fees and Expenses	\$	41,000
Miscellaneous	\$	5,000
Total	\$	333,471

#### Item 15. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act. Our amended and restated certificate of incorporation permits indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law, and our amended and restated bylaws provide that we will indemnify our directors and officers and permit us to indemnify our employees and other agents, in each case to the maximum extent permitted by the Delaware General Corporation Law.

We have entered into indemnification agreements with our directors and officers, whereby we have agreed to indemnify our directors and officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee, or agent of our company, provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, the best interest of our company.

At present, there is no pending litigation or proceeding involving a director or officer of our company regarding which indemnification is sought, nor is the registrant aware of any threatened litigation that may result in claims for indemnification.

We maintain insurance policies that indemnify our directors and officers against various liabilities arising under the Securities Act and the Exchange Act that might be incurred by any director or officer in his capacity as such.



## Item 16. Exhibits

Exhibit Number	Description of Document
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- |      |   |
|------|---|
| 3.1  | <a href="#">Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 14, 2020).</a>  |
| 3.2  | <a href="#">Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 14, 2020).</a>  |
| 4.1  | Reference is made to Exhibits 3.1 and 3.2.  |
| 4.2  | <a href="#">Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-248924), filed with the SEC on October 5, 2020).</a>  |
| 4.3  | <a href="#">Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 9, 2023).</a>  |
| 4.4  | <a href="#">Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 9, 2023).</a>  |
| 4.5  | <a href="#">Securities Purchase Agreement, dated February 8, 2023, by and among the Registrant and the Purchasers listed on Exhibit A thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 9, 2023).</a> |
| 5.1  | <a href="#">Opinion of Cooley LLP.</a>  |
| 23.1 | <a href="#">Consent of independent registered public accounting firm.</a>   |
| 23.2 | <a href="#">Consent of Cooley LLP (included in Exhibit 5.1).</a>  |
| 24.1 | <a href="#">Power of Attorney (included on signature page).</a>   |
| 107  | <a href="#">Filing Fee Table.</a>   |

## Item 17. Undertakings

The undersigned registrant hereby undertakes:

- (a) (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act;
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
  - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; *provided, however*, that the undertakings set forth in paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not

apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the SEC by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that are incorporated by reference in this registration statement or are contained in a form of prospectus filed pursuant to Rule 424(b) that is part of this registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act to any purchaser:
  - (i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
  - (ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.
- (b) The registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in South San Francisco, California on March 16, 2023.

**Spruce Biosciences, Inc.**

By: /s/ Javier Szwarcberg  
Name: Javier Szwarcberg, M.D., MPH  
Title: Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Javier Szwarcberg, M.D., MPH and Samir Gharib, and each one of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in their name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by this registration statement that is to be effective on filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ Javier Szwarcberg</u> Javier Szwarcberg, M.D., MPH	Chief Executive Officer (Principal Executive Officer)	March 16, 2023
<u>/s/ Samir Gharib</u> Samir Gharib	President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2023
<u>/s/ Michael Grey</u> Michael Grey	Executive Chairman	March 16, 2023
<u>/s/ Tiba Aynечи</u> Tiba Aynечи, Ph.D.	Director	March 16, 2023
<u>/s/ Dina Chaya</u> Dina Chaya, Ph.D., C.F.A.	Director	March 16, 2023
<u>/s/ Bali Muralidhar</u> Bali Muralidhar, M.D., Ph.D.	Director	March 16, 2023
<u>/s/ Niall O'Donnell</u> Niall O'Donnell, Ph.D.	Director	March 16, 2023
<u>/s/ Camilla V. Simpson</u> Camilla V. Simpson, M.Sc.	Director	March 16, 2023
<u>/s/ Daniel Spiegelman</u> Daniel Spiegelman	Director	March 16, 2023
<u>/s/ Kirk Ways</u> Kirk Ways, M.D., Ph.D.	Director	March 16, 2023



KRISTIN VANDERPAS  
+1 415 693 2097  
kvanderpas@cooley.com

March 16, 2023

Spruce Biosciences, Inc.  
611 Gateway Boulevard, Suite 740  
South San Francisco, California 94080

Ladies and Gentlemen:

We have acted as counsel to Spruce Biosciences, Inc., a Delaware corporation (the "**Company**"), with respect to certain matters in connection with the filing by the Company of a Registration Statement on Form S-3 (the "**Registration Statement**") with the Securities and Exchange Commission (the "**Commission**"), including a related prospectus included in the Registration Statement (the "**Prospectus**"), covering the registration for resale of up to 29,603,000 shares of the common stock, \$0.0001 par value (the "**Common Stock**"), of the Company consisting of (a) 16,116,000 currently outstanding shares of Common Stock (the "**Shares**"), and (b) up to 13,487,000 shares (the "**Warrant Shares**") of Common Stock issuable upon the exercise of certain warrants (the "**Warrants**").

In connection with this opinion, we have examined and relied upon the Registration Statement, the Prospectus, the Warrants, the Company's certificate of incorporation and bylaws, each as currently in effect, and originals or copies certified to our satisfaction of such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to originals of all documents submitted to us as copies, the accuracy, completeness and authenticity of certificates of public officials and the due authorization, execution and delivery of all documents by all persons other than the Company where authorization, execution and delivery are prerequisites to the effectiveness thereof. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not independently verified such matters.

Our opinion is expressed only with respect to the General Corporation Law of the State of Delaware. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state antifraud law, rule or regulation relating to securities or to the sale or issuance thereof.

With respect to the Warrant Shares, we express no opinion to the extent that future issuances of securities of the Company, including the Warrant Shares, adjustments to outstanding securities of the Company and/or other matters cause the Warrants to be exercisable for more shares of Common Stock than the number that remain available for issuance by the Company. Further, we have assumed the exercise price of the Warrants will not be adjusted to an amount below the par value per share of the Common Stock.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that (i) the Shares have been validly issued and are fully paid and nonassessable, and (ii) the Warrant Shares, when sold and issued in accordance with the terms of the Warrants, will be validly issued, fully paid and nonassessable.

COOLEY LLP 3 EMBARCADERO CENTER, 20<sup>TH</sup> FLOOR SAN FRANCISCO, CA 94111  
T: (415) 693-2000 F: (415) 693-2222 COOLEY.COM

We consent to the reference to our firm under the caption "Legal Matters" in the Prospectus and to the filing of this opinion as an exhibit to the Registration Statement. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

Very truly yours,

Cooley LLP

By: /s/ Kristin VanderPas  
Kristin VanderPas

COOLEY LLP 3 EMBARCADERO CENTER, 20<sup>TH</sup> FLOOR SAN FRANCISCO, CA 94111  
T: (415) 693-2000 F: (415) 693-2222 COOLEY.COM

Consent of Independent Registered Public Accounting Firm

Spruce Biosciences, Inc.  
South San Francisco, California

We hereby consent to the incorporation by reference in the Prospectus constituting a part of this Registration Statement of our report dated March 16, 2023, relating to the financial statements of Spruce Biosciences, Inc. appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

We also consent to the reference to us under the caption "Experts" in the Prospectus.

/s/ BDO USA, LLP  
Las Vegas, Nevada

March 16, 2023

## Calculation of Filing Fee Tables

**Form S-3**  
(Form Type)

**Spruce Biosciences, Inc.**  
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

	Security Type	Security Class Title	Fee Calculation Rule	Amount Registered(1)(2)	Proposed Maximum Offering Price Per Share(3)	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Fees to Be Paid	Equity	Common Stock, par value \$0.0001 per share	457(c)	29,603,000	\$2.29	\$67,790,870	0.00011020	\$7,471
	<b>Total Offering Amounts</b>					\$67,790,870		\$7,471
	<b>Total Fees Previously Paid</b>							—
	<b>Total Fee Offsets</b>							—
	<b>Net Fee Due</b>							\$7,471

- (1) The shares of common stock will be offered for resale by the selling stockholders pursuant to the prospectus contained herein. Pursuant to Rule 416 under the Securities Act of 1933, as amended (the “**Securities Act**”), this registration statement also covers any additional number of shares of common stock issuable upon stock splits, stock dividends, or other distribution, recapitalization or similar events with respect to the shares of common stock being registered pursuant to this registration statement.
- (2) This registration statement registers the resale of (i) 16,116,000 outstanding shares of common stock of the Registrant held by the selling stockholders, (ii) 800,000 shares of common stock of the Registrant issuable upon the exercise of outstanding pre-funded warrants to purchase shares of common stock held by the selling stockholders and (iii) 12,687,000 shares of common stock of the Registrant issuable upon the exercise of outstanding warrants to purchase shares of common stock held by the selling stockholders.
- (3) Estimated solely for purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act, based on average of high and low price per share of the common stock as reported on the Nasdaq Global Select Market on March 10, 2023.