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): September 15, 2021

Spruce Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39594**	**81-2154263**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2001 Junipero Serra Boulevard, Suite 640	
Daly City, California	**94014**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 655-4168

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	SPRB	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On September 15, 2021, Spruce Biosciences, Inc. (the "Company") will participate in the 2021 Baird Global Healthcare Conference. Richard King, Chief Executive Officer of the Company, will host a presentation at 1:25pm ET to provide an overview of the Company's clinical development programs for tildacerfont in classic congenital adrenal hyperplasia and polycystic ovary syndrome, which will include a slide presentation, furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

All of the information furnished in this Item 7.01 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Slide Presentation for the Spruce Biosciences, Inc. for the 2021 Baird Global Healthcare Conference September 15, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SPRUCE BIOSCIENCES, INC.

Date: September 15, 2021

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

Exhibit 99.1

Focused on developing and commercializing novel therapies for rare endocrine disorders with significant unmet medical need

Baird 2021 Global Healthcare Conference

FORWARD-LOOKING STATEMENTS

This presentation contains forward-looking statements about Spruce Biosciences, Inc. ("we," "Spruce" or the "Company"). All statements other than statements of historical facts contained in this presentation are forward-looking statements, including statements about our strategy, our expectations regarding the timing and achievement of our product candidate's development activities and ongoing and planned clinical trials, and plans and expectations for future operations. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, but not limited to: the effects of the evolving and ongoing COVID-19 pandemic; our limited operating history; net losses; our expectation that we will incur net losses for the foreseeable future, and that we may never be profitable; our need for additional funding and related risks for our business, product development programs and future commercialization activities; the timing and success of clinical trials we conduct; the ability to obtain and maintain regulatory approval of our product candidate; the ability to commercialize our product candidate; our ability to compete in the marketplace; risks regarding our license agreement; our ability to obtain and maintain intellectual property protection for our product candidate; and our ability to manage our growth. We operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in our expectations.

Certain information contained in this presentation and statements made orally during this presentation relate to or are based on studies, publications, surveys and other data obtained from third-party sources and Spruce's own internal estimates and research. While Spruce believes these third-party studies, publications, surveys and other data to be reliable as of the date of this presentation, it has not independently verified, and makes no representations as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, no independent source has evaluated the reasonableness or accuracy of Spruce's internal estimates or research and no reliance should be made on any information or statements made in this presentation relating to or based on such internal estimates and research.

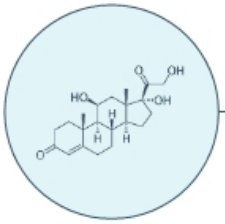
This presentation discusses a product candidate that is under clinical study and which has not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of this product candidate for the use for which it is being studied.

SPRUCE AT-A-GLANCE

Tildacerfont poised to transform treatment paradigm in classic CAH	**Two late-stage clinical studies initiated; Enriched patient populations across two studies designed to observe clinically meaningful outcomes**
Multiple expansion opportunities	**Initiation of Phase 2 programs in pediatric classic CAH (age 6 to 17 years of age) and polycystic ovary syndrome (FAH-PCOS) in 2H 2021.**
Significant commercial opportunity	**~$3B+ worldwide market opportunity in classic CAH**
Strong IP protection	**Comprehensive IP portfolio based on issued patents provides exclusivity to 2038 in U.S. combined with Orphan Drug Designation in U.S. and Europe**
Highly experienced leadership team	**Management has contributed to development and commercial launch of 40 products, including within endocrine and rare disease space**

CLASSIC CAH DISEASE OVERVIEW

Classic CAH is a chronic and potentially life-threatening rare disease



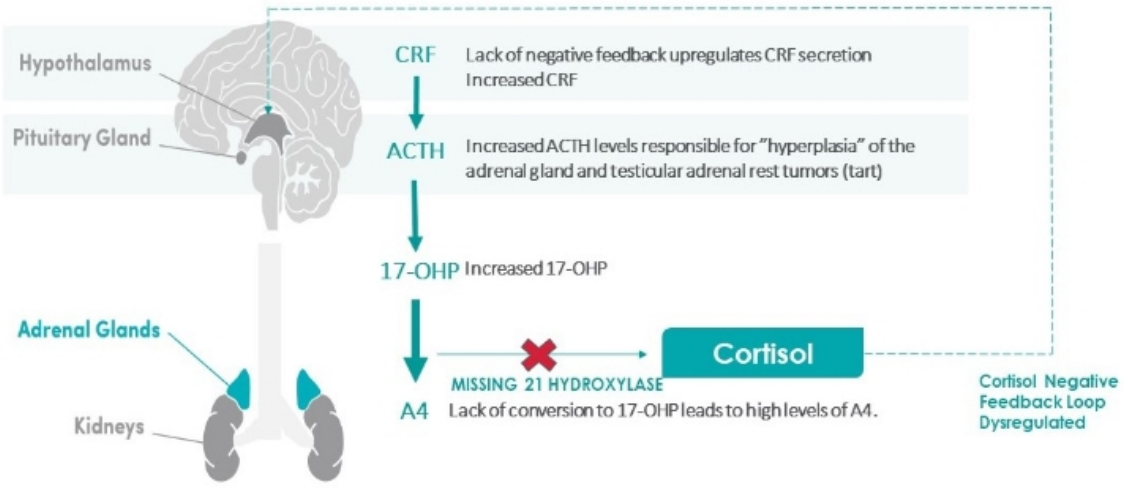
Classic CAH is an autosomal recessive disease characterized by an inability to produce cortisol, leading to a chronic imbalance of key hormones and an overproduction of adrenal androgens.

Due to the severity and high incidence of the disease, most developed countries have established newborn screening programs to test for classic CAH at birth.

We estimate the total classic CAH population to be approximately 20,000-30,000 people in the U.S., 50,000 people in the EU, and at least 145,000 people in China.

HPA AXIS FUNCTION IN CLASSIC CAH PATIENTS

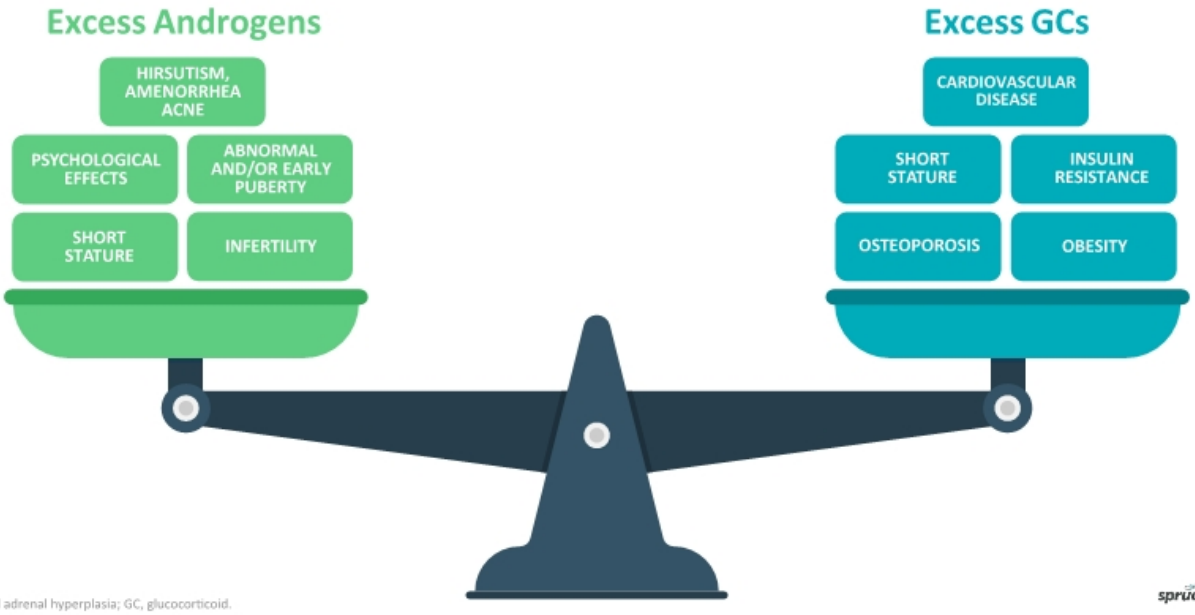
Lack of cortisol leads to overproduction of ACTH and precursor steroid molecules, resulting in excessive adrenal androgens



The dysregulation of the HPA axis in classic CAH.

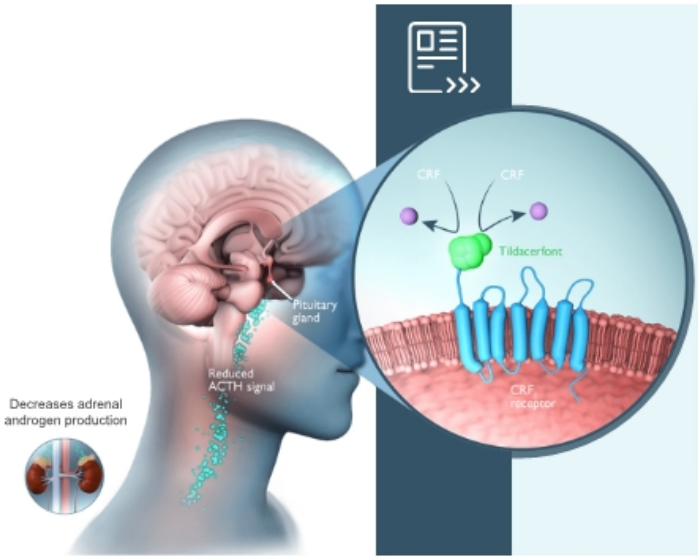
CURRENT CHALLENGES IN TREATING CLASSIC CAH

Patients and physicians must **choose between the detrimental effects** of chronically **high adrenal androgen levels** or the **harmful consequences of excessive, life-long GC use**



CAH, congenital adrenal hyperplasia; GC, glucocorticoid.

TILDACERFONT IS A NOVEL CRF_1 RECEPTOR ANTAGONIST



Tildacerfont is an oral, second generation CRF_1 receptor antagonist[1]

Tildacerfont binds to CRF_1 receptors in the pituitary gland, blocking receptor stimulation by the hypothalamus[1]

ACTH, adrenocorticotropic hormone; CRF, corticotropin-releasing factor; CRF_1, corticotropin-releasing factor 1.

1. Sarafoglou K, *et al. J Clin Endocrinol Metab.* 2021:dgab438. DOI: https://doi.org/10.1210/clinem/dgab438 [Epub ahead of print].

KEY FINDINGS FROM PHASE 1 AND 2 STUDIES: SUMMARY

Two distinct patient populations:[1]

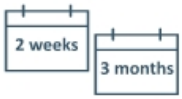
Poor disease control

Good disease control

These form the basis of the late-stage clinical program

Efficacy

Treatment with tildacerfont resulted in:[1]



Reduced adrenal androgens at **2 weeks** (Study 201) and **3 months** (Study 202) in poor disease control patients

Robust reduction in ACTH at the **lowest dose studied** (200mg QD)[1]

- No added benefit observed with higher or more frequent dosing
- Evidence of clinical outcome improvement (TART reduction)

Safety

Tildacerfont was generally well-tolerated in both:

Healthy adults[2]

People with CAH[1]

No drug-related SAEs reported to date[1,2]

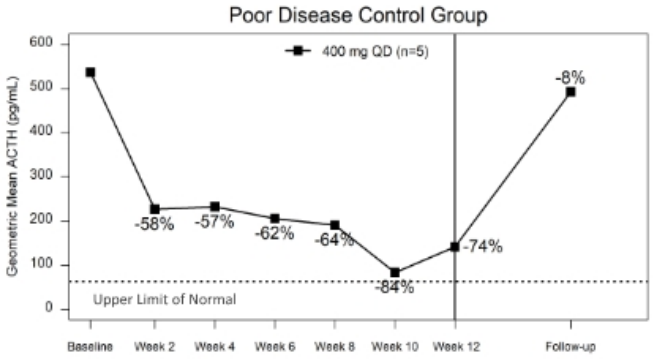
ACTH, adrenocorticotropic hormone; ALT, alanine aminotransferase; AST, aspartate aminotransferase; CAH, congenital ad erplasia; QD, once daily; SAE, serious adverse event; TART, testicular adrenal rest tumor. Liver icon by Edwin PM, Noun Project.

1. Sarafoglou K, et al. J Clin Endocrinol Metab. 2021:dgab438. DOI: https://doi.org/10.1210/clinem/dgab438 [Epub ahead of print]; 2. Barnes C, et al. J Endocr Soc 2021; 5(Suppl 1): A67.

SPR001-202: ROBUST REDUCTION IN ACTH IN POORLY CONTROLLED DISEASE

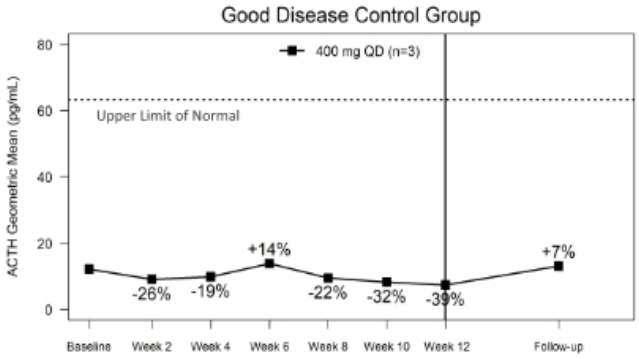
In the poor disease control group, a robust initial drop in ACTH was seen at week 2, followed by further reduction over 12 weeks; there was a maximum reduction in ACTH of **84%** at week 10 of the study in the poor disease control group

POOR DISEASE CONTROL



- Normalization of ACTH achieved in 60% of patients*

GOOD DISEASE CONTROL



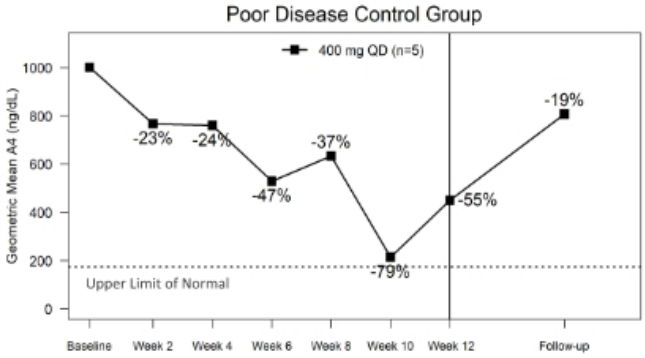
- No excessive suppression of adrenal function

*One subject at week 2 prior to discontinuation from the trial and two patient during month 3.
ACTH, adrenocorticotropic hormone; QD, once daily.
Sarafoglou K, et al. *J Clin Endocrinol Metab.* 2021:dgab438. DOI: https://doi.org/10.1210/clinem/dgab438 [Epub ahead of print].

SPR001-202: SUSTAINED REDUCTION IN A4 IN POORLY CONTROLLED DISEASE

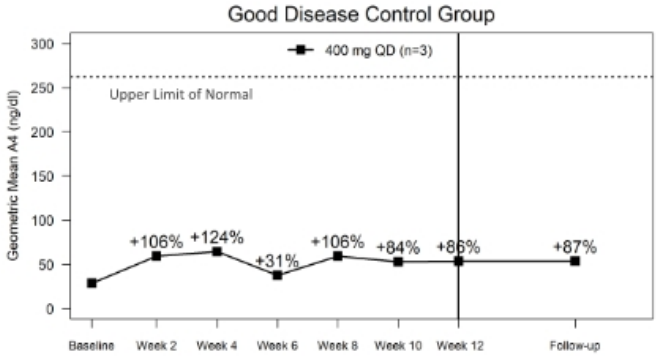
In poor disease control group, an initial drop in A4 was seen at week 2, followed by further reduction over 12 weeks; there was a maximum reduction in A4 of **79% at week 10** of study in the poor disease control group

POOR DISEASE CONTROL



- Normalization of A4 achieved in 40% of patients

GOOD DISEASE CONTROL

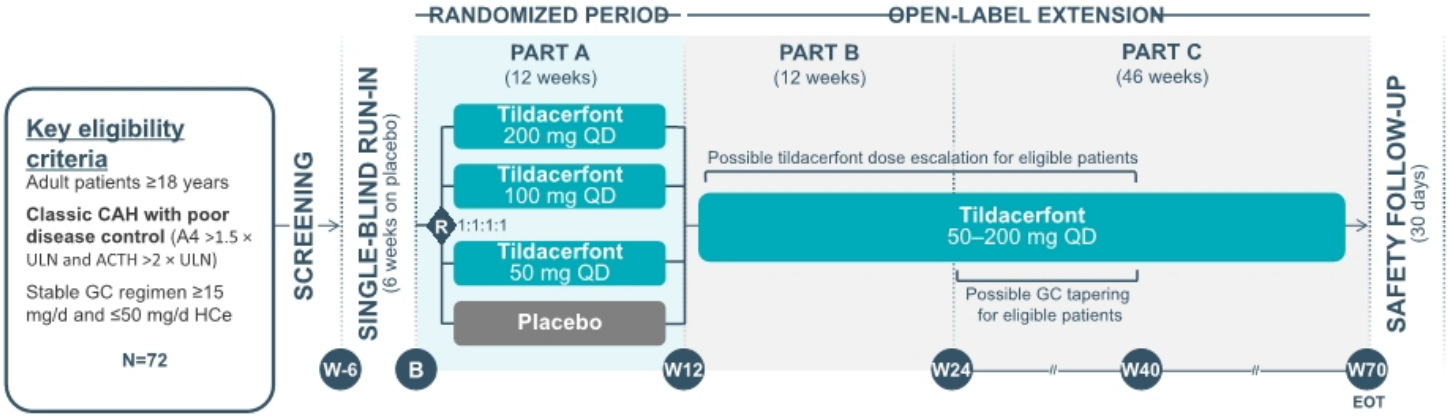


- No excessive suppression of adrenal function

A4, androstenedione; QD, once daily.
Sarafoglou K, et al. *J Clin Endocrinol Metab.* 2021:dgab438. DOI: https://doi.org/10.1210/clinem/dgab438 [Epub ahead of print].

CAHmelia-203: ADRENAL ANDROGEN REDUCTION STUDY

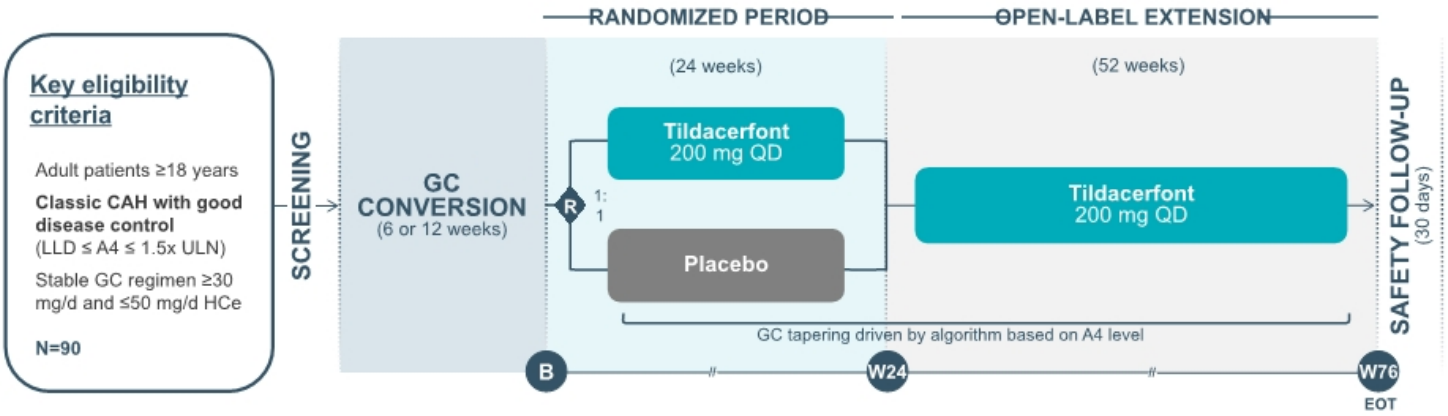
A randomized, double-blind, placebo-controlled, dose-ranging Phase 2b study to evaluate the efficacy and safety of tildacerfont in adult patients with classic CAH



Study schema is not drawn to scale.

CAHmelia-204: GC REDUCTION STUDY

A randomized, double-blind, placebo-controlled Phase 2b study to evaluate the efficacy and safety of tildacerfont in reducing supraphysiologic GC use in adult patients with classic CAH



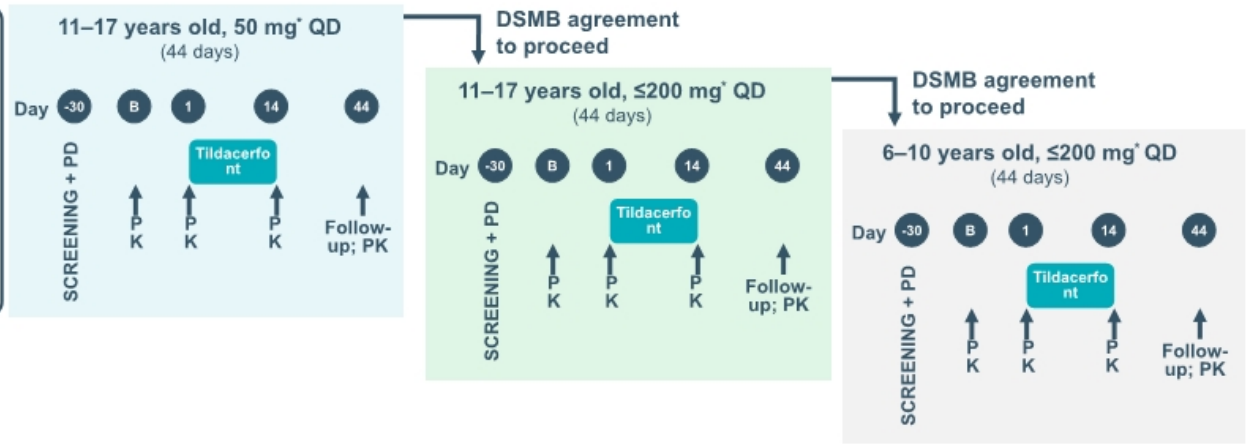
Study schema is not drawn to scale.

PHASE 2 STUDY IN PEDIATRIC CAH

Key eligibility criteria

- Pediatric patients (male and female) aged 6–17 years at Screening
- **Classic CAH**
- 17-OHP >400ng/dl at Screening

N=20



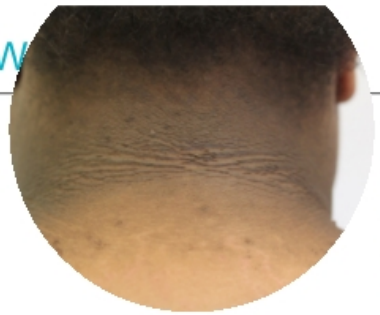
PRIMARY ENDPOINT
Safety

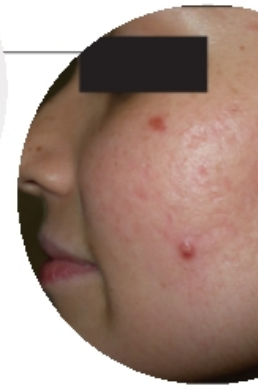
SECONDARY ENDPOINT
PK on Day 14 (of protocol)

OTHER ENDPOINTS
Change in PD biomarkers (ACTH, 17-OHP, A4)

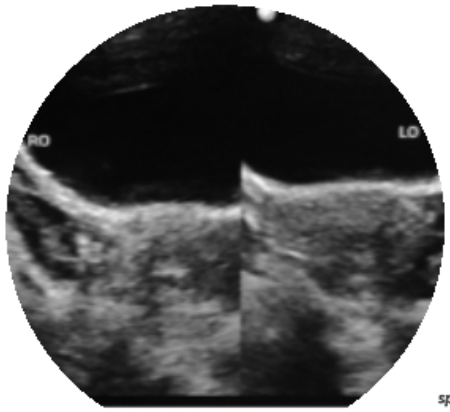
Study schema is not drawn to scale.
*Weight-based dosing at adult/effective dose equivalents.
17-OHP, 17-hydroxyprogesterone; A4, androstenedione; ACTH, adrenocorticotropic hormone; B, baseline; CAH, congenital adrenal hyperplasia; DSMB, Data Safety and Monitoring Board; GC, glucocorticoid; HCe, hydrocortisone equivalent(s); PD, pharmacodynamics; PK, pharmacokinetics; QD, once daily.
Spruce Biosciences. Data on file.

POLYCYSTIC OVARY SYNDROME OVERVIEW





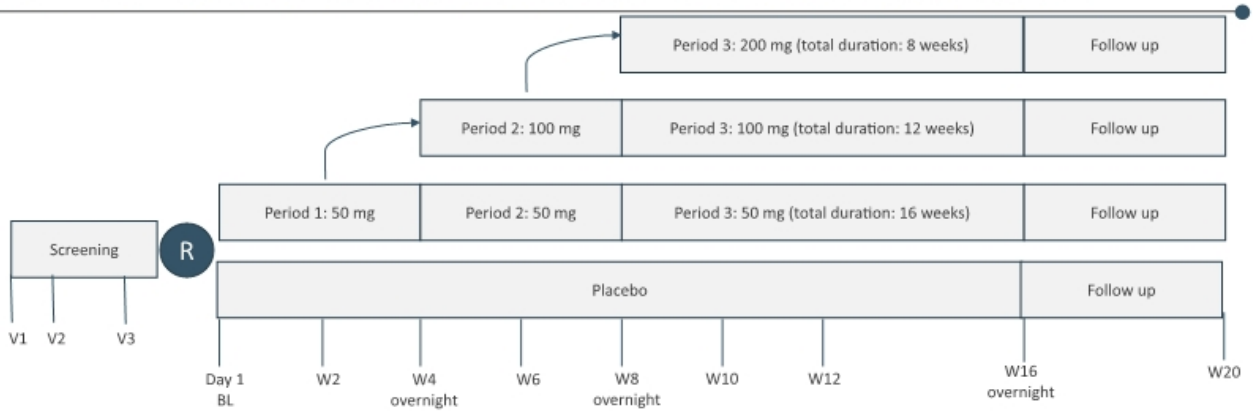
- Polycystic ovary syndrome (PCOS) is a complex condition characterized by elevated androgen levels, menstrual irregularities, and/or small cysts on one or both ovaries.
- 5% to 10% of females 18 to 44 years of age are affected by PCOS (~5 million women in the U.S.), making it the most common endocrine abnormality among women of reproductive age in the U.S. [1]
- Adolescents typically present with hirsutism, acne resistant to topical therapies, and menstrual irregularities.
- Adult women usually seek care for oligomenorrhea and hyperandrogenism and if applicable, fertility concerns due to ovulatory dysfunction.
- Underlying disease can be driven by Functional Ovarian Hyperandrogenism (FOH), Functional Adrenal Hyperandrogenism (FOH), combined FOH/FAH, or idiopathic sources.
- We are focused on FAH, representing 3-5% of PCOS.
- Costs to the U.S. health care system for the identification and management of PCOS are approximately $4 billion per year. [2]



1. National Institutes of Health Department of Health and Human Services. *Beyond Infertility: Polycystic Ovary Syndrome (PCOS)* NIH Pub. No. 08-5863, April 2008
2. ACOG Practice Bulletin No. 108: Polycystic ovary syndrome. *Obstet Gynecol. 2009 Oct; 114(4):936.*

spruceBIOSCIENCES

PHASE 2 POC STUDY IN POLYCYSTIC OVARY SYNDROME



Design	**Randomized, Double Blind, Placebo-controlled, Intra-subject dose-escalation**
Sample size	40 subjects; 20 per treatment group; 1:1 randomization Strata: DHEAS (baseline DHEAS ≤ 1.2 x ULN, DHEAS > 1.2x ULN) and by source of androgen excess (FAH, FAH+FOH)
Key Eligibility Criteria	Adult PCOS 18-30 yrs, BMI <38 kg/m^2; DHEAS > ULN at all screening visit No use of COC
Endpoints	1° Endpoint: Safety / Tolerability of escalating doses Additional Endpoints: - Reduction of DHEAS Baseline change > 30%, DHEAS < ULN - ACTH, 17OHP, T, A4, 11OHA4, 11OHT, 11KA4, 11KT: baseline change - Ovulation + metabolic parameters

KEY ANTICIPATED MILESTONES

2H2021	Initiate Phase 2 proof-of-concept (POC) trial in PCOS
2H2021	Initiate Phase 2 trial in pediatric classic CAH
1H2022	Topline results in adu lt classic CAH (CAHmelia-203)*
2H2022	Topline results in adult classic CAH (CAHmelia-204)*
1H2023	Phase 2 results in pediatric classic CAH and PCOS*

* Clinical data milestones subject to change based on continued assessment of study progress

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Focused on developing and commercializing novel therapies for rare endocrine disorders with significant unmet medical need