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): June 5, 2023

SPRINGWORKS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39044**	**83-4066827**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

100 Washington Blvd
Stamford, CT 06902
(Address of principal executive offices, including zip code)

(203) 883-9490
(Registrant's telephone number, including area code)

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	SWTX	The 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 8.01 Other Events.

On June 5, 2023, SpringWorks Therapeutics, Inc. announced that the U.S. Food and Drug Administration (FDA) has updated the Prescription Drug User Fee Act (PDUFA) action date for the New Drug Application (NDA) for nirogacestat for the treatment of adults with desmoid tumors. The previously disclosed August 27, 2023 PDUFA date has been extended by the standard extension period of three months.

The FDA notified SpringWorks on June 2, 2023 that it required more time to review additional analyses of previously submitted data that had been provided by SpringWorks in response to the FDA's information requests. The submission of this additional information was determined by the FDA to constitute a Major Amendment to the NDA, thereby resulting in an extension of the PDUFA action date. No additional data or studies have been requested by the FDA at this time.

SpringWorks announced the extension of the PDUFA date pursuant to a press release attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.
(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated June 5, 2023
104	Cover page interactive data file (embedded within the Inline XBRL document)

SIGNATURE

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 hereunto duly authorized.

SpringWorks Therapeutics, Inc.

Date: June 5, 2023

By: /s/ Francis I. Perier, Jr.
Francis I. Perier, Jr.
Chief Financial Officer

Exhibit 99.1

SpringWorks Therapeutics Announces PDUFA Date Extension for Nirogacestat NDA

- FDA Extending PDUFA Date by Three Months to Allow More Time to Complete Their Review; New PDUFA Date Set to November 27, 2023 -

STAMFORD, Conn., June 5, 2023 – SpringWorks Therapeutics, Inc. (Nasdaq: SWTX), a clinical-stage biopharmaceutical company focused on developing life-changing medicines for patients with severe rare diseases and cancer, announced today that the U.S. Food and Drug Administration (FDA) has updated the Prescription Drug User Fee Act (PDUFA) action date for the New Drug Application (NDA) for nirogacestat for the treatment of adults with desmoid tumors. The previously disclosed August 27, 2023 PDUFA date has been extended by the standard extension period of three months.

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"We are confident that the comprehensive data from our Phase 3 DeFi trial demonstrate the transformative benefits that nirogacestat can bring to people with desmoid tumors, who currently do not have an approved therapy," said Saqib Islam, Chief Executive Officer of SpringWorks. "We remain committed to bringing this much needed therapy to patients and believe that our operational and manufacturing readiness positions us well to rapidly serve the desmoid tumor community following an approval. We look forward to continuing to work closely with the FDA as they complete their review of the nirogacestat NDA."

The NDA for nirogacestat was granted Priority Review upon its acceptance by FDA in February 2023 and is being reviewed under the FDA's Real-Time Oncology Review (RTOR) program. It is based on positive data from the Phase 3 DeFi trial which were published in the March 9, 2023 edition of the *New England Journal of Medicine*.[1] The FDA previously granted Breakthrough Therapy, Fast Track and Orphan Drug designations for nirogacestat. In addition, SpringWorks expects to file a Marketing Authorization Application for nirogacestat with the European Medicines Agency in 2024.

About DeFi

DeFi (NCT03785964) is a global, randomized (1:1), double-blind, placebo-controlled Phase 3 trial evaluating the efficacy, safety and tolerability of nirogacestat in adult patients with progressing desmoid tumors. The double-blind phase of the study randomized 142 patients (nirogacestat, n=70; placebo n=72) to receive 150 mg of nirogacestat or placebo twice daily. Key eligibility criteria included tumor progression by ≥20% as measured by Response Evaluation Criteria in Solid Tumors (RECIST 1.1) within 12 months prior to screening. The primary endpoint was progression-free survival, as assessed by blinded independent central review, or death by any cause. Secondary and exploratory endpoints included safety and tolerability measures, objective response rate (ORR), duration of response, changes in tumor volume assessed by magnetic resonance imaging (MRI), and changes in patient-reported outcomes (PROs). DeFi includes an open-label extension phase, which is ongoing.

About Desmoid Tumors

Desmoid tumors are rare, aggressive, locally invasive, potentially morbid tumors of the soft tissues.[2,3] While they do not metastasize, desmoid tumors are associated with a high rate of recurrence.[3,4,5] Sometimes referred to as aggressive fibromatosis, or desmoid fibromatosis, these soft tissue tumors can be serious, debilitating, and in rare cases when vital organs are impacted, they can be life-threatening.[3,6]

Desmoid tumors are most commonly diagnosed in patients between the ages of 20 to 44 years, with a two-to-three times higher prevalence in females.[5,7,8,9] It is estimated that there are 1,000-1,650 new cases diagnosed per year in the United States.[8,9,10]

Historically, desmoid tumors were treated with surgical resection, but this approach has become less favored due to a high recurrence rate after surgery.[2,5,11] There are currently no FDA-approved therapies for the treatment of desmoid tumors.

About Nirogacestat

Nirogacestat is an oral, selective, small molecule gamma secretase inhibitor in Phase 3 clinical development for desmoid tumors. SpringWorks is also evaluating nirogacestat as a potential treatment for patients with ovarian granulosa cell tumors and for patients with multiple myeloma as part of several B-cell maturation agent (BCMA) combination therapy regimens in collaboration with leaders in industry and academia. Nirogacestat is an investigational drug for which safety and efficacy have not been established.

The U.S. Food and Drug Administration (FDA) granted Priority Review for the New Drug Application (NDA) for nirogacestat for the treatment of adults with desmoid tumors, which is being reviewed under the FDA's Real-Time Oncology Review program, in February 2023. The FDA also previously granted Fast Track and Breakthrough Therapy Designations to nirogacestat for the treatment of adult patients with progressive, unresectable, recurrent or refractory desmoid tumors or deep fibromatosis. In addition, nirogacestat has received Orphan Drug Designation from the FDA for the treatment of desmoid tumors and from the European Commission for the treatment of soft tissue sarcoma.

Gamma secretase cleaves multiple transmembrane protein complexes, including Notch, which is believed to play a role in activating pathways that contribute to growth of desmoid and ovarian granulosa cell tumors. Gamma secretase has also been shown to directly cleave membrane-bound BCMA, resulting in the release of the BCMA extracellular domain (ECD) from the cell surface. By inhibiting gamma secretase, membrane-bound BCMA can be preserved, increasing target density while reducing levels of soluble BCMA ECD, which may serve as decoy receptors for BCMA-directed therapies. SpringWorks is evaluating nirogacestat as a BCMA potentiator and has several collaborations with industry-leading BCMA developers and academic partners to evaluate nirogacestat in BCMA combinations across modalities.

About SpringWorks Therapeutics

SpringWorks is a clinical-stage biopharmaceutical company applying a precision medicine approach to acquiring, developing and commercializing life-changing medicines for patients living with severe rare diseases and cancer. SpringWorks has a differentiated targeted oncology pipeline spanning solid tumors and hematological cancers, including two late-stage clinical trials in rare tumor types as well as several programs addressing highly prevalent, genetically defined cancers. SpringWorks' strategic approach and operational excellence in clinical development have enabled it to rapidly advance its two lead product candidates into late-stage clinical trials while simultaneously entering into multiple shared-value partnerships with innovators in industry and academia to unlock the full potential for its portfolio and create more solutions for patients with cancer. For more information, visit www.springworkstx.com and follow @SpringWorksTx on Twitter and LinkedIn.

SpringWorks Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, relating to our business, operations, and financial conditions, including, but not limited to, current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our development plans, our preclinical and clinical results, as well as relating to other future conditions. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "would," "should" and "could," and similar expressions or words, identify forward-looking statements. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks relating to: (i) whether the preclinical and clinical results of the nirogacestat studies will meet the regulatory requirements for an approval by the FDA of nirogacestat for the treatment of adults with desmoid tumors, (ii) interactions with the FDA, including reviews and inspections, the timing related thereto and the outcome thereof, in each case including with respect to the extension of the PDUFA date, (iii) the potential therapeutic benefits, safety profile and effectiveness of nirogacestat, (iv) whether the NDA for nirogacestat will be approved, (v) if approved, whether nirogacestat will be commercially successful, (vi) our expectations regarding the transformative benefits that nirogacestat can bring to patients with desmoid tumors, our expectations regarding the approval of nirogacestat for adults with desmoid tumors, and (vii) uncertainties and assumptions regarding the impact of the COVID-19 pandemic on SpringWorks' business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines.

Except as required by applicable law, we do not plan 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. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements.

For further information regarding the risks, uncertainties and other factors that may cause differences between SpringWorks' expectations and actual results, you should review the "Risk Factors" in Item 1A of Part II of SpringWorks' Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, as well as discussions of potential risks, uncertainties and other important factors in SpringWorks' subsequent filings.

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