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): November 2, 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)**	**(IRS Employer Identification No.)**

100 Washington Blvd Stamford, CT	**06902**
(Address of principal executive offices)	(Zip Code)

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

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 14a12 under the Exchange Act (17 CFR 240.14a12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e4(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 (§240.12b2 of this chapter).

Emerging growth company ☐

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

Item 2.02. Results of Operations and Financial Condition.

On November 2, 2023, SpringWorks Therapeutics, Inc. announced its financial results for the quarter ended September 30, 2023. A copy of the press release issued in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by SpringWorks Therapeutics, Inc. on November 2, 2023, furnished herewith.
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: November 2, 2023

By: /s/ Francis I. Perier, Jr.

Francis I. Perier, Jr.

Chief Financial Officer

Exhibit 99.1

SpringWorks Therapeutics Reports Third Quarter 2023 Financial Results and Recent Business Highlights

– PDUFA target action date for nirogacestat NDA in adults with desmoid tumors remains set for November 27, 2023 –

– On track to report topline data from the Phase 2b ReNeu trial of mirdametinib in patients with NF1-PN in the fourth quarter of 2023 –

– Presented additional Phase 3 DeFi data at CTOS demonstrating statistically significant and clinically meaningful improvements in functional status in desmoid tumor patients treated with nirogacestat –

– First patient dosed in Regeneron-sponsored Phase 1b study arm evaluating nirogacestat in combination with linvoseltamab in patients with multiple myeloma –

STAMFORD, Conn., November 2, 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, today reported third quarter financial results for the period ended September 30, 2023 and provided an update on recent business highlights.

“We continue to work closely with the FDA as they complete their review of our nirogacestat NDA and are ready to serve the desmoid tumor community following an approval,” said Saqib Islam, Chief Executive Officer of SpringWorks. “We are also on track to report topline data from our Phase 2b ReNeu trial of mirdametinib in patients with NF1-PN, which, if positive, would position us to file an NDA in the first half of 2024. Together, these anticipated milestones position us to have two medicines approved to treat patients with two distinct devastating diseases. In addition to these near-term events, we continue to advance our broader targeted oncology pipeline, which includes rare oncology, BCMA combinations in multiple myeloma, and biomarker-defined metastatic solid tumor programs, and look forward to providing further updates on our progress over the coming months.”

Recent Business Highlights and Upcoming Milestones

Rare Oncology

- The Prescription Drug User Fee Act (PDUFA) target action date for the New Drug Application (NDA) for nirogacestat for the treatment of adults with desmoid tumors is November 27, 2023. SpringWorks expects to file a Marketing Authorisation Application for nirogacestat with the European Medicines Agency (EMA) in the first half of 2024.
- In November 2023, additional data from the Phase 3 DeFi trial evaluating the impact of nirogacestat on functional status in patients with desmoid tumors were presented at the 2023 Connective Tissue Oncology Society (CTOS) Annual Meeting. Statistically significant and clinically meaningful improvements in physical and role functioning were observed in patients receiving nirogacestat compared with those who received placebo by Cycle 10 across the three prespecified assessment tools evaluated. Patients receiving nirogacestat were five times more likely to have a clinically meaningful improvement in physical functioning and two times more likely to have a clinically meaningful improvement in role functioning compared to placebo at Cycle 10. These improvements began as early as Cycle 2 (the first post-treatment timepoint) and were sustained through Cycle 24 (the final assessment). Improvements in functioning were consistent

with the improvements in pain measures, disease-related symptoms, and overall health-related quality of life that were previously reported with nirogacestat.
- The ongoing Phase 2 trial evaluating nirogacestat as a monotherapy in patients with recurrent ovarian granulosa cell tumors is fully enrolled. SpringWorks expects to report initial data from the trial in 2024.
- SpringWorks expects to present topline data from the pediatric and adult cohorts of the Phase 2b ReNeu trial evaluating mirdametinib, an investigational MEK inhibitor, in NF1-associated plexiform neurofibromas (NF1-PN) in the fourth quarter of 2023. If these data are positive, SpringWorks plans to submit an NDA to the FDA for mirdametinib for the treatment of NF1-PN in the first half of 2024.

B-cell Maturation Antigen (BCMA) Combinations in Multiple Myeloma

- SpringWorks continues to evaluate nirogacestat as part of several BCMA combination therapy regimens across treatment lines in collaboration with industry leaders.
- In September 2023, the first patient was dosed in the Regeneron-sponsored Phase 1b study arm evaluating nirogacestat in combination with Regeneron's linvoseltamab, a bispecific antibody targeting BCMA and CD3.

Biomarker-Defined Metastatic Solid Tumors

- The dose expansion portion of the Phase 1b trial evaluating brimarafenib (BGB-3245) is ongoing in adult patients with RAF mutant solid tumors. Brimarafenib is an investigational, selective RAF dimer inhibitor being developed by MapKure, LLC, a joint venture between SpringWorks and BeiGene, Ltd.
- Patients continue to be enrolled in the dose escalation phase of the SpringWorks-sponsored Phase 1/2a combination study of brimarafenib and mirdametinib.
- In August 2023, MapKure filed an Investigational New Drug Application (IND) for a combination study of brimarafenib with panitumumab, a monoclonal antibody targeting EGFR, in colorectal and pancreatic cancer patients with known MAPK pathway mutations and expects to initiate a Phase 1/2a study in the first quarter of 2024. Amgen Inc. is supplying panitumumab pursuant to a clinical trial collaboration agreement with MapKure.
- Dose expansion cohort is ongoing in the BeiGene-sponsored Phase 1b/2 trial evaluating mirdametinib in combination with BeiGene's RAF dimer inhibitor, lifirafenib, in adult patients with NRAS mutant solid tumors.
- In September 2023, preclinical data were published in *Molecular Cancer Therapeutics* characterizing SWTX-143, a TEAD inhibitor tool compound, and describing the potential of TEAD inhibitors to treat multiple Hippo-mutant solid tumor types. SpringWorks plans to file an IND for SW-682, the Company's TEAD inhibitor development candidate, in the fourth quarter of 2023.

General Corporate

- In September 2023, SpringWorks appointed Tai-An Lin, Ph.D., as Chief Scientific Officer. Dr. Lin brings more than 25 years of biotechnology and global pharmaceutical experience in advancing drug discovery programs from target identification through early clinical trials across the therapeutic areas of oncology, immuno-oncology, and immunology.

Third Quarter 2023 Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses were $37.5 million for the third quarter, compared to $36.1 million for the comparable period of 2022. The increase in R&D expenses was primarily attributable to an increase in internal costs driven by the growth in employee costs associated with increases in the number of personnel, including an increase in stock-based compensation expense, partially offset by a decrease in external costs related to drug manufacturing, clinical trials and other research.
- **General and Administrative (G&A) Expenses**: G&A expenses were $46.5 million for the third quarter, compared to $35.7 million for the comparable period of 2022. The increase in G&A expenses was largely attributable to commercial readiness activities to support the U.S. launch of nirogacestat, if approved, for the treatment of adults with desmoid tumors.
- **Net Loss Attributable to Common Stockholders:** SpringWorks reported a net loss of $79.4 million, or $1.27 per share, for the third quarter of 2023. This compares to a net loss of $72.4 million, or $1.37 per share, for the comparable period of 2022.
- **Cash Position:** Cash, cash equivalents and marketable securities were $422.4 million as of September 30, 2023.

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, For more information, visit www.springworkstx.com and follow @SpringWorksTx on X (formerly Twitter), LinkedIn, and YouTube.

SpringWorks uses its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. Such disclosures will be included on SpringWorks' website in the Investors & Media section. Accordingly, investors should monitor such portions of the SpringWorks website, in addition to following press releases, SEC filings and public conference calls and webcasts.

Forward-Looking Statements

This presentation 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, the potential for nirogacestat to become an important new treatment for adult patients with desmoid tumors, expectations regarding the timing and results of the FDA's review of the NDA for nirogacestat, including the FDA's PDUFA target action date for the NDA, and the adequacy of the data contained in the NDA to serve as the basis for an approval of nirogacestat for the treatment of adults with desmoid tumors, our plans to submit a Marketing Authorisation Application for nirogacestat with the European Medicines Agency in the first half of 2024, expectations regarding the timing of initial data from the Phase 2 trial evaluating nirogacestat as a monotherapy in patients with recurrent ovarian granulosa cell tumors, expectations regarding the timing and results of topline data from the Phase 2b ReNeu trial, the potential for the results of the Phase 2b ReNeu trial to support an NDA submission for mirdametinib, the potential for mirdametinib to become an important new treatment for patients with NF1-PN, our plans for seeking regulatory approval for and making mirdametinib available for NF1-PN patients, if approved, our plans to

file an IND for SW-682 in the fourth quarter of 2023, our plans to report additional clinical data of nirogacestat in combination with BCMA-directed therapies and to initiate additional planned Phase 1 collaborator studies, our expectations regarding the potential for the Phase 1b dose expansion phase of brimarafenib and the Phase 1b/2 dose expansion phase of mirdametinib with lifirafenib, expectations to initiate a Phase 1/2a study of brimarafenib with panitumumab, expectations about whether our patents or market exclusivity for our lead assets will adequately protect SpringWorks against competition, 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) the success and timing of our product development activities, including the initiation and completion of SpringWorks' clinical trials, (ii) the fact that topline data or interim data from our clinical studies may not be predictive of the final or more detailed results of such study, or the results of other ongoing or future studies, (iii) the success and timing of our collaboration partners' ongoing and planned clinical trials, (iv) the timing of our planned regulatory submissions and interactions and the timing and outcome of decisions made by the FDA, EMA, and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; (v) whether FDA, EMA, or other regulatory authorities will require additional information or further studies, or may fail or refuse to approve or may delay approval of our product candidates, including nirogacestat and mirdametinib, (vi) our ability to obtain and maintain regulatory approval of any of our product candidates, (vii) our plans to research, discover and develop additional product candidates, (viii) our ability to enter into collaborations for the development of new product candidates and our ability to realize the benefits expected from such collaborations, (ix) our ability to maintain adequate patent protection and successfully enforce patent claims against third parties, (x) the adequacy of our cash position to fund our operations through any time period indicated herein, (xi) our ability to establish manufacturing capabilities, and our and our collaboration partners' abilities to manufacture our product candidates and scale production, and (xii) our ability to meet any specific milestones set forth herein.

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 September 30, 2023, as well as discussions of potential risks, uncertainties and other important factors in SpringWorks' subsequent filings.

SpringWorks Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except share and per-share data)	**2023**	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	37,453	36,067	106,835	108,194
General and administrative	46,546	35,673	137,715	94,026
Total operating expenses	83,999	71,740	244,550	202,220
Loss from operations	(83,999)	(71,740)	(244,550)	(202,220)
Interest and other income (expense):				
Other expense, net	(76)	(74)	(373)	(291)
Interest income, net	5,662	912	17,344	1,482
Total interest and other income	5,586	838	16,971	1,191
Equity investment loss	(1,024)	(1,486)	(3,203)	(2,210)
Net loss	$ (79,437)	$ (72,388)	$ (230,782)	$ (203,239)
Net loss per share, basic and diluted	$ (1.27)	$ (1.37)	$ (3.70)	$ (4.04)
Weighted average common shares outstanding, basic and diluted	62,521,772	52,900,819	62,386,496	50,298,015

SpringWorks Therapeutics, Inc.
Selected Balance Sheet Data
(Unaudited)

	September 30, 2023	December 31, 2022
(in thousands)		
Cash, cash equivalents and marketable securities	$ 422,419	$ 597,006
Working Capital (1)	382,100	548,711
Total assets	467,654	630,242
Total liabilities	72,755	72,050
Accumulated deficit	(800,712)	(569,930)
Total stockholders' equity	394,899	558,192

(1) We define Working Capital as current assets less current liabilities.

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