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): February 28, 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)	(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 14d2(b) under the Exchange Act (17 CFR 240.14d2(b))

☐ Pre-commencement communications pursuant to Rule 13e4(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 12b2 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 February 28, 2023, SpringWorks Therapeutics, Inc. announced its financial results for the full year and quarter ended December 31, 2022. 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.

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 February 28, 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: February 28, 2023

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

Francis I. Perier, Jr.

Chief Financial Officer

SpringWorks Therapeutics Reports Fourth Quarter and Full-Year 2022 Financial Results and Recent Business Highlights

– NDA for Nirogacestat in Adults with Desmoid Tumors Accepted by the FDA and Granted Priority Review; PDUFA Action Date Set for August 27, 2023 –

– Topline Data from Phase 2b ReNeu Trial Evaluating Mirdametinib in Adult and Pediatric Patients with NF1-Associated Plexiform Neurofibromas Expected in the Second Half of 2023 –

– Dosed First Patient in Phase 1/2a Combination Study of BGB-3245 and Mirdametinib –

– Expanded Intellectual Property Portfolio, Strengthening Protection for Nirogacestat into 2042 and for Mirdametinib into 2041 –

– Ended 2022 with $597.0 Million in Cash, Cash Equivalents and Marketable Securities –

STAMFORD, Conn., February 28, 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 financial results for the fourth quarter and full-year periods ended December 31, 2022 and provided an update on recent company developments.

“2022 was a pivotal year for SpringWorks. We delivered highly positive data from our Phase 3 DeFi trial of nirogacestat in desmoid tumors, which served as the basis for our New Drug Application that was recently accepted by the FDA and granted Priority Review. We are excited to have the opportunity to change the treatment landscape for the desmoid tumor community following an anticipated approval later this year," said Saqib Islam, Chief Executive Officer of SpringWorks. "We are equally encouraged by the potential for mirdametinib to be a best-in-class therapy for children and adults with NF1-PN. We look forward to reporting topline data from our Phase 2b ReNeu trial this year, which could support an NDA submission in the first half of 2024, and to advancing our emerging portfolio of BCMA combinations in multiple myeloma and biomarker-defined metastatic solid tumor programs. We believe that our continued strong execution, a financial position that we expect will fund us well into 2026, and durable intellectual property protections for our lead assets will support our long-term growth as we work towards our ambition of achieving two product launches by 2025."

Recent Business Highlights and Upcoming Milestones

Rare Oncology

- In February 2023, the U.S. Food and Drug Administration (FDA) accepted SpringWorks' New Drug Application (NDA) for nirogacestat, an investigational oral, small molecule gamma secretase inhibitor, in development as a monotherapy for the treatment of adults with desmoid tumors. The application has been granted Priority Review and given a Prescription Drug User Fee Act (PDUFA) action date of August 27, 2023. In addition, the FDA has stated that it is not currently planning to hold an advisory committee meeting to discuss the application.SpringWorks also expects to file a Marketing Authorization Application for nirogacestat with the European Medicines Agency in 2024.
- In the fourth quarter of 2022, the Phase 2 study sponsored by the Children’s Oncology Group evaluating nirogacestat in pediatric patients with desmoid tumors met its accrual goal.
- In the fourth quarter of 2022, SpringWorks participated in a Type C meeting with the FDA to align on the statistical analysis plan for the Phase 2b ReNeu trial evaluating mirdametinib, an

investigational MEK inhibitor, in adult and pediatric patients with NF1-associated plexiform neurofibromas (NF1-PN) and expectations for an anticipated NDA submission in this indication. SpringWorks expects to present topline data from the pediatric and adult cohorts of the Phase 2b ReNeu trial of mirdametinib in NF1-PN in the second half of 2023. Pending these data, SpringWorks anticipates submitting an NDA for mirdametinib as a treatment for NF1-PN in the first half of 2024.
- Patients continue to be enrolled in a Phase 2 trial evaluating nirogacestat in ovarian granulosa cell tumors.

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

- SpringWorks continues to advance nirogacestat as a potential cornerstone of BCMA combination therapy across modalities in collaboration with industry leaders. In 2023, SpringWorks expects that additional clinical data of nirogacestat in combination with BCMA-directed therapies will be presented and that additional planned Phase 1 collaborator studies will be initiated.

Biomarker-Defined Metastatic Solid Tumors

- The Phase 1 trial evaluating BGB-3245, a selective RAF dimer inhibitor, as a monotherapy in adult patients with RAF mutant solid tumors is advancing into cohort expansion studies. SpringWorks expects data from this trial to be presented at a medical conference in the first half of 2023. In February 2023, the first patient was dosed in a Phase 1/2a combination study of BGB-3245 and mirdametinib. BGB-3245 is being developed by MapKure, LLC, a joint venture between SpringWorks and BeiGene.
- The BeiGene-sponsored Phase 1b/2 clinical trial evaluating mirdametinib with BeiGene's RAF dimer inhibitor, lifirafenib, in adult patients with RAS/RAF mutant and other MAPK pathway aberrant solid tumors is ongoing. SpringWorks expects data from this trial to be presented at a medical conference in the first half of 2023.
- In the fourth quarter of 2022, SpringWorks nominated TEAD inhibitor development candidate, SW-682. The Company expects to present additional preclinical data of SW-682 at a medical conference in the first half of 2023 and to file an Investigational New Drug Application for SW-682 in 2023.

General Corporate

- SpringWorks has expanded and strengthened its intellectual property portfolio, including a new patent issued by the United States Patent and Trademark Office (USPTO) in November 2022 directed to pharmaceutical compositions of nirogacestat (U.S. Patent No. 11,504,354), which expires in 2042 and represents the seventh Orange Book-listable patent for nirogacestat. In addition, in February 2023, the USPTO granted a new patent directed to dispersible formulations of mirdametinib (U.S. Patent No. 11,571,402), which expires in 2041; this patent covers the formulation of mirdametinib that is being developed for pediatric patients with NF1-PN.

Fourth Quarter and Full Year 2022 Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses were $37.9 million and $146.1 million for the 2022 fourth quarter and full-year periods, respectively, compared to $29.3 million and $101.7 million for the comparable periods of 2021. The increase in R&D expense for the 2022 full-year period was primarily attributable to a $31.8 million 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, and an increase of $22.6 million in external costs related to drug manufacturing, clinical trial and other research, with the full year increase partially offset by an $11.0 million decrease in licensing costs related to the nonrefundable upfront payment to Katholieke Universiteit Leuven and the Flanders Institute for Biotechnology for the in-licensing of the TEAD inhibitor program in May 2021.

- **General and Administrative (G&A) Expenses:** G&A expenses were $40.5 million and $134.6 million for the 2022 fourth quarter and full-year periods, respectively, compared to $26.5 million and $71.8 million for the comparable periods of 2021. The increase in G&A expense 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 as we continue to expand our operations to support the organization, and an increase in information technology costs and consulting and professional services, including legal, regulatory and compliance, as we continue to build new capabilities, including commercial.
- **Net Loss Attributable to Common Stockholders:** SpringWorks reported a net loss of $74.2 million, or $1.19 per share, for the fourth quarter of 2022 and a net loss of $277.4 million, or $5.21 loss per share, for the year ended December 31, 2022. This compares to a net loss of $56.1 million, or $1.15 per share, for the fourth quarter of 2021 and a net loss of $173.9 million, or $3.59 per share for the year ended December 31, 2021.
- **Cash Position:** Cash, cash equivalents and marketable securities were $597.0 million as of December 31, 2022.

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 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 the Company's 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, the potential for Marketing Authorization Application for nirogacestat, 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, the potential for the results of the Phase 2b ReNeu clinical 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 report data from the Phase 1b/2 trial evaluating mirdametinib with lifirafenib at an upcoming medical conference, our plans to report additional data from the Phase 1 study evaluating BGB-3245 at an upcoming medical conference, our plans to report additional preclinical data of SW-682 at an upcoming medical conference, our plans to file an Investigational New Drug Application for SW-682 in 2023, our plans to report additional clinical data of nirogacestat in combination with BCMA-directed therapies and initiate additional planned Phase 1 collaborator studies, our plans to begin dosing a Phase 1/2a combination study of BGB-3245 and mirdametinib, expectations about whether our patents 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 and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies, (v) whether FDA or other regulatory authorities will require additional information or further studies, or may fail or refuse to approve or may delay approval of our drug 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, (xii) our ability to meet any specific milestones set forth herein, and (xiii) 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 I of SpringWorks' Annual Report on Form 10-K for the year ended December 31, 2022, 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)

(in thousands, except share and per-share data)	Year Ended December 31, 2022	2021	2020
Licensing revenue	$ —	$ —	$ 35,000
Operating expenses:			
Research and development	146,122	101,676	51,859
General and administrative	134,552	71,792	29,465
Total operating expenses	280,674	173,468	81,324
Loss from operations	(280,674)	(173,468)	(46,324)
Interest and other (expense) income:			
Other (expense) income, net	(138)	(152)	25
Interest income, net	6,285	698	1,330
Total interest and other income	6,147	546	1,355
Equity investment loss	(2,890)	(988)	(605)
Net loss	$ (277,417)	$ (173,910)	$ (45,574)
Net loss per share, basic and diluted	$ (5.21)	$ (3.59)	$ (1.05)
Weighted average common shares outstanding, basic and diluted	53,290,528	48,497,790	43,300,063

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

(in thousands)	As of December 31, 2022	2021
Cash, cash equivalents and marketable securities	$ 597,006	$ 432,731
Working Capital (1)	548,711	352,941
Total assets	630,242	452,494
Total liabilities	72,050	30,098
Accumulated deficit	(569,930)	(292,513)
Total stockholders' equity	558,192	422,396

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

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