
**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 03, 2022

SPRINGWORKS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39044
(Commission
File Number)

83-4066827
(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 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 November 3, 2022, SpringWorks Therapeutics, Inc. announced its financial results for the quarter ended September 30, 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 November 3, 2022, 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 3, 2022

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

Francis I. Perier, Jr.

Chief Financial Officer



SpringWorks Therapeutics Reports Third Quarter 2022 Financial Results and Recent Business Highlights

- Presented Positive Data from Phase 3 DeFi Trial Evaluating Nirogacestat in Adult Patients with Progressing Desmoid Tumors at the European Society for Medical Oncology (ESMO) Congress 2022 –
- Expanded Global, Non-Exclusive Collaboration with GSK to Continue Evaluating Nirogacestat in Combination with Belantamab Mafodotin (Belamaf) in Patients with Multiple Myeloma –
- Dosed First Patient in Phase 2 Trial Evaluating Nirogacestat in Patients with Ovarian Granulosa Cell Tumors –
- Strengthened Financial Position to Over \$650 Million in Cash, Cash Equivalents and Marketable Securities –

STAMFORD, Conn., November 3, 2022 – 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, 2022 and provided an update on recent company developments.

"In the third quarter of 2022, we were very pleased to present positive data from our Phase 3 DeFi trial of nirogacestat in patients with desmoid tumors during a Presidential Symposium at ESMO, expand our collaboration with GSK to enable further development of nirogacestat in combination with belamaf in patients with multiple myeloma across lines of therapy, and initiate a new Phase 2 trial of nirogacestat in patients with ovarian granulosa cell tumors," said Saqib Islam, Chief Executive Officer of SpringWorks. "In addition, we significantly strengthened our financial position, providing us with sufficient runway into 2026 to continue executing on our mission to make a profound impact on the lives of patients with devastating cancers. We look forward to completing our NDA filing package for nirogacestat in desmoid tumors to potentially enable our first product launch in 2023 and to further advancing our diversified targeted oncology pipeline."

Recent Business Highlights and Upcoming Milestones

Rare Oncology

- In September 2022, SpringWorks presented positive data from the Phase 3 DeFi trial of nirogacestat in adult patients with progressing desmoid tumors in a late-breaking oral presentation during a Presidential Symposium at the European Society for Medical Oncology (ESMO) Congress 2022; the data were presented by Bernd Kasper, M.D., Ph.D., University of Heidelberg, Mannheim Cancer Center, Mannheim, Germany. The DeFi trial met its primary endpoint of improving progression-free survival (PFS), as assessed by blinded independent central review, demonstrating a statistically significant improvement for nirogacestat over placebo, with a 71% reduction in the risk of disease progression (hazard ratio (HR) = 0.29 (95% CI: 0.15, 0.55); $p < 0.001$). In addition, all key secondary endpoints achieved statistical significance, including objective response rate and improvements in six different patient-reported outcomes; notably, a significant reduction in pain severity compared with placebo ($p < 0.001$) was observed. Nirogacestat also exhibited a manageable safety profile in the DeFi trial. These data will be highlighted by Mrinal Gounder, M.D., Medical Oncologist, Memorial Sloan Kettering Cancer Center in an encore presentation at the Connective Tissue Oncology Society (CTOS) 2022 Annual Meeting in Vancouver, BC, Canada on Saturday, November 19, at 1:30pm PT (4:30pm ET). In this

oral session, Dr. Gounder will also present an assessment of the GODDESS® (GOunder/Desmoid Tumor Research Foundation DEsmoid Symptom/Impact Scale) tool for evaluating changes in disease-specific symptom severity and impact in desmoid tumors as assessed in the DeFi trial. SpringWorks plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2022 for review under the FDA's Real-Time Oncology Review (RTOR) program.

- In September 2022, the first patient was dosed in a Phase 2 trial evaluating nirogacestat as a monotherapy in patients with recurrent ovarian granulosa cell tumors.
- Dosing is ongoing in the Phase 2b ReNeu trial evaluating mirdametinib in adult and pediatric patients with NF1-associated plexiform neurofibromas (NF1-PN). As previously announced, this trial is fully enrolled. SpringWorks expects to provide an update on the ReNeu trial in the first half of 2023.

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 September 2022, SpringWorks announced that it entered into an expanded global, non-exclusive license and collaboration agreement with GSK plc (GSK) for nirogacestat in combination with belantamab mafodotin (belamaf) in patients with multiple myeloma. The expanded agreement includes the potential for continued development and commercialization of the combination of belamaf and nirogacestat in earlier lines of treatment, including in newly diagnosed multiple myeloma patients. In connection with the expanded agreement, SpringWorks received a \$75 million equity investment from GSK and is also eligible to receive up to \$550 million in development and commercial milestones. SpringWorks continues to retain full commercial rights to nirogacestat. Additionally, SpringWorks will supply nirogacestat for future belamaf clinical trials and will seek to make nirogacestat commercially available in markets where approval has been sought by GSK for a combination with belamaf. GSK continues to fund all development costs, except for those related to the supply of nirogacestat and certain expenses related to intellectual property rights.
- A Phase 2 randomized DREAMM-5 study is ongoing evaluating low-dose belamaf in combination with nirogacestat in patients with relapsed or refractory multiple myeloma. In addition, two new sub-studies evaluating belamaf plus nirogacestat in combination with standard of care agents in patients with relapsed or refractory multiple myeloma have been initiated and are dosing patients: sub-study 6 (belamaf plus nirogacestat plus lenalidomide plus dexamethasone) and sub-study 7 (belamaf plus nirogacestat plus pomalidomide plus dexamethasone).
- In September 2022, SpringWorks entered into a collaborative study agreement with GSK and Memorial Sloan Kettering Cancer Center (MSKCC) to conduct a Phase 1b study to evaluate the combination of belamaf and nirogacestat in patients with relapsed/refractory multiple myeloma. Malin Hultcrantz, M.D., Ph.D. will serve as the principal investigator of the study.

Biomarker-Defined Metastatic Solid Tumors

- The BeiGene-sponsored Phase 1b/2 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.
- The Phase 1 trial evaluating BGB-3245, a selective RAF dimer inhibitor being developed by MapKure, LLC, a joint venture between SpringWorks and BeiGene, in adult patients with RAF mutant solid tumors is ongoing. SpringWorks expects data from this trial to be presented at a medical conference in the first half of 2023. BGB-3245 monotherapy is advancing into cohort expansion studies and SpringWorks expects to begin dosing a Phase 1/2a combination study of BGB-3245 and mirdametinib in the first half of 2023.

General Corporate

- In July 2022, SpringWorks appointed Carlos Albán to its Board of Directors. Mr. Albán previously served as Vice Chairman and Chief Commercial Officer at AbbVie until his retirement last year and brings over 30 years of experience in global commercial strategy and operations.
- In August 2022, SpringWorks sold approximately 2.25 million shares of its common stock as pursuant to its at-the-market (ATM) offering program, raising approximately \$67.8 million in net proceeds. In September 2022, SpringWorks sold approximately 8.65 million shares of its common stock to a select group of institutional investors in a private placement transaction, raising approximately \$216.8 million in net proceeds.

Third Quarter 2022 Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses were \$36.1 million for the third quarter, compared to \$22.9 million for the comparable period of 2021. The increase in R&D expense was primarily attributable to an increase in external costs related to drug manufacturing, clinical trial and other research, and 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.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$35.7 million for the third quarter, compared to \$18.0 million for the comparable period 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 \$72.4 million, or \$1.37 per share, for the third quarter of 2022. This compares to a net loss of \$41.0 million, or \$0.84 per share, for the comparable period of 2021.
- **Cash Position:** Cash, cash equivalents and marketable securities were \$651.9 million as of September 30, 2022. This includes net proceeds of approximately \$67.8 million received pursuant to sales under the Company's ATM program, net proceeds of approximately \$216.8 million from a private placement in September 2022, and proceeds from an equity investment of \$75.0 million from GSK in September 2022 related to the expanded global, non-exclusive license and collaboration agreement between SpringWorks and GSK.

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 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 ongoing and continued progression of our clinical trials, our plans to report additional data from the Phase 3 DeFi clinical trial at an upcoming medical conference, the potential for the results of the Phase 3 DeFi clinical trial to support an NDA submission, the timing of our planned NDA submission for nirogacestat, and our plans for seeking regulatory approval for and making nirogacestat available to desmoid tumor 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 begin dosing a Phase 1/2a combination study of BGB-3245 and mirdametinib 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, including the NDA for nirogacestat planned for the fourth quarter of 2022 and the timing and outcome of decisions made by the U.S. Food and Drug Administration (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 establish manufacturing capabilities, and our and our collaboration partners’ abilities to manufacture our product candidates and scale production, (x) our ability to meet any specific milestones set forth herein, and (xi) 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’ Quarterly Report on Form 10-Q for the quarter ended September 30, 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)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	36,067	22,866	108,194	72,332
General and administrative	35,673	18,029	94,026	45,340
Total operating expenses	71,740	40,895	202,220	117,672
Loss from operations	(71,740)	(40,895)	(202,220)	(117,672)
Interest and other income (expense):				
Other expense, net	(74)	(58)	(291)	(96)
Interest income, net	912	179	1,482	617
Total interest and other income	838	121	1,191	521
Equity investment loss	(1,486)	(267)	(2,210)	(687)
Net loss	\$ (72,388)	\$ (41,041)	\$ (203,239)	\$ (117,838)
Net loss per share, basic and diluted	\$ (1.37)	\$ (0.84)	\$ (4.04)	\$ (2.43)
Weighted average common shares outstanding, basic and diluted	52,900,819	48,595,420	50,298,015	48,417,300

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

(in thousands)	September 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	\$ 651,943	\$ 432,731
Working Capital (1)	607,793	352,941
Total assets	681,554	452,494
Total liabilities	69,154	30,098
Accumulated deficit	(495,752)	(292,513)
Total stockholders' equity	612,400	422,396

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

Contacts:

Kim Diamond
Vice President, Communications and Investor Relations
Phone: 203-561-1646
Email: kdiamond@springworkstx.com

Samantha Hilson Sandler
Director, Investor Relations
Phone: 203-461-5501
Email: samantha.sandler@springworkstx.com