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): August 04, 2022

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 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 August 4, 2022, SpringWorks Therapeutics, Inc. announced its financial results for the quarter ended June 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 August 4, 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: August 4, 2022

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

Francis I. Perier, Jr.

Chief Financial Officer

Exhibit 99.1

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

– Phase 3 DeFi Trial Evaluating Nirogacestat in Adult Patients with Progressing Desmoid Tumors Met Its Primary and All Key Secondary Endpoints –

– Encouraging Preliminary Data from Phase 1/2 Study Evaluating Nirogacestat in Combination with Low Dose Belantamab Mafodotin in Patients with Relapsed or Refractory Multiple Myeloma Presented at ASCO; Combination Continues in Ongoing Phase 2 Trial and Expands into Additional Sub-Studies with Standard of Care Agents –

– Mirdametinib Monotherapy and Combination Therapy Studies in Rare Oncology Indications and Biomarker-Defined Solid Tumors Continue to Progress –

– BGB-3245 Monotherapy to Advance into Cohort Expansion Studies and Combination Study of BGB-3245 and Mirdametinib Planned to Initiate in 2H 2022 –

STAMFORD, Conn., August 4, 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 second quarter financial results for the period ended June 30, 2022 and provided an update on recent company developments.

“In the second quarter of 2022, we were very pleased to report positive data across each of our core focus areas of rare oncology, BCMA combinations in multiple myeloma, and biomarker-defined metastatic solid tumors, most notably the positive topline data from the Phase 3 DeFi trial as well as encouraging preliminary data from the study evaluating nirogacestat with low-dose belantamab mafodotin in patients with multiple myeloma," said Saqib Islam, Chief Executive Officer of SpringWorks. "The second half of 2022 will be focused on continued preparation for our first potential product launch, including submitting our NDA for nirogacestat in desmoid tumors and progressing the commercial preparations to serve patients with desmoid tumors while continuing to advance our diversified targeted oncology pipeline."

Recent Business Highlights and Upcoming Milestones

Rare Oncology

- In May 2022, SpringWorks announced positive topline results from the Phase 3 DeFi trial evaluating nirogacestat in adult patients with progressing desmoid tumors. The DeFi trial met its primary endpoint of improving progression-free survival, or PFS, 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, the trial met all key secondary endpoints, with nirogacestat demonstrating statistically significant improvements as compared to placebo in objective response rate, and patient-reported outcomes. Nirogacestat was generally well tolerated with a manageable safety profile. Additional data are expected to be presented at a medical conference in the second half of 2022 and published in a peer-reviewed journal publication. In addition, SpringWorks plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in the second half of 2022, which will be reviewed under the FDA’s Real-Time Oncology Review (RTOR) program.
- In June 2022, updated data from the National Cancer Institute, or NCI, sponsored Phase 2 study of nirogacestat in patients with progressing desmoid tumors were presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. Of the 16 evaluable patients, no disease progression has been observed for any patient while on study. The median time on treatment for

all evaluable patients was 4.4 years (range 0.17-7.99 years) with 4/16 patients remaining on treatment over 7 years.
- 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.
- Recruitment is ongoing in a Phase 1/2 clinical trial evaluating mirdametinib in children and young adults with low-grade glioma. Initial data from the first 11 patients treated across two initial dose levels during the Phase 1 dose escalation study were presented at the International Symposium on Pediatric Neuro-Oncology (ISPNO) 2022 meeting.

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 eight industry leaders. Five studies are currently ongoing: nirogacestat + GSK's belantamab mafodotin, nirogacestat + Allogene's ALLO-715, nirogacestat + Janssen's teclistamab, nirogacestat + Precision Biosciences' PBCAR269A, and nirogacestat + Pfizer's elranatamab; three additional studies are planned: nirogacestat + Seagen's SEA-BCMA, nirogacestat + AbbVie's ABBV-383, and nirogacestat + Regeneron's REGN5458.
- In June 2022, initial clinical data from the GSK-sponsored Phase 1/2 study evaluating nirogacestat in combination with low-dose belantamab mafodotin in patients with relapsed or refractory multiple myeloma were presented at the 2022 ASCO Annual Meeting. At the time of data cut-off, the objective response rate at low-dose (0.95 mg/kg) belantamab mafodotin plus nirogacestat across the dose escalation, or DE, and cohort expansion, or CE, arms was 38% in 24 patients, with 17% of patients achieving a very good partial response or better. An encouraging safety profile for the combination was observed, with Grade 3 ocular adverse events occurring in 1/14 (7%) patients in the CE cohort with the low-dose belantamab mafodotin plus nirogacestat combination compared to 7/14 patients (50%) in the belantamab mafodotin monotherapy arm, using the Keratopathy Visual Acuity, or KVA, ocular toxicity grading scale. The DE cohort utilized the CTCAE-5 ocular toxicity grading scale; the low-dose belantamab mafodotin plus nirogacestat combination demonstrated Grade 3 ocular adverse events in 2/10 (20%) patients. SpringWorks expects the next data cut from the randomized Phase 2 cohort expansion study to occur towards end of 2022. In addition, new sub-studies will evaluate low-dose belantamab mafodotin and nirogacestat with lenalidomide/dexamethasone and pomalidomide/dexamethasone to support potential development in earlier lines of therapy.
- In July 2022, SpringWorks entered into a co-supported collaborative study agreement with GSK and the Hellenic Society of Haematology to conduct a Phase 1/2 study to evaluate low-dose belantamab mafodotin and nirogacestat in combination with lenalidomide and dexamethasone in transplant-ineligible newly diagnosed multiple myeloma patients. Evangelos Terpos, MD, PhD, Professor of Hematology in the Department of Clinical Therapeutics of the National & Kapodistrian University of Athens, School of Medicine, Athens, Greece will serve as the principal investigator of the study.

Biomarker-Defined Metastatic Solid Tumors

- Initial clinical data from 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 were presented at a SpringWorks-sponsored R&D Day in June 2022. Clinical responses were observed across a range of MAPK-altered tumors during the dose escalation portion of the study and there was evidence of acceptable safety and tolerability with multiple patients exposed to the combination for more than two years. SpringWorks expects these data to be presented at a medical conference in the second half of 2022.
- Initial clinical data from a 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 were presented at a SpringWorks-sponsored R&D Day in June

2022. Objective responses were seen in patients with BRAF, KRAS, and NRAS mutations, including in some patients who had exhausted standard of care therapeutic options, and the emerging safety profile of BGB-3245 is consistent with other MAPK pathway inhibitors. SpringWorks expects these data to be presented at a medical conference in the second half of 2022. BGB-3245 monotherapy is advancing into cohort expansion studies and SpringWorks expects to initiate a combination study of BGB-3245 and mirdametinib in the second half of 2022. To support the further advancement of BGB-3245, an additional equity financing in MapKure was completed in June 2022, which included participation from SpringWorks and BeiGene.

- In July 2022, SpringWorks entered into a Cooperative Research and Development Agreement (CRADA) with the NCI Cancer Therapy Evaluation Program (CTEP) to collaborate on the non-clinical and clinical development of mirdametinib.

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.

Second Quarter 2022 Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses were $38.0 million for the second quarter, compared to $32.1 million for the comparable period of 2021. The increase in R&D 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, and an increase in external costs related to drug manufacturing, clinical trial and other research, partially offset by a decrease in licensing costs related to the nonrefundable upfront payment to KU Leuven and VIB for the in-licensing of the TEAD inhibitor program in May 2021.
- **General and Administrative (G&A) Expenses**: G&A expenses were $31.0 million for the second quarter, compared to $14.9 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 net loss of $69.1 million, or $1.41 per share, for the second quarter of 2022. This compares to a net loss of $47.0 million, or $0.97 per share, for the comparable period of 2021.
- **Cash Position:** Cash, cash equivalents and marketable securities were $334.5 million as of June 30, 2022.

COVID-19 Update

To date, the COVID-19 pandemic has had a relatively modest impact on SpringWorks' business operations, in particular on SpringWorks' clinical trial programs, and SpringWorks is undertaking considerable efforts to mitigate the various challenges presented by this crisis. For further details and descriptions of the risks associated with the COVID-19 pandemic, please see the Risk Factors in SpringWorks' periodic filings with the Securities and Exchange Commission, or SEC, and refer to the Forward-Looking Statements section in this press release.

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 potentially registrational 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 additional data from the dose escalation portion of the Phase 1b/2 trial evaluating mirdametinib with lifirafenib at an upcoming medical conference, our plans to report additional data from the Phase 1b/2a platform study evaluating BGB-3245 at an upcoming medical conference, 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 from the Phase 3 DeFi trial or topline or interim data from other 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 second half 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, (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 June 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 June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Operating expenses:				
Research and development	$ 38,024	$ 32,091	$ 72,127	$ 49,466
General and administrative	30,987	14,930	58,353	27,311
Total operating expenses	69,011	47,021	130,480	76,777
Loss from operations	(69,011)	(47,021)	(130,480)	(76,777)
Interest and other income (expense):				
Other expense, net	(24)	(41)	(217)	(38)
Interest income, net	372	211	570	438
Total interest and other income	348	170	353	400
Equity investment loss	(387)	(159)	(724)	(420)
Net loss	$ (69,050)	$ (47,010)	$ (130,851)	$ (76,797)
Net loss per share, basic and diluted	$ (1.41)	$ (0.97)	$ (2.67)	$ (1.59)
Weighted average common shares outstanding, basic and diluted	49,071,590	48,422,921	48,989,690	48,326,764

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

(in thousands)	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 334,541	$ 432,731
Working Capital (1)	307,085	352,941
Total assets	365,919	452,494
Total liabilities	40,185	30,098
Accumulated deficit	(423,364)	(292,513)
Total stockholders' equity	325,734	422,396

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

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