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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 04, 2021**

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**SPRINGWORKS THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

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**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)

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Check the appropriate box below if the Form 8K 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.

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**Item 2.02. Results of Operations and Financial Condition.**

On November 4, 2021, SpringWorks Therapeutics, Inc. announced its financial results for the quarter ended September 30, 2021. 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.**

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release issued by SpringWorks Therapeutics, Inc. on November 4, 2021, furnished herewith.</a>
104	Cover page interactive data file (embedded within the Inline XBRL document)

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**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 4, 2021

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

Francis I. Perier, Jr.

Chief Financial Officer



## SpringWorks Therapeutics Reports Third Quarter 2021 Financial Results and Recent Business Highlights

- *Announced Advancement into Randomized Phase 2 Expansion and Addition of New Sub-studies to Existing Clinical Collaboration with GlaxoSmithKline Evaluating Nirogacestat in Combination with BLENREP in Patients with Relapsed or Refractory Multiple Myeloma –*
- *Expanded Targeted Oncology Pipeline with In-License of Portfolio of Next-Generation Mutation-Selective EGFR Inhibitors –*
- *Initiated Mirdametinib Phase 1/2 Basket Study in ER+ Metastatic Breast Cancer and MEK 1/2 Mutant Solid Tumors –*
- *Announced Issuance of New U.S. Composition of Matter Patents to Polymorphic Form of Mirdametinib, Extending Patent Protection Into 2041 –*

**STAMFORD, Conn., November 4, 2021** – 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 third quarter and year-to-date periods ended September 30, 2021 and provided an update on recent company developments.

“In the third quarter of 2021, we continued to execute across our diversified portfolio of targeted oncology programs being evaluated as standalone and combination therapies for patients with rare tumors, hematological cancers and biomarker-defined metastatic solid tumors,” said Saqib Islam, Chief Executive Officer of SpringWorks. “Our team remains focused on advancing our 16 development programs on behalf of oncology patients while simultaneously building our commercial organization in anticipation of serving patients with desmoid tumors as well as expanding our drug discovery capabilities to continue growing our early-stage pipeline.”

### Recent Business Highlights and Upcoming Milestones

#### **Late-Stage Rare Oncology**

- SpringWorks is conducting the Phase 3 DeFi trial evaluating nirogacestat in adult patients with progressing desmoid tumors. DeFi is an event-driven trial with a primary endpoint of progression-free survival. SpringWorks expects to reach the 51 events required for the study analysis by the end of the year. The Company expects to report topline results from the study, after data validation and analysis, by the end of the fourth quarter of 2021 or in early 2022.
- Recruitment is ongoing in a Phase 2 study sponsored by the Children’s Oncology Group evaluating nirogacestat in pediatric patients with desmoid tumors.
- SpringWorks expects to complete enrollment in the Phase 2b ReNeu trial evaluating mirdametinib in adult and pediatric patients with NF1-associated plexiform neurofibromas (NF1-PN) in the second half of 2021, as previously disclosed.
- Patients continue to be dosed in a Phase 1/2 clinical trial evaluating mirdametinib in children and young adults with low-grade glioma.

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

- In October 2021, SpringWorks announced an update from its ongoing clinical collaboration with GlaxoSmithKline evaluating nirogacestat in combination with BLENREP (belantamab mafodotin-blmf) in patients with relapsed or refractory multiple myeloma. The first combination dose level, which is evaluating 0.95 mg/kg Q3W BLENREP plus nirogacestat, has been expanded based on encouraging preliminary data observed in the dose exploration Phase 1 portion of the nirogacestat DREAMM-5 sub-study. This dose level has advanced into a randomized Phase 2 cohort expansion and is now enrolling patients to further explore the safety and efficacy profile compared to a 2.5 mg/kg Q3W BLENREP monotherapy control arm, which is the same as the FDA approved monotherapy dose and schedule of BLENREP. In parallel, additional dose levels and schedules of BLENREP plus nirogacestat continue to be evaluated in the Phase 1 portion of the study. In addition, two new sub-studies will evaluate the BLENREP plus nirogacestat combination with standard-of-care multiple myeloma therapies in the DREAMM-5 trial (pomalidomide plus dexamethasone and lenalidomide plus dexamethasone). Data from these two new sub-studies may enable future clinical trials in earlier lines of multiple myeloma.
- SpringWorks continues to evaluate nirogacestat as a potential cornerstone of BCMA-directed therapy across modalities in collaboration with six industry leaders. In addition to the current ongoing studies, SpringWorks expects that a Pfizer-sponsored trial of nirogacestat + elranatamab (PF-0686313) will initiate enrollment in the second half of 2021, as previously disclosed, and a Seagen-sponsored trial of nirogacestat + SEA-BCMA will initiate enrollment in the first quarter of 2022.
- In August 2021, SpringWorks entered into a research collaboration agreement with Dana-Farber Cancer Institute to further investigate nirogacestat with anti-BCMA agents in a variety of preclinical multiple myeloma models.

## Biomarker-Defined Metastatic Solid Tumors

- Enrollment is ongoing in a 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. Initial clinical data from the BeiGene-sponsored trial are expected to be presented at an upcoming SpringWorks-sponsored R&D Day.
- Enrollment is ongoing in a Phase 1 trial of BGB-3245 in adult patients with RAF mutant solid tumors. BGB-3245 is a selective RAF dimer inhibitor being developed by MapKure, LLC, a joint venture between SpringWorks and BeiGene. Initial clinical data from the MapKure-sponsored trial are expected to be presented at an upcoming SpringWorks-sponsored R&D Day.
- In August 2021, SpringWorks announced a platform study sponsored by Memorial Sloan Kettering Cancer Center to evaluate mirdametinib both as a monotherapy and as a combination therapy in advanced solid tumors harboring selected MAPK-activating mutations. This trial initiated enrollment in September 2021 and is exploring mirdametinib in two patient cohorts: the first in combination with fulvestrant, a selective estrogen receptor degrader, in patients with estrogen receptor-positive metastatic breast cancer with MAPK alterations, and the second as a monotherapy in advanced solid tumors harboring oncogenic *MEK1* or *MEK2* mutations.
- In October 2021, SpringWorks entered into an exclusive worldwide license agreement with Dana-Farber Cancer Institute (Dana-Farber) and a sponsored research agreement with Stanford Medicine for a portfolio of novel small molecule inhibitors of Epidermal Growth Factor Receptor (EGFR) designed for the treatment of EGFR-mutant cancers. In addition, SpringWorks entered into a collaboration agreement with Ab Magnitude Ventures Group, LLC and Ab Magnitude Fund, LP (collectively, "Ab Magnitude") to collaborate on target discovery and initial hit finding to advance next generation oncology therapeutics. SpringWorks and Ab Magnitude will also collaborate on the portfolio of EGFR inhibitors licensed by SpringWorks from Dana-Farber, with Ab Magnitude supporting optimization and characterization of the portfolio using its computational structural biology platform.

## General Corporate

- In the second half of 2021, the United States Patent and Trademark Office issued two new composition of matter patents, U.S. Patent Nos. 11,066,358 and 11,084,780, covering several polymorphic forms of mirdametinib, including the polymorphic form that is currently in clinical development. These patents expire in 2041.

### Third Quarter 2021 Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses were \$22.9 million for the third quarter, compared to \$13.9 million for the comparable period of 2020. The increases in R&D expenses were attributable to an increase in internal costs driven by the growth in employee costs associated with increases in the number of R&D personnel and an increase in stock-based compensation expense as well as an increase in external costs related to drug manufacturing and trial costs.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$18.0 million for the third quarter, compared to \$7.7 million for the comparable period of 2020. The increases in G&A expenses were primarily attributable to the hiring of additional personnel in our G&A functions, as we continued to expand our operations to support the organization, including commercialization preparation efforts that are underway, and an increase in stock-based compensation expense. In addition, G&A expenses included an increase in information technology costs, and consulting and professional services, including legal, regulatory and compliance.
- **Net Loss Attributable to Common Stockholders:** SpringWorks reported net loss of \$41.0 million, or \$0.84 per share, for the third quarter of 2021. This compares to a net loss of \$21.7 million, or \$0.51 per share, for the comparable period of 2020.
- **Cash Position:** Cash, cash equivalents and marketable securities were \$480.6 million as of September 30, 2021.

### 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 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 portfolio of small molecule product candidates and is advancing 16 development programs, 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 expand its portfolio and create more solutions for patients with cancer. For more information, visit [www.springworkstx.com](http://www.springworkstx.com) and follow @SpringWorksTx on [Twitter](https://twitter.com/SpringWorksTx) and [LinkedIn](https://www.linkedin.com/company/springworkstx).

*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 press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding SpringWorks' clinical trials and its strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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, those related to SpringWorks' financial results, the timing for initiation, progress and completion of SpringWorks' clinical trials or third-party clinical trials of its product candidates, the timing for expected data readouts from partners and partners' clinical trials, the expected benefits of collaborations, the fact that interim results from a clinical study may not be predictive of the final results of such study or the results of other ongoing or future studies, whether and when, if at all, SpringWorks' product candidates will receive approval from the U.S. Food and Drug Administration, or FDA, or other foreign regulatory authorities, uncertainties and assumptions regarding the impact of the COVID-19 pandemic on SpringWorks' business, operations, clinical trials involving its product candidates, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, and other risks identified in SpringWorks' SEC filings. SpringWorks cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. SpringWorks disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent SpringWorks' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

**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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 22,866	\$ 13,923	\$ 72,332	\$ 36,597
General and administrative	18,029	7,669	45,340	20,946
Total operating expenses	40,895	21,592	117,672	57,543
Loss from operations	(40,895)	(21,592)	(117,672)	(57,543)
Interest and other income:				
Other income	(58)	—	(96)	—
Interest income, net	179	63	617	1,156
Total interest and other income	121	63	521	1,156
Equity investment loss	(267)	(130)	(687)	(459)
Net loss	\$ (41,041)	\$ (21,659)	\$ (117,838)	\$ (56,846)
Net loss per share, basic and diluted	\$ (0.84)	\$ (0.51)	\$ (2.43)	\$ (1.35)
Weighted average common shares outstanding, basic and diluted	48,595,420	42,148,837	48,417,300	41,961,691

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

(in thousands)	September 30, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	\$ 480,643	\$ 561,820
Working Capital (1)	404,914	495,788
Total assets	495,275	576,191
Total liabilities	28,597	19,133
Accumulated deficit	(236,441)	(118,603)
Total stockholders' equity	466,678	557,058

<sup>(1)</sup> We define Working Capital as current assets less current liabilities.

**Contact:**

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