
**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 25, 2021

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 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(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 (§ 240.12b-2 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 25, 2021, SpringWorks Therapeutics, Inc. announced its financial results for the fourth quarter and year ended December 31, 2020. 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	<u>Press Release issued by SpringWorks Therapeutics, Inc. on February 25, 2021, furnished herewith.</u>

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 25, 2021

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

Francis I. Perier, Jr.

Chief Financial Officer



SpringWorks Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Recent Business Highlights

- *Reported Interim Data from Phase 2b ReNeu Trial of Mirdametinib in NF1-PN Demonstrating Encouraging Clinical Activity and Tolerability in the First 20 Adult Patients Enrolled -*
- *Allogene- and Janssen-Sponsored Phase 1 Trials Evaluating Nirogacestat in Combination with BCMA Therapies Have Initiated -*
 - *Continued to Strengthen Nirogacestat Patent Portfolio -*
- *Multiple Data Readouts Expected in 2021 Across Pipeline, Including Topline Data from Phase 3 DeFi Trial in Desmoid Tumors and Initial Nirogacestat BCMA Combination Data -*
 - *Ended 2020 with \$561.8 Million in Cash, Cash Equivalents and Marketable Securities -*

STAMFORD, Conn – February 25, 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 fourth quarter and full-year financial results for the period ended December 31, 2020 and provided an update on recent company developments.

“2020 was a year characterized by strong performance for SpringWorks as we advanced our diversified targeted oncology portfolio, which currently spans 10 development programs across our three core focus areas: late-stage rare oncology, BCMA combinations in multiple myeloma and biomarker-defined metastatic solid tumors,” said Saqib Islam, Chief Executive Officer of SpringWorks. “Our clinical execution has set the stage for multiple important data readouts in 2021, including the interim ReNeu data announced this morning and topline data from our Phase 3 DeFi trial later this year, and our business development efforts have allowed us to pursue additional combination therapy programs, continuing to grow our portfolio of opportunities across a broad range of potentially high-value and high-unmet need oncology patient settings. We look forward to reporting on our progress throughout 2021.”

Recent Business Highlights and Upcoming Milestones

Late-Stage Rare Oncology

- In February 2021, SpringWorks reported interim data from the adult stratum of the ongoing potentially registrational Phase 2b ReNeu trial evaluating mirdametinib in pediatric and adult patients with NF1-associated plexiform neurofibromas. Of the first 20 adult patients enrolled, 50% had achieved an objective response, the primary endpoint of the study, as assessed by blinded independent central review, and 16 of these 20 patients (80%) remained on study as of the January 22, 2021 data cutoff. In addition, mirdametinib was generally well tolerated, with the majority of treatment-related adverse events (TRAE) being Grade 1 or 2 and only one Grade 3 TRAE reported; there have been no Grade 4 or 5 AEs reported. SpringWorks reported that the ReNeu trial has reached approximately 70% of its final enrollment target of 100 patients and the Company expects to complete enrollment of the ReNeu trial in the second half of 2021.
 - SpringWorks expects to report topline data from the Phase 3 DeFi trial in the second half of 2021.
 - Recruitment is ongoing in a Phase 2 study sponsored by the Children’s Oncology Group evaluating nirogacestat in pediatric patients with desmoid tumors.
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B-cell Maturation Antigen (BCMA) Combinations in Multiple Myeloma

- Enrollment is ongoing in a Phase 1b trial sponsored by GSK evaluating nirogacestat in combination with BLENREP (belantamab mafodotin-blmf), GSK's anti-B-cell maturation antigen (BCMA) antibody-drug conjugate, in adult patients with relapsed or refractory multiple myeloma. Initial clinical data from this study are expected in 2021.
- Two collaborator-sponsored Phase 1 studies were initiated evaluating nirogacestat in combination with BCMA therapies: nirogacestat + Allogene's ALLO-715 and nirogacestat + Janssen's teclistamab. SpringWorks also expects that two additional collaborator-sponsored trials will initiate in the first half of 2021, as previously disclosed: nirogacestat + Pfizer's elranatamab (PF-06863135) and nirogacestat + Precision's PBCAR269A.

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. BeiGene is sponsoring this trial and SpringWorks and BeiGene expect to report initial clinical data in 2021.
- 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 Phase 1 trial are expected in 2021.
- In December 2020, SpringWorks entered into a research collaboration agreement with Dr. Tatu Pentsar and Dr. Antti Poso at the University of Eastern Finland to conduct novel computational biology research to characterize the effector protein dynamics of different RAS mutations. The objective of the collaboration is to understand the biological consequences of KRAS-effector protein interactions and downstream oncogenic signaling with the goal of guiding patient selection strategies and exploring novel targets for future targeted therapy development.

General Corporate

- In February 2021, a Notice of Allowance was received from the United States Patent and Trademark Office for Patent Application No. 16/886,622 (the '622 application) with composition of matter claims covering several polymorphic forms of nirogacestat, including the polymorphic form that is currently in clinical development, which is also covered by U.S. Patent 10,590,087 (the '087 patent, issued in March 2020). Pursuant to an existing worldwide license agreement with Pfizer, SpringWorks has exclusive rights to the patent issuing from the '622 application. The patent granting from the '622 application, as well as the '087 patent, will both expire in August 2039.
 - In October 2020, SpringWorks completed a follow-on public offering that raised \$269.5 million in net proceeds, which included the underwriters' full exercise of their option to purchase additional shares of common stock.
 - In October 2020, SpringWorks and Jazz Pharmaceuticals entered into an asset purchase and exclusive license agreement under which Jazz acquired SpringWorks' fatty acid amide hydrolase (FAAH) inhibitor program. Under the terms of the agreement, Jazz made an upfront payment of \$35 million to SpringWorks, with potential future milestone payments of up to \$375 million payable to SpringWorks based upon the achievement of certain clinical development, regulatory and commercial milestones. In addition, SpringWorks will receive incremental tiered royalties on future net sales of JZP-150 (formerly PF-04457845) in the mid- to high-single digit percentages.
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Fourth Quarter and Full Year 2020 Financial Results

- **Revenue:** Revenue of \$35.0 million for the fourth quarter and year ended December 31, 2020 was attributable to the nonrefundable upfront payment from Jazz in October 2020, related to the asset purchase and exclusive license agreement between SpringWorks and Jazz.
- **Research and Development (R&D) Expenses:** R&D expenses were \$15.3 million and \$51.9 million for the fourth quarter and year-to-date periods, respectively, compared to \$12.2 million and \$42.5 million for the comparable periods of 2019. The increases in R&D expenses in 2020 were primarily attributable to growth in employee costs associated with increases in the number of R&D personnel, including non-cash share-based compensation expenses, and increases in external costs related to drug manufacturing and clinical trial costs.
- **General and Administrative (G&A) Expenses:** G&A expenses were \$8.5 million and \$29.5 million for the fourth quarter and year-to-date periods, respectively, compared to \$5.2 million and \$16.7 million for the comparable periods of 2019. The increases in G&A expenses in 2020 were primarily attributable to growth in employee costs associated with increases in the number of G&A personnel supporting the growth of the organization, including non-cash share-based compensation expenses, as well as increases in expenses related to the expansion of business activities.
- **Net Loss Attributable to Common Stockholders:** SpringWorks reported net income of \$11.3 million, or \$0.24 per share, for the fourth quarter, and a net loss of \$45.6 million, or \$1.05 loss per share, for the year ended December 31, 2020. This compares to net losses of \$16.2 million, or \$0.39 loss per share, and \$50.6 million, or \$3.81 loss per share, for the comparable periods of 2019, respectively.
- **Cash Position:** Cash, cash equivalents and marketable securities were \$561.8 million as of December 31, 2020. This includes the net proceeds of \$269.5 million from the Company's follow-on public offering completed in October 2020, and the \$35.0 million upfront payment from Jazz Pharmaceuticals in October 2020, related to the asset purchase and exclusive license agreement between SpringWorks and Jazz.

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 underserved patient populations suffering from devastating rare diseases and cancer. SpringWorks has a differentiated portfolio of small molecule targeted oncology product candidates and is advancing two potentially registrational clinical trials in rare tumor types, as well as several other 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 industry leaders to expand its portfolio. 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 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 completion of SpringWorks' clinical trials or third-party clinical trials of its product candidates, 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.
Consolidated Statements of Operations
(Unaudited)

(in thousands, except share, unit, per-unit and per-share data)	Year Ended December 31,		
	2020	2019	2018
Licensing revenue	\$ 35,000	\$ —	\$ —
Operating expenses:			
Research and development	51,859	42,545	9,898
General and administrative	29,465	16,694	8,593
Total operating expenses	81,324	59,239	18,491
Loss from operations	(46,324)	(59,239)	(18,491)
Other income:			
Other income	25	—	—
Interest income, net	1,330	3,547	678
Total other income	1,355	3,547	678
Equity investment loss	(605)	(2,614)	—
Net loss	\$ (45,574)	\$ (58,306)	\$ (17,813)
Reconciliation of net loss to net loss attributable to common stockholders and unit holders:			
Net loss	\$ (45,574)	\$ (58,306)	\$ (17,813)
Net gain attributable to extinguishment of Series A convertible preferred and Junior Series A convertible preferred units	—	7,729	—
Net loss attributable to common stockholders and unit holders, basic and diluted	\$ (45,574)	\$ (50,577)	\$ (17,813)
Net loss per unit, basic and diluted	\$ —	\$ —	\$ (52.24)
Net loss per share, basic and diluted	\$ (1.05)	\$ (3.81)	\$ —
Weighted average common units outstanding, basic and diluted	—	—	341,014
Weighted average common shares outstanding, basic and diluted	43,300,063	13,274,836	—

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

(in thousands)	As of December 31,	
	2020	2019
Cash, cash equivalents and marketable securities	\$ 561,820	\$ 327,652
Working Capital ⁽¹⁾	495,788	319,391
Total Assets	576,191	334,831
Total liabilities	19,133	12,759
Accumulated deficit	(118,603)	(73,029)
Total stockholders' (deficit) equity	557,058	322,072

⁽¹⁾ We define working capital as current assets less current liabilities.

Contact:

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