

**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): May 2, 2024

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

Delaware <small>(State or other jurisdiction of incorporation)</small>	001-39044 <small>(Commission File Number)</small>	83-4066827 <small>(IRS Employer Identification No.)</small>
100 Washington Blvd Stamford, CT <small>(Address of principal executive offices)</small>		06902 <small>(Zip Code)</small>

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 May 2, 2024, SpringWorks Therapeutics, Inc. announced its financial results for the quarter ended March 31, 2024. 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 and is incorporated herein by reference.

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 May 2, 2024, 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: May 2, 2024

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

Francis I. Perier, Jr.

Chief Financial Officer



SpringWorks Therapeutics Reports First Quarter 2024 Financial Results and Highlights Recent Business Updates

- Achieved \$21.0 million in OGSIVEO® (nirogacestat) net product revenue in the first quarter –
- Received validation from the EMA for MAA of nirogacestat for the treatment of adults with desmoid tumors –
- Initiated rolling submission of NDA to the FDA for mirdametinib for the treatment of children and adults with NF1-PN –
- Phase 2b ReNeu trial results accepted for oral presentation at the 2024 ASCO Annual Meeting –

STAMFORD, Conn., May 2, 2024 – SpringWorks Therapeutics, Inc. (Nasdaq: SWTX), a commercial-stage biopharmaceutical company focused on severe rare diseases and cancer, today reported first quarter financial results for the period ended March 31, 2024 and provided an update on recent company developments.

"We are very encouraged by the strong start to the OGSIVEO launch and are focused on continuing our momentum towards establishing OGSIVEO as the standard of care treatment for adults with desmoid tumors," said Saqib Islam, Chief Executive Officer of SpringWorks. "We are also pleased to have initiated the rolling NDA submission for mirdametinib in children and adults with NF1-PN, which would be our second marketed product serving another group of patients who are currently suffering with a high unmet need, if approved. We are making significant progress across our commercial, development and corporate objectives and look forward to providing updates throughout the year."

Recent Business Highlights and Upcoming Milestones

OGSIVEO® (Nirogacestat)

- Strong execution in the first full quarter of launch, with net product revenue of \$21.0 million in the first quarter of 2024.
- Received U.S. Food and Drug Administration (FDA) approval of a Supplemental New Drug Application (NDA) for OGSIVEO 150 mg and 100 mg tablets in new blister packaging, which have been developed to enhance patient convenience with OGSIVEO. The blister packs are expected to be on the market in mid-May 2024.
- Received validation from the European Medicines Agency (EMA) on a Marketing Authorization Application (MAA) for nirogacestat for the treatment of adult patients with desmoid tumors in February 2024.
- Additional data from the Phase 3 DeFi trial of nirogacestat in adults with desmoid tumors were accepted for presentation at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting. An abstract describing the onset and resolution of ovarian toxicity for desmoid tumor patients treated with nirogacestat was selected as an oral presentation to be delivered on May 31, 2024. Two additional sub-group analyses evaluating nirogacestat in desmoid tumor patients with poor prognostic factors and in those with adenomatous polyposis (APC) mutations will also be presented on June 1, 2024.
- On track to report initial data from the Phase 2 trial evaluating nirogacestat as a monotherapy in patients with recurrent ovarian granulosa cell tumors in the second half of 2024.

- Continuing to support several industry and academic collaborator studies evaluating nirogacestat as part of B-cell maturation antigen (BCMA) combination therapy regimens across treatment lines in patients with multiple myeloma.

Mirdametinib

- Initiated rolling submission of an NDA to the FDA for mirdametinib for the treatment of children and adults with NF1-PN in March 2024. SpringWorks expects to complete the NDA submission in the second quarter of 2024 and expects to file a MAA with the EMA for mirdametinib for the treatment of children and adults with NF1-PN in the European Union the second half of 2024.
- Data from the pediatric and adult cohorts of the Phase 2b ReNeu trial were accepted for oral presentation as a rapid oral abstract at the 2024 ASCO Annual Meeting on June 3, 2024. SpringWorks also expects to publish the ReNeu trial results in a peer-reviewed journal in 2024.

Emerging Pipeline

- On track to present additional data from the dose expansion portion of the Phase 1b trial evaluating brimarafenib (BGB-3245) in adult patients with RAF mutant solid tumors in the second half of 2024. Brimarafenib is an investigational, selective RAF dimer inhibitor being developed by MapKure, LLC, a joint venture between SpringWorks and BeiGene, Ltd.
- Patients continue to be enrolled in the dose escalation phase of the SpringWorks-sponsored Phase 1/2a combination study of brimarafenib and mirdametinib.
- MapKure initiated a Phase 1b combination trial of brimarafenib with panitumumab, a monoclonal antibody targeting Epidermal Growth Factor Receptor in colorectal and pancreatic cancer patients with known MAPK pathway mutations; patient dosing is currently underway.
- Dose expansion in adult patients with NRAS mutant solid tumors is ongoing in the BeiGene-sponsored Phase 1b trial evaluating mirdametinib in combination with BeiGene's RAF dimer inhibitor, lifirafenib.
- On track to initiate a Phase 1a trial of SW-682, an investigational novel, oral, potent, and selective pan-TEAD inhibitor, in Hippo-mutant solid tumors in the second quarter of 2024.

General Corporate

- The U.S. Patent and Trademark Office has recently issued five new patents for OGSIVEO. The U.S. patent portfolio for OGSIVEO now includes 21 Orange Book listed patents, providing protection into 2043.

First Quarter 2024 Financial Results

- **Revenues:** OGSIVEO net product revenues were \$21.0 million in the first quarter of 2024, the first full quarter of the U.S. launch.
- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses were \$60.1 million for the first quarter of 2024, compared to \$44.2 million for the comparable period of 2023. The increase in SG&A expense was primarily attributable to commercial activities supporting the U.S. launch of OGSIVEO.
- **Research and Development (R&D) Expenses:** R&D expenses were \$53.6 million for the first quarter of 2024, compared to \$33.5 million for the comparable period of 2023. The increase in R&D expenses was primarily attributable to an increase in costs related to drug manufacturing, clinical trials, other research, consulting and professional services, and an increase in employee costs associated with headcount growth.
- **Net Loss Attributable to Common Stockholders:** SpringWorks reported a net loss of \$87.4 million, or \$1.18 per share, for the first quarter of 2024. This compares to a net loss of \$73.4 million, or \$1.18 per share, for the comparable period of 2023.
- **Cash, Cash Equivalents, and Marketable Securities:** Cash, cash equivalents and marketable securities were \$573.0 million as of March 31, 2024.

Conference Call Information

SpringWorks will host a conference call and webcast today, Thursday, May 2, at 8:30 a.m. ET to review its first quarter 2024 financial results and discuss recent business updates. To join the live webcast and view the corresponding slides, please click [here](#). To access the live call by phone, please pre-register for the call by clicking [here](#). Once registration is complete, participants will be provided with a dial-in number and conference code to access the call. A replay of the webcast will be available for a limited time following the event on the Investors and Media section of the Company's website at <https://ir.springworkstx.com>.

About SpringWorks Therapeutics

SpringWorks is a commercial-stage biopharmaceutical company applying a precision medicine approach to developing and delivering life-changing medicines for people with severe rare diseases and cancer. OGSIVEO® (nirogacestat), approved in the United States for the treatment of adult patients with progressing desmoid tumors who require systemic treatment, is the Company's first FDA-approved therapy. SpringWorks also has a diversified targeted therapy pipeline spanning solid tumors and hematological cancers, with programs ranging from preclinical development through advanced clinical trials. In addition to its wholly owned programs, SpringWorks has also entered into multiple collaborations with innovators in industry and academia to unlock the full potential for its portfolio and create more solutions for patients in need.

For more information, visit www.springworkstx.com and follow [@SpringWorksTx](#) on X (formerly Twitter), [LinkedIn](#), and [YouTube](#).

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 press release 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 and commercialization plans, our preclinical and clinical results, the market potential of OGSIVEO for adult patients with desmoid tumors, expectations regarding the adequacy of the data contained in the MAA to serve as the basis for marketing approval of nirogacestat for the treatment of desmoid tumors in the European Union, the potential for the results of the Phase 2b ReNeu clinical trial to support an NDA submission for mirdametinib in the second quarter of 2024 or an MAA submission in the second half of 2024, our plans to report additional data from the Phase 2b ReNeu clinical trial at an upcoming medical conference and submit for publication data from such clinical trial in a peer-reviewed medical journal in 2024, our plans to present additional data from the Phase 3 DeFi trial of nirogacestat at upcoming conferences, 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, expectations regarding the timing and initial data from the Phase 2 trial evaluating nirogacestat in patients with recurrent ovarian granulosa cell tumors, our plans to initiate a Phase 1a trial of SW-682 in Hippo mutant solid tumors in the second quarter of 2024, our plans to report additional clinical data of nirogacestat in combination with BCMA-directed therapies and initiate additional planned Phase 1 collaborator studies, our expectations regarding the potential for and the timing of the Phase 1b dose expansion phase of brimarafenib, our plans to present additional data for brimarafenib monotherapy in MAPK-mutant solid tumors in second half of 2024, 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 presentation 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 presentation, including, without limitation, risks relating to: (i) the success of our commercialization efforts with respect to OGSIVEO, (ii) our limited experience as a commercial company, (iii) our ability to obtain or maintain adequate coverage and reimbursement for OGSIVEO, (iv) the success and timing of our product development activities, including the initiation and completion of our clinical trials, (v) our expectations regarding the potential clinical benefit of OGSIVEO for adult patients with desmoid tumors who require systemic treatment, (vi) the potential for OGSIVEO to become the new standard of care for adult patients with desmoid tumors, (vii) estimates regarding the number of adult patients who are diagnosed with desmoid tumors annually per year in the U.S. and the potential market for OGSIVEO, (viii) the fact that topline or interim data from 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, (ix) the success and timing of our collaboration partners’ ongoing and planned clinical trials, (x) the timing of our planned regulatory submissions and interactions, including the timing and outcome of decisions made by the FDA, EMA, and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies, (xi) whether FDA, EMA, or other regulatory authorities will require additional information or further studies, or may fail or refuse to approve or may delay approval of our product candidates, including nirogacestat and mirdametinib, (xii) our ability to obtain regulatory approval of any of our product candidates or maintain regulatory approvals granted for our products, (xiii) our plans to research, discover and develop additional product candidates, (xiv) our ability to enter into collaborations for the development of new product candidates and our ability to realize the benefits expected from such collaborations, (xv) our ability to maintain adequate patent protection and successfully enforce patent claims against third parties, (xvi) the adequacy of our cash position to fund our operations through any time period indicated herein, (xvii) our ability to establish manufacturing capabilities, and our and our collaboration partners’ abilities to manufacture our product candidates and scale production, and (xviii) our ability to meet any specific milestones set forth herein.

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 II of SpringWorks’ Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, 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 March 31,	
	2024	2023
Revenue:		
Product revenue, net	\$ 21,006	\$ —
Total revenue	21,006	—
Operating costs and expenses:		
Cost of product revenue	1,202	—
Selling, general and administrative	60,113	44,175
Research and development	53,622	33,524
Total operating costs and expenses	114,937	77,699
Loss from operations	(93,931)	(77,699)
Interest and other income:		
Interest and other income, net	7,571	5,557
Total interest and other income	7,571	5,557
Equity method investment loss	(1,025)	(1,278)
Net loss	\$ (87,385)	\$ (73,420)
Net loss per share, basic and diluted	\$ (1.18)	\$ (1.18)
Weighted average common shares outstanding, basic and diluted	73,768,603	62,326,992

SpringWorks Therapeutics, Inc.

Selected Balance Sheet Data
(Unaudited)

(in thousands)	March 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	\$ 572,987	\$ 662,588
Working Capital (1)	402,881	422,742
Total assets	656,832	725,788
Total liabilities	89,392	99,569
Accumulated deficit	(982,419)	(895,034)
Total stockholders' equity	567,440	626,219

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

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