SpringWorks Therapeutics Reports Second Quarter 2024 Financial Results and Recent Business Highlights

August 7, 2024

– Achieved $40.2 million in OGSIVEO® (nirogacestat) net product revenue in the second quarter –

– Completed submission of NDA to the FDA for mirdametinib for the treatment of children and adults with NF1-PN –

– Presented Phase 2b ReNeu trial results and additional analyses from Phase 3 DeFi trial at the 2024 ASCO Annual Meeting –

– Initiated Phase 1a trial of SW-682 in patients with Hippo mutant solid tumors –

STAMFORD, Conn., Aug. 07, 2024 (GLOBE NEWSWIRE) -- SpringWorks Therapeutics, Inc. (Nasdaq: SWTX), a commercial-stage biopharmaceutical company focused on severe rare diseases and cancer, today reported financial results for the second quarter of 2024 and provided an update on recent company developments.

"We are very pleased with the continued strong momentum of our U.S. launch of OGSIVEO for adults with desmoid tumors. In the second quarter, we also completed the submission of our NDA for mirdametinib in NF1-PN, which positions us to potentially have our second medicine available for patients in 2025," said Saqib Islam, Chief Executive Officer of SpringWorks. "Our focus for the second half of 2024 will be to drive broader adoption of OGSIVEO, to advance our commercial preparations for the launch of mirdametinib for children and adults with NF1-PN, to continue advancing OGSIVEO and mirdametinib through the European regulatory process, and to progress our emerging portfolio for patient populations with high unmet needs."

Recent Business Highlights and Upcoming Milestones

OGSIVEO® (Nirogacestat)

- Strong commercial execution of the OGSIVEO launch, with net product revenue of $40.2 million in the second quarter of 2024.
- In May 2024, SpringWorks introduced OGSIVEO 150 mg and 100 mg tablets in blister packaging, which was developed to enhance patient convenience with OGSIVEO.
- A Marketing Authorization Application (MAA) for nirogacestat for the treatment of adult patients with desmoid tumors is under review with the European Medicines Agency (EMA).
- Additional data from the Phase 3 DeFi trial of nirogacestat in adults with desmoid tumors highlighting consistent safety and efficacy across subgroups of high-risk patient populations and updated ovarian toxicity resolution data supporting the transience of ovarian toxicity were presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting.
- SpringWorks expects to present long-term follow-up data from the Phase 3 DeFi trial at a medical conference in the second half of 2024.
- SpringWorks expects 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.
- SpringWorks is 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

- SpringWorks completed the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for mirdametinib for the treatment of children and adults with NF1-PN.
- The Company expects to complete the submission of an MAA for mirdametinib for the treatment of children and adults with NF1-PN in the European Union in the second half of 2024.
- Data from the pediatric and adult cohorts of the Phase 2b ReNeu trial were presented in an oral presentation at the 2024 ASCO Annual Meeting and were also featured at the 2024 Global NF Conference and at the International Symposium on Pediatric Neuro-Oncology (ISPNO) 2024 meeting. Results showed robust objective response rates confirmed by blinded independent central review, deep responses, significant reductions in pain, improvement in other quality of life measures, and a manageable and tolerable safety profile were achieved across both the pediatric and adult cohorts. SpringWorks expects to publish the ReNeu trial results in a peer-reviewed journal in the second half of 2024.
- A poster evaluating the dispersible tablet of mirdametinib in children with NF1-PN in the ReNeu trial was presented at the ISPNO 2024 meeting. Patients and caregivers reported high acceptability scores for ease of swallowing and willingness to take the dispersible tablet formulation, indicating that this formulation provides an acceptable option for children or adults with swallowing difficulties.

- Initial data from the Phase 1/2 trial evaluating mirdametinib in patients with pediatric low-grade gliomas (pLGG) were presented at the ISPNO 2024 meeting. Results from 23 patients enrolled in the Phase 1 portion of the study suggested that mirdametinib, which has high blood brain barrier penetration, has encouraging clinical activity in patients with recurrent/progressive pLGG across a variety of MAPK pathway aberrations. The Phase 2 portion of the study is ongoing and recruiting patients.

Emerging Pipeline

- A Phase 1b trial evaluating brimarafenib (BGB-3245) in adult patients with RAF mutant solid tumors is ongoing; additional data from the dose expansion portion of the study is expected to be presented in the first half of 2025. 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 several combination therapy oncology programs: a Phase 1/2a study of brimarafenib and mirdametinib in MAPK mutant solid tumors, a Phase 1b trial of brimarafenib and Amgen's EGFR inhibitor, panitumumab, in colorectal and pancreatic cancer patients with known MAPK pathway mutations, and a Phase 1b trial of mirdametinib with BeiGene's RAF dimer inhibitor, lifirafenib, in adult patients with NRAS mutant solid tumors.
- SpringWorks initiated 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

- In July, SpringWorks appointed Martin Mackay, Ph.D. to the Company's Board of Directors. Dr. Mackay is a highly accomplished R&D executive with more than 30 years of pharmaceutical and biotech R&D experience, including leadership roles at Pfizer, AstraZeneca and Alexion.

Second Quarter 2024 Financial Results

- **Product Revenue:** OGSIVEO net product revenue was $40.2 million in the second quarter of 2024.
- **Selling, General and Administrative (SG&A) Expenses**: SG&A expenses were $57.8 million for the second quarter of 2024, compared to $47.0 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, as well as commercial readiness activities to support the U.S. launch of mirdametinib, if approved.
- **Research and Development (R&D) Expenses:** R&D expenses were $44.4 million for the second quarter of 2024, compared to $35.9 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 $39.9 million, or $0.54 per share, for the second quarter of 2024. This compares to a net loss of $77.9 million, or $1.25 per share, for the comparable period of 2023.
- **Cash, Cash Equivalents, and Marketable Securities:** Cash, cash equivalents and marketable securities were $521.9 million as of June 30, 2024.

Conference Call Information

SpringWorks will host a conference call and webcast today, Wednesday, August 7, at 8:30 a.m. ET to review its second 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 nirogacestat 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 approval of the mirdametinib NDA or an MAA submission for mirdametinib 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 expectations and the timing of the Phase 1a trial of SW-682, 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 and the timing of the Phase 1b dose expansion phase of brimarafenib, our expectations regarding the timing of enrollment in our combination therapy oncology programs, 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 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 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 June 30, 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)

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands, except share and per-share data)	**2024**	**2023**	**2024**	**2023**
Revenue:				
Product revenue, net	$ 40,186	$ —	$ 61,192	$ —
Other revenue [(1)]	19,547	—	19,547	—
Total revenue	59,733	—	80,739	—
Operating costs and expenses:				
Cost of product revenue	2,453	—	3,655	—
Selling, general and administrative	57,839	46,994	117,952	91,169
Research and development	44,362	35,858	97,984	69,382
Total operating costs and expenses	104,654	82,852	219,591	160,551
Loss from operations	(44,921)	(82,852)	(138,852)	(160,551)
Interest and other income:				
Interest and other income, net	6,778	5,828	14,349	11,385
Total interest and other income	6,778	5,828	14,349	11,385

Equity method investment loss	(1,776)	(901)	(2,801)	(2,179)
Net loss	$ (39,919)	$ (77,925)	$ (127,304)	$ (151,345)
Net loss per share, basic and diluted	$ (0.54)	$ (1.25)	$ (1.72)	$ (2.43)
Weighted average common shares outstanding, basic and diluted	74,121,014	62,464,081	73,944,809	62,360,651

(1) Related to recognition of all previously deferred revenue associated with the GSK License Agreement following notice of termination of the agreement received from GSK, as announced in June 2024.

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

(in thousands)	**June 30, 2024**	**December 31, 2023**
Cash, cash equivalents and marketable securities	$ 521,933	$ 662,588
Working Capital (1)	376,824	422,742
Total assets	617,331	725,788
Total liabilities	60,601	99,569
Accumulated deficit	(1,022,338)	(895,034)
Total stockholders' equity	556,730	626,219

(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
Senior Director, Investor Relations
Phone: 203-461-5501
Email: samantha.sandler@springworkstx.com