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

November 12, 2024

– Achieved $49.3 million in OGSIVEO® (nirogacestat) net product revenue in the third quarter –

– Long-term follow-up data from the Phase 3 DeFi trial of nirogacestat in adults with desmoid tumors highlight further reductions in tumor size, increase in ORR, sustained improvement in desmoid tumor symptoms, and consistent safety profile –

– Granted FDA Priority Review on NDA and received validation of EU Marketing Authorization Application for mirdametinib for the treatment of adults and children with NF1-PN –

– $498 million in cash, cash equivalents and marketable securities as of September 30, 2024; expected to fund the Company through profitability, which is anticipated in the first half of 2026 –

– Conference call and webcast scheduled for 8:30 a.m. ET today –

STAMFORD, Conn., Nov. 12, 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 third quarter of 2024 and provided an update on recent company developments.

"In the third quarter, we continued to see robust growth in the U.S. launch of OGSIVEO for adults with desmoid tumors. As we approach nearly one full year on market, we are very encouraged by the metrics we are seeing regarding the breadth of physician prescribing, the number of patients on OGSIVEO, and the number of patients identified who may stand to benefit in the future from our medicine. We were also very pleased to receive Priority Review on our NDA for mirdametinib in NF1-PN this quarter, which positions us to potentially have a second approved medicine in early 2025," said Saqib Islam, Chief Executive Officer of SpringWorks. "Our focus for the remainder of the year is to continue building on OGSIVEO's momentum in the U.S. while working to also bring it to patients in Europe, to advance our commercial preparations for mirdametinib in anticipation of serving patients with NF1-PN in the U.S. and Europe, and to progress our emerging portfolio."

Recent Business Highlights and Upcoming Milestones

OGSIVEO® (Nirogacestat)

- Continued strong commercial execution of the OGSIVEO launch, with net product revenue of $49.3 million in the third quarter of 2024, representing a 23% increase over the second quarter of 2024.
- In September, more than 800 unique desmoid tumor patients filled an OGSIVEO script. As of the end of the third quarter of 2024, approximately 420 treatment centers have ordered OGSIVEO since approval and approximately 65 percent of OGSIVEO patients on OGSIVEO are receiving the product in the 150 mg or 100 mg tablets blister packages. SpringWorks expects to complete the full transition to blister packages by the end of the year. In addition, through August 2024, approximately 10,000 unique desmoid tumor patients have been identified through the new desmoid tumor ICD-10 diagnostic code since the introduction of the code in October 2023.
- 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).
- Long-term follow-up data from the Phase 3 DeFi trial of nirogacestat in adults with progressing desmoid tumors will be presented as a late-breaking oral presentation at the upcoming Connective Tissue Oncology Society (CTOS) 2024 Annual Meeting. These results, utilizing an August 2024 data cutoff date, showed that longer-term treatment with nirogacestat (median duration of treatment: 34 months) was associated with further reductions in tumor size, increase in objective response rate with additional partial responses and complete responses, sustained improvements in desmoid tumor symptoms including pain, and a consistent safety profile compared to the April 2022 data cutoff date for the primary results of the trial.
- 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 first half of 2025.
- 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' New Drug Application (NDA) for mirdametinib for the treatment of children and adults with NF1-PN was granted Priority Review by the U.S. Food and Drug Administration (FDA) and assigned a Prescription Drug User Fee Act (PDUFA) action date of February 28, 2025.

- SpringWorks' MAA for mirdametinib for the treatment of children and adults with NF1-PN was validated by the EMA and is currently under review.
- Results from the Phase 2b ReNeu trial were published in the *Journal of Clinical Oncology.*
- Additional data from the pediatric and adult cohorts of the Phase 2b ReNeu trial will be presented in oral and poster presentations at the 2024 Society for Neuro-Oncology (SNO) meeting. Data demonstrate that the deep responses in tumor volume reduction seen in ReNeu were achieved regardless of age, sex, target PN volume at baseline, tumor location, or progression status at baseline and suggest a trend between deep response and earlier achievement of a first confirmed response. Patients with deep responses also had a trend of longer treatment duration. In addition, adults and children with NF1-PN had clinically meaningful, early, and sustained improvement in health-related quality of life over the course of mirdametinib treatment.
- Data from the Phase 1/2 trial evaluating mirdametinib in pediatric and young adult patients with low-grade gliomas (LGG) are being presented in an oral presentation at the 2024 SNO meeting. Results from 23 patients enrolled in the Phase 1 portion of the study suggested that mirdametinib, which has shown high blood brain barrier penetration, has encouraging clinical activity in patients with recurrent/progressive LGG across a variety of MAPK pathway aberrations. Twelve (63%) of the 19 patients with measurable tumors achieved an objective response (one major, six partial, and five minor responses). 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 second half of 2025. Brimarafenib is an investigational, selective RAF dimer inhibitor being developed by MapKure, LLC, a joint venture between SpringWorks and BeiGene, Ltd.
- Several combination therapy oncology programs are ongoing: 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.
- In October, SpringWorks presented preclinical data at the EORTC-NCI-AACR symposium on Molecular Targets and Cancer therapeutics demonstrating the utility of SW-682 as a monotherapy and in combination with mirdametinib in subsets of head and neck cancer as well as in combination with KRAS G12C inhibitors in KRAS G12C mutant NSCLC. SW-682 is an investigational novel, oral, potent, and selective pan-TEAD inhibitor and patients are being enrolled in a Phase 1a trial in Hippo-mutant solid tumors.

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.

Third Quarter 2024 Financial Results

- **Product Revenue:** OGSIVEO net product revenue was $49.3 million in the third quarter of 2024.
- **Selling, General and Administrative (SG&A) Expenses**: SG&A expenses were $61.6 million for the third quarter of 2024, compared to $46.5 million for the comparable period of 2023. The increase in SG&A expense was primarily attributable to commercial readiness activities to support the U.S. launch of mirdametinib, if approved.
- **Research and Development (R&D) Expenses:** R&D expenses were $42.3 million for the third quarter of 2024, compared to $37.5 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.
- **Net Loss Attributable to Common Stockholders:** SpringWorks reported a net loss of $53.5 million, or $0.72 per share, for the third quarter of 2024. This compares to a net loss of $79.4 million, or $1.27 per share, for the comparable period of 2023.
- **Cash, Cash Equivalents, and Marketable Securities:** Cash, cash equivalents and marketable securities were $498.1 million as of September 30, 2024. SpringWorks expects this cash position to fund the Company through profitability, which is expected in the first half of 2026.

Conference Call Information

SpringWorks will host a conference call and webcast today, Tuesday, November 12, at 8:30 a.m. ET to review its third 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 to transition to blister packaging for OGSIVEO by the end of the year, 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 mirdametinib to become an important new treatment for adult and pediatric NF1-PN patients, expectations regarding the timing and results of the reviews by the FDA and the EMA, as applicable, of each of the NDA and the MAA for mirdametinib for the treatment of adult and pediatric NF1-PN patients, including the FDA's PDUFA target action date for the NDA, our plans to report additional data from the Phase 2b ReNeu clinical trial at an upcoming medical conference in the fourth quarter of 2024, our plans to present additional data from the Phase 3 DeFi trial of nirogacestat at upcoming conferences, 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 September 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 September 30,		Nine Months Ended September 30,	
(in thousands, except share and per-share data)	**2024**	**2023**	**2024**	**2023**
Revenue:				

Product revenue, net	$ 49,301	$ —	$ 110,493	$ —
Other revenue (1)	—	—	19,547	—
Total revenue	49,301	—	130,040	—
Operating costs and expenses:				
Cost of product revenue	3,341	—	6,996	—
Selling, general and administrative	61,601	46,546	179,553	137,715
Research and development	42,296	37,453	140,280	106,835
Total operating costs and expenses	107,238	83,999	326,829	244,550
Loss from operations	(57,937)	(83,999)	(196,789)	(244,550)
Interest and other income:				
Interest and other income, net	6,216	5,586	20,565	16,971
Total interest and other income	6,216	5,586	20,565	16,971
Equity method investment loss	(1,809)	(1,024)	(4,610)	(3,203)
Net loss	$ (53,530)	$ (79,437)	$ (180,834)	$ (230,782)
Net loss per share, basic and diluted	$ (0.72)	$ (1.27)	$ (2.44)	$ (3.70)
Weighted average common shares outstanding, basic and diluted	74,264,501	62,521,772	74,052,151	62,386,496

(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)	**September 30, 2024**	**December 31, 2023**
Cash, cash equivalents and marketable securities	$ 498,123	$ 662,588
Working Capital (1)	364,498	422,742
Total assets	608,878	725,788
Total liabilities	76,297	99,569
Accumulated deficit	(1,075,868)	(895,034)
Total stockholders' equity	532,581	626,219

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

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