Disc Medicine Highlights Recent Achievements and Key Business Objectives and Milestones for 2026

January 12, 2026

- Bitopertin was awarded the Commissioner's National Priority Review Voucher (CNPV) and NDA is currently under FDA review
- Updated data from the Phase 2 study of DISC-0974 in patients with myelofibrosis (MF) and anemia expected in H2 2026, followed by an End of Phase 2 Meeting
- Initial data from the ongoing Phase 2 study of DISC-3405 in polycythemia vera (PV) and Phase 1b study in sickle cell disease (SCD) expected in H2 2026

WATERTOWN, Mass., Jan. 12, 2026 (GLOBE NEWSWIRE) -- Disc Medicine, Inc. (NASDAQ:IRON), a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of novel treatments for patients suffering from serious hematologic diseases, today outlined its recent pipeline progress and strategic priorities for 2026.

"2025 was a transformative year for Disc, marked by strong execution across our portfolio and meaningful progress toward becoming a fully integrated clinical and commercial organization," said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc. "Most notably, bitopertin received CNPV designation and we submitted our NDA under the accelerated approval pathway, positioning the NDA for rapid review by the FDA. We also reported positive initial Phase 2 data from the RALLY-MF study of DISC-0974 in anemia of myelofibrosis, demonstrating robust and broad hematologic activity, and advanced our third program DISC-3405 into proof-of-concept studies for polycythemia vera and sickle cell disease."

"As we look ahead to 2026, we are entering an exciting and pivotal period for Disc," continued Dr. Quisel. "We are preparing to execute a successful US launch of bitopertin for EPP while continuing enrollment in the global APOLLO confirmatory study. Across our pipeline, we expect multiple Phase 2 updates for DISC-0974 and DISC-3405, including important regulatory interactions and expansion into new indications. Together, we believe these milestones position Disc for sustained growth as we work to deliver meaningful new therapies to patients with serious hematologic diseases."

Summary of Key Achievements During 2025

- Bitopertin NDA submitted and accepted under the accelerated approval pathway with priority review
- Bitopertin awarded the Commissioner's National Priority Voucher (CNPV), a pilot program designed to accelerate the NDA review period to 1-2 months
- Transition to commercial-ready organization through build out of marketing, market access, medical science liaison, and sales teams and related infrastructure
- Presentation of positive initial data from the Phase 2 RALLY-MF study of DISC-0974 for anemia of MF, demonstrating robust and broad hematologic efficacy across patient segments
- Issuance of a Composition of Matter patent for DISC-0974, providing patent exclusivity until 2041, not including potential extensions
- Initiated Phase 2 study of DISC-3405 in PV and Phase 1b study of DISC-3405 in SCD
- Strengthened balance sheet through two equity offerings, bringing unaudited cash, cash equivalents, and marketable securities to $791 million as of December 31, 2025, which provides runway into 2029

Key Business Objectives and Milestones for 2026
Bitopertin: GlyT1 Inhibitor (Heme Synthesis)

- Anticipate FDA approval decision regarding NDA for bitopertin for the treatment of EPP under the CNPV program
- Successful launch and initial commercialization of bitopertin in the US, if approved
- Continue enrollment of the global, confirmatory APOLLO study with topline data expected by early 2027

DISC-0974: Anti-hemojuvelin Antibody (Hepcidin Suppression)

- Progress ongoing Phase 2 MF anemia trial with updated data expected H2 2026
- Conduct End of Phase 2 meeting with the FDA about DISC-0974 in MF anemia in H2 2026
- Initiate a Phase 2 study of DISC-0974 in patients with anemia and inflammatory bowel disease (IBD)

DISC-3405: Anti-TMPRSS6 Antibody (Hepcidin Induction)

- Progress ongoing Phase 2 PV trial with updated data expected H2 2026
- Progress ongoing Phase 1b SCD trial with updated data expected H2 2026

Bitopertin, DISC-0974, and DISC-3405 are investigational agents and are not approved for use as therapies in any jurisdiction worldwide.

About Disc Medicine

Disc Medicine (NASDAQ:IRON) is a clinical stage biopharmaceutical company committed to discovering, developing, and commercializing novel treatments for patients who suffer from serious hematologic diseases. We are building a portfolio of innovative, potentially first-in-class therapeutic candidates that aim to address a wide spectrum of hematologic diseases by targeting fundamental biological pathways of red blood cell biology, specifically heme biosynthesis and iron homeostasis. For more information, please visit www.discmedicine.com.

Disc Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, express or implied statements regarding: Disc's expectations with respect to the next stages of its development programs for bitopertin, DISC-0974 and DISC-3405, including projected timelines for the initiation and completion of its clinical trials, anticipated timing of release of data, and other clinical activities; the registrational pathway for bitopertin, including the potential for accelerated approval, benefits of the CNPV, expected review period and the timing of approval, if granted; Disc's expectations with respect to the potential launch and commercialization of bitopertin, if approved; anticipated discussions with regulatory agencies; Disc's preliminary unaudited cash, cash equivalents and marketable securities as of December 31, 2025; and the strength of its financial position and its anticipated cash runway. The use of words such as, but not limited to, "believe," "expect," "estimate," "project," "intend," "future," "potential," "continue," "may," "might," "plan," "will," "should," "seek," "anticipate," or "could" or the negative of these terms and other similar words or expressions that are intended to identify forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on Disc's current beliefs, expectations and assumptions regarding the future of Disc's business, future plans and strategies, clinical results and other future conditions. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Disc may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and investors should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements as a result of a number of material risks and uncertainties including but not limited to: the adequacy of Disc's capital to support its future operations and its ability to successfully initiate and complete clinical trials; the nature, strategy and focus of Disc; the difficulty in predicting the time and cost of development of Disc's product candidates; Disc's plans to research, develop and commercialize its current and future product candidates; the timing of initiation of Disc's planned preclinical studies and clinical trials; the timing of the availability of data from Disc's clinical trials; Disc's ability to identify additional product candidates with significant commercial potential and to expand its pipeline in hematological diseases; the timing and anticipated results of Disc's preclinical studies and clinical trials and the risk that the results of Disc's preclinical studies and clinical trials may not be predictive of future results in connection with future studies or clinical trials and may not support further development and marketing approval; final audit adjustments and other developments that may arise that would cause Disc's expectations with respect to the estimate of cash, cash equivalents and marketable securities as of December 31, 2025 to differ, perhaps materially, from the financial results that will be reflected in Disc's audited consolidated financial statements for the fiscal year ended December 31, 2025; and the other risks and uncertainties described in Disc's filings with the Securities and Exchange Commission, including in the "Risk Factors" section of Disc's Annual Report on Form 10-K for the year ended December 31, 2024, and in subsequent Quarterly Reports on Form 10-Q. Any forward-looking statement speaks only as of the date on which it was made. None of Disc, nor its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law.

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