Disc Medicine Reports Third Quarter 2025 Financial Results and Provides Business Update

November 6, 2025

- *Submitted a New Drug Application (NDA) for accelerated approval of bitopertin in erythropoietic protoporphyria (EPP) on September 29, 2025; Awarded the FDA Commissioner's National Priority Voucher (CNPV), which is designed to shorten the expected NDA review period to 1-2 months from NDA acceptance*
- *Acceleration of ongoing efforts to support the potential earlier approval and commercialization of bitopertin for EPP in the US, expected in late 2025 or early 2026*
- *Initial data from Phase 2 study of DISC-0974 in patients with anemia of myelofibrosis (MF) to be presented at the American Society of Hematology (ASH) conference in December*
- *Progressing ongoing Phase 2 study of DISC-3405 in polycythemia vera (PV) and initiated a Phase 1b study of DISC-3405 in sickle cell disease (SCD) in October*
- *Strong financial position ending Q3 with approximately $616 million in cash, cash equivalents, and marketable securities; completed a public offering in October 2025, with net proceeds of approximately $211M expected to extend cash runway into 2029*

WATERTOWN, Mass., Nov. 06, 2025 (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 reported financial results for the third quarter ended September 30, 2025, and provided a review of recent program and corporate developments.

"We are incredibly proud of the progress across our entire pipeline this quarter, most notably around our NDA submission for bitopertin in EPP at the end of September and subsequent receipt of the CNPV," said John Quisel, J.D., Ph.D., Chief Executive Officer and President of Disc. "Achieving this milestone is a strong testament to our team's commitment to execution and dedication to bringing a potential new treatment option to the EPP patient community. We continue to work with the Agency on their review of our application, and we are furthering our commercial infrastructure in preparation for a potential launch."

"Beyond bitopertin, our broader pipeline is progressing well, as we expect new data from the Phase 2 trial of DISC-0974 in MF anemia by the end of the year and data from studies of DISC-3405 in PV and SCD next year. With a strong balance sheet providing cash runway into 2029, we are well-positioned to prepare for the anticipated launch of bitopertin and ultimately advancing towards our goal of delivering new treatment options to patients suffering from hematological diseases."

Recent Highlights and Anticipated Milestones:

Bitopertin: GlyT1 Inhibitor (Heme Synthesis Modulator)

- Submitted NDA for bitopertin in EPP seeking priority review and accelerated approval with reduction in protoporphyrin IX (PPIX) as the surrogate endpoint for approval supported by clinical results from BEACON and AURORA Phase 2 trials
- Received the CNPV, which is designed to shorten the NDA review process to 1-2 months from NDA acceptance
- Accelerating activities to support a potential US approval and launch in late 2025 or early 2026
- Progressing confirmatory Phase 3 APOLLO clinical trial of bitopertin in adults and adolescents with EPP

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

- Initial data from Phase 2 RALLY-MF trial of DISC-0974 in patients with anemia of myelofibrosis (MF) to be presented at ASH Annual Meeting in December, with topline data expected in 2026
- Data from recently completed multiple-dose cohorts of Phase 1b study of DISC-0974 in patients with anemia of NDD-CKD to be presented at ASN Kidney Week
    - DISC-0974 was generally well-tolerated with substantial decreases in hepcidin, increases in iron, and improvements in markers of erythropoiesis
    - Meaningful hemoglobin increases observed in only a subset of patients were in part driven by those with higher baseline erythropoietin (EPO) levels
    - Disc is assessing options for the program based on full analysis of the data
- Phase 2 study in patients with inflammatory bowel disease (IBD) and anemia anticipated to begin in Q1 2026

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

- Progressing ongoing Phase 2 study of DISC-3405 in patients with PV with initial data expected in 2026
- Initiated Phase 1b study of DISC-3405 in patients with SCD in October 2025 with initial data expected in 2026

Third Quarter 2025 Financial Results:

- **Cash Position:** Cash, cash equivalents, and marketable securities were $615.9 million as of September 30, 2025. In October 2025, Disc completed a public offering with net proceeds of approximately $211 million, extending cash runway into 2029.
- **Research and Development Expenses:** R&D expenses were $50.3 million for the three months ended September 30, 2025, as compared to $24.7 million for the three months ended September 30, 2024. The increase in R&D expenses was primarily driven by the progression of Disc's portfolio, including bitopertin's clinical studies and drug manufacturing, the advancement of the DISC-0974 program, and increased headcount, as well as a payment of a $10.0 million milestone upon first administration to a patient in the Phase 2 trial of DISC-3405.
- **Selling, General and Administrative Expenses:** SG&A expenses were $17.4 million for the three months ended September 30, 2025, as compared to $8.2 million for the three months ended September 30, 2024. The increase in SG&A expenses was primarily due to increased headcount including establishing infrastructure to support potential commercialization.
- **Net Loss:** Net loss was $62.3 million for the three months ended September 30, 2025, as compared to $26.6 million for the three months ended September 30, 2024. The increase was primarily due to higher operating costs in the current period to support the continued advancement of our pipeline.

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.

Available Information

Disc announces material information to the public about the Company, its products and services, and other matters through a variety of means, including filings with the U.S. Securities and Exchange Commission (SEC), press releases, public conference calls, webcasts and the investor relations section of the Company website at ir.discmedicine.com in order to achieve broad, non-exclusionary distribution of information to the public and for complying with its disclosure obligations under Regulation FD.

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; anticipated discussions with regulatory agencies; ongoing preparations for the potential launch of bitopertin; 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; the content and timing of decisions made by the FDA and other regulatory authorities; 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.

DISC MEDICINE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 50,334	$ 24,685	$ 124,416	$ 71,874
Selling, general and administrative	17,362	8,171	44,636	23,296
Total operating expenses	67,696	32,856	169,052	95,170
Loss from operations	(67,696)	(32,856)	(169,052)	(95,170)
Other income (expense), net	5,477	6,371	17,672	15,449
Income tax expense	(102)	(114)	(273)	(179)
Net loss	$ (62,321)	$ (26,599)	$ (151,653)	$ (79,900)
Net loss per share, basic and diluted	$ (1.77)	$ (0.89)	$ (4.39)	$ (2.98)
Weighted-average common shares outstanding, basic and diluted	35,178,691	29,935,551	34,516,134	26,809,605

DISC MEDICINE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)

	September 30, 2025	December 31, 2024
	(Unaudited)	
Assets		
Cash, cash equivalents, and marketable securities	$ 615,920	$ 489,881
Other current assets	11,248	3,734
Total current assets	627,168	493,615
Non-current assets	3,288	3,158
Total assets	$ 630,456	$ 496,773
Liabilities and Stockholders’ Equity		
Current liabilities	$ 26,744	$ 23,316
Non-current liabilities	30,321	29,870
Total liabilities	57,065	53,186
Total stockholders’ equity	573,391	443,587
Total liabilities and stockholders’ equity	$ 630,456	$ 496,773

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