Disc Medicine Reports Third Quarter 2026 Financial Results and Provides Business Update

November 5, 2026

- *Pivotal Phase 3 APOLLO trial of bitopertin in erythropoietic protoporphyria (EPP) successfully met all primary and secondary endpoints*
- *Bitopertin NDA resubmission planned by end of 2026, with an FDA decision for potential approval in EPP anticipated by mid-2027*
- *Feedback from the upcoming end of phase 2 meeting with the FDA on selcodebart in anemia of myelofibrosis (MF) and plans for pivotal development in anemia of MF to be announced by the end of the year*
- *Presented positive initial results from the Phase 2 RESTORE-PV study of DISC-3405 in polycythemia vera (PV)*
- *Updated data from RESTORE-PV and initial data from a Phase 1b study of DISC-3405 in sickle cell disease (SCD) to be presented at the 68th American Society of Hematology (ASH) annual meeting in December 2026*
- *Strong financial position ending Q3 with approximately $683 million in cash, cash equivalents, and marketable securities; completed a public offering in October 2026, with net proceeds of approximately $486 million extending cash runway into 2030*

WATERTOWN, Mass., Nov. 05, 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 reported financial results for the third quarter ended September 30, 2026, and provided a review of recent program and corporate developments.

“In our first pivotal trial readout as a company, APOLLO delivered strong and compelling evidence of the potential clinical benefit of bitopertin for patients with EPP,” said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc. “We look forward to engaging with regulators with the goal of bringing an important, innovative medicine to this community as efficiently as possible.”

“We also made significant progress across our broader pipeline, including encouraging initial RESTORE-PV data that reinforce the potential of DISC-3405 to maintain target hematocrit levels and improve symptoms for patients with polycythemia vera,” Dr. Quisel added. “Alongside our anticipated end-of-Phase 2 FDA meeting for selcodebart in anemia of myelofibrosis in the fourth quarter and a strengthened balance sheet, we are well positioned to support the anticipated launch of bitopertin and advance two additional programs toward pivotal-stage development in 2027.”

Recent Highlights and Anticipated Milestones:

Bitopertin: GlyT1 Inhibitor (Heme Synthesis Modulator)

- Positive topline data from the Phase 3 APOLLO clinical trial of bitopertin in EPP achieved statistical significance on both co-primary endpoints of reduction in whole blood metal-free PPIX from baseline and average monthly total time in sunlight without pain during month 6 of treatment vs. placebo. The data showed:
  - Bitopertin reduced whole-blood metal-free PPIX by 41.4% versus placebo ($p<0.0001$) and increased average monthly total time in light without pain by 12.2 hours during month 6 ($p=0.0010$)
  - Positive and statistically significant results from all secondary endpoints, including reductions in phototoxic reactions and improvements on multiple measures of light tolerance. Exploratory endpoints of quality-of-life benefits were also positive and statistically significant.
- Bitopertin was generally well-tolerated. Consistent with prior studies, dizziness was the most commonly reported treatment emergent adverse event (TEAE) in the bitopertin group (50%) and was mild or moderate and generally transient. There were no TEAEs above Grade 3.
- Successful APOLLO results add to bitopertin’s robust clinical data package. Based on these results, Disc plans to resubmit a New Drug Application (NDA) to the U.S. FDA by the end of 2026, with a decision from the agency anticipated by mid-2027

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

- Updated data from the RALLY-MF trial to be presented at ASH in December
- Feedback from an end of phase 2 meeting with the FDA and plans for pivotal development in anemia of MF to be announced by the end of the year
- Progressing Phase 2 study of selcodebart in patients with inflammatory bowel disease (IBD) with initial data expected in 2027

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

- Presented positive initial results from the RESTORE-PV Phase 2 clinical trial of DISC-3405 in patients with PV at the SOHO Annual Meeting. Efficacy data was presented for the Q2 weekly dosed cohort. Across escalation and maintenance periods, results demonstrated:
    - DISC-3405 increased hepcidin and lowered serum iron, translating to controlled hematocrit, reduced phlebotomy, and improved symptoms in PV patients
    - Generally well-tolerated with adverse events that are consistent with underlying disease and a low rate of injection site reactions which were mild and self-limited
- Updated data from RESTORE-PV, including initial efficacy data on the Q4 weekly dosed cohort, to be presented at ASH in December
- Initial data from Phase 1b study of DISC-3405 in patients with sickle cell disease also to be presented at ASH

Third Quarter 2026 Financial Results:

- **Cash Position:** Cash, cash equivalents, and marketable securities were $682.8 million as of September 30, 2026. In October 2026, Disc completed a public offering with net proceeds of approximately $485.9 million. Together with such net proceeds, we believe that our cash, cash equivalents, and marketable securities will be sufficient to fund our current operating and capital expenditure plans and our debt service obligations into 2030.

- **Research and Development Expenses:** R&D expenses were $44.1 million for the three months ended September 30, 2026, as compared to $50.3 million for the three months ended September 30, 2025. The decrease in R&D expenses was primarily driven by a $10.0 million milestone payment and drug manufacturing in the comparative period that did not recur in the current period. These decreases were partially offset by increased investment across our development portfolio, including higher personnel-related costs driven by increased headcount.

- **Selling, General and Administrative Expenses:** SG&A expenses were $20.1 million for the three months ended September 30, 2026, as compared to $17.4 million for the three months ended September 30, 2025. The increase in SG&A expenses was primarily due to increased headcount.

- **Net Loss:** Net loss was $59.5 million for the three months ended September 30, 2026, as compared to $62.3 million for the three months ended September 30, 2025. The decrease was primarily due to lower research and development expenses resulting from costs incurred in the prior-year period that did not recur in the current period, partially offset by continued investment in advancing our pipeline and higher personnel-related costs.

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, selcodebart (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 timeline for an NDA resubmission and the timing of an FDA decision; anticipated discussions with regulatory agencies; the potential launch and commercialization of bitopertin, if approved; 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, 2025, 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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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,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 44,080	$ 50,334	$ 136,917	$ 124,416
Selling, general and administrative	20,081	17,362	61,843	44,636
Total operating expenses	64,161	67,696	198,760	169,052
Loss from operations	(64,161)	(67,696)	(198,760)	(169,052)
Other income (expense), net	4,735	5,477	16,418	17,672
Income tax expense	(109)	(102)	(229)	(273)
Net loss	$ (59,535)	$ (62,321)	$ (182,571)	$ (151,653)
Net loss per share, basic and diluted	$ (1.53)	$ (1.77)	$ (4.72)	$ (4.39)
Weighted-average common shares outstanding, basic and diluted	38,904,676	35,178,691	38,695,405	34,516,134

DISC MEDICINE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands)

	September 30, 2026	December 31, 2025
	(Unaudited)	
Assets		
Cash, cash equivalents, and marketable securities	$ 682,816	$ 791,152
Other current assets	14,589	12,746
Total current assets	697,405	803,898
Non-current assets	2,083	2,981
Total assets	$ 699,488	$ 806,879
Liabilities and Stockholders' Equity		
Current liabilities	$ 34,360	$ 36,641
Non-current liabilities	60,878	30,412
Total liabilities	95,238	67,053
Total stockholders' equity	604,250	739,826
Total liabilities and stockholders' equity	$ 699,488	$ 806,879