UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 07, 2025

DISC MEDICINE, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39438**	**85-1612845**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

321 Arsenal Street **Suite 101** **Watertown, Massachusetts** **(Address of Principal Executive Offices)**	**02472** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 617 674-9274

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	IRON	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 7, 2025, Disc Medicine, Inc. announced its financial results for the first quarter ended March 31, 2025 and provided a corporate update. A copy of the press release in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 of this Current Report on Form 8-K shall be deemed to be furnished and not filed:

Exhibit No.	Description
99.1	Press release issued by Disc Medicine, Inc. on May 7, 2025, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DISC MEDICINE, INC.

Date: May 7, 2025

By: /s/ John Quisel, J.D., Ph.D.
Name: John Quisel, J.D., Ph.D.
Title: Chief Executive Officer

Exhibit 99.1

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

- *Company remains on track to submit NDA for bitopertin in erythropoietic protoporphyria (EPP) in H2 2025*
- *Initiated APOLLO, a confirmatory clinical trial of bitopertin in adults and adolescents with EPP*
- *Plan to initiate Phase 2 study of DISC-3405 in polycythemia vera (PV) in H1 2025*
- *Expect data readouts for DISC-0974 program in H2 2025, including initial results of Phase 2 anemia of myelofibrosis (MF) study and multiple dose data from Phase 1b anemia of non-dialysis dependent chronic kidney disease (NDD-CKD) study*
- *Strong financial position supported by $259 million public offering in January 2025; ended Q1 with $695 million in cash, cash equivalents, and marketable securities, which is expected to fund operations into 2028*
- *Company to host virtual MF Anemia KOL Day on Friday, May 9 at 1:00 PM ET / 10:00 AM PT*

WATERTOWN, Mass., May 7, 2025 – 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 first quarter ended March 31, 2025, and provided a recap of recent program and corporate developments.

“2025 is off to a strong start for Disc as we continue to make operational progress across our portfolio. On our lead program, bitopertin in EPP, we are proud to share that the APOLLO trial is officially up and running. We believe that bitopertin has the potential to be a life-altering therapy and thank the EPP physician, advocate, and patient communities for their ongoing enthusiasm and partnership in the development process,” said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc. “We also appreciate the continued and timely engagement from regulators, including during the latest CMC-focused meeting where we reached alignment on key CMC items needed to support our plan to submit an NDA in H2 2025.

“Backed by a solid financial foundation which provides a cash runway into 2028, we are well-positioned to progress our commercial preparation efforts for bitopertin as well as development of the rest of our pipeline. We expect data from ongoing trials of DISC-0974, the Phase 2 MF anemia study and the Phase 1b NDD-CKD anemia study, to read out in the second half of this year and expect to initiate a Phase 2 study of DISC-3405 in PV in the coming months.”

Recent Highlights and Anticipated Milestones:

Bitopertin: GlyT1 Inhibitor (Heme Synthesis Modulator)

- Initiated APOLLO, a double-blind, placebo-controlled, confirmatory trial of bitopertin in adults and adolescents with EPP. The APOLLO trial is designed to support conversion of a U.S. accelerated approval, if granted, to a full approval
- On track to submit NDA for bitopertin in EPP in H2 2025 under the accelerated approval pathway using protoporphyrin IX (PPIX) reduction as surrogate endpoint, based on existing clinical data, including results from BEACON and AURORA Phase 2 trials
- Successful manufacturing-focused end-of-Phase 2 meeting:
  - Engaged with the FDA’s Office of Pharmaceutical Quality (OPQ) which collaborates with the Division of Dermatology and Dentistry within CDER on the review and evaluation for bitopertin
  - Achieved alignment on proposed Chemistry, Manufacturing, and Controls (CMC) components of the NDA package
- Bitopertin drug substance and drug product are manufactured in the US
- Scheduled pre-NDA meeting to align with the FDA on format and content of the NDA package with the goal of facilitating an efficient review

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

- Company to host a virtual MF Anemia KOL Day on Friday, May 9, featuring key opinion leaders Dr. Prithvi Bose and Dr. Aaron Gerds as well as Disc management, to discuss DISC-0974 and its potential to play a significant role in the treatment of anemia in patients with MF
  - Live webcast can be accessed on the Events & Presentations page on the investor relations portion of the Company website
- Progressing ongoing Phase 2 study of DISC-0974 in patients with anemia of MF with initial data expected in H2 2025
- Progressing ongoing Phase 1b study of DISC-0974 in patients with anemia of NDD-CKD with multiple-dose data expected in H2 2025

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

- On track to initiate Phase 2 study in PV in H1 2025

Corporate:

- Successfully completed a public offering with gross proceeds of $259 million in January 2025, extending cash runway into 2028

First Quarter 2025 Financial Results:

- **Cash Position:** Cash, cash equivalents, and marketable securities were $694.7 million as of March 31, 2025, which are expected to fund operational plans into 2028.
- **Research and Development Expenses:** R&D expenses were $27.8 million for the three months ended March 31, 2025, as compared to $23.7 million for the three months ended March 31, 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.
- **Selling, General and Administrative Expenses:** SG&A expenses were $12.2 million for the three months ended March 31, 2025, as compared to $7.8 million for the three months ended March 31, 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 $34.1 million for the three months ended March 31, 2025, as compared to $26.9 million for the three months ended March 31, 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 product candidates, 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; 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; and the other risks and uncertainties described in Disc's filings with the SEC, 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 March 31,	
	2025	2024
Operating expenses:		
Research and development	$ 27,763	$ 23,704
Selling, general and administrative	12,183	7,758
Total operating expenses	39,946	31,462
Loss from operations	(39,946)	(31,462)
Other income (expense), net	5,980	4,518
Income tax expense	(119)	(5)
Net loss	$ (34,085)	$ (26,949)
Net loss per share, basic and diluted	$ (1.02)	$ (1.09)
Weighted-average common shares outstanding, basic and diluted	33,324,745	24,809,869

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

	March 31, 2025 (Unaudited)	December 31, 2024
Assets		
Cash, cash equivalents, and marketable securities	$ 694,662	$ 489,881
Other current assets	10,938	3,734
Total current assets	705,600	493,615
Non-current assets	3,666	3,158
Total assets	$ 709,266	$ 496,773
Liabilities and Stockholders' Equity		
Current liabilities	$ 18,741	$ 23,316
Non-current liabilities	30,163	29,870
Total liabilities	48,904	53,186
Total stockholders' equity	660,362	443,587
Total liabilities and stockholders' equity	$ 709,266	$ 496,773

Media Contact

Peg Rusconi
Deerfield Group
peg.rusconi@deerfieldgroup.com

Investor Relations Contact

Christina Tartaglia
Precision AQ
christina.tartaglia@precisionaq.com