

**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): February 27, 2025

DISC MEDICINE, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39438
(Commission
File Number)

85-1612845
(IRS Employer
Identification No.)

321 Arsenal Street, Suite 101, Watertown, MA 02472
(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 (*see* General Instruction A.2. below):

- 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 February 27, 2025, Disc Medicine, Inc. announced its financial results for the fourth quarter and fiscal year ended December 31, 2024 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 February 27, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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

DISC MEDICINE, INC.

Date: February 27, 2025

By: /s/ Jean Franchi

Name: Jean Franchi

Title: Chief Financial Officer



Disc Medicine Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

- *Targeting NDA submission for bitopertin in erythropoietic protoporphyria (EPP) in H2 2025 through accelerated approval pathway; on track to initiate APOLLO post-marketing confirmatory trial by mid-2025*
- *Positive update from Phase 1b trial of DISC-0974 in patients with anemia of myelofibrosis (MF) presented at ASH 2024; initial data from ongoing Phase 2 expected in H2 2025*
- *Positive data from initial cohorts of ongoing Phase 1b study of DISC-0974 in patients with anemia of non-dialysis-dependent chronic kidney disease (NDD-CKD) presented at ASN Kidney Week 2024; initial data from multiple dose portion of this study expected in H2 2025*
- *Presented first-in-human SAD/MAD data from Phase 1 trial of DISC-3405 demonstrating proof-of-mechanism; a Phase 2 study in polycythemia vera (PV) expected to initiate in H1 2025*
- *Strong financial position ending 2024 with \$490 million in cash, cash equivalents, and marketable securities, further strengthened by the net proceeds of our public offering in January 2025, expected to fund operations into 2028*

WATERTOWN, Mass. (February 27, 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 fourth quarter and full year ended December 31, 2024, and provided a recap of recent program and corporate developments.

“2024 was a transformative year for Disc, marked by the achievement of several milestones, most notably opening the door to a potential accelerated approval for bitopertin based on Phase 2 results linking PPIX reduction to improvement on clinical outcomes in EPP patients, and subsequently gaining alignment on the design of the APOLLO trial as a confirmatory study,” said John Quisel, J.D., Ph.D., Chief Executive Officer and President of Disc. “These achievements bring us meaningfully closer to delivering a potentially disease-modifying and life-altering treatment to patients. We expect to initiate the APOLLO trial in mid-2025 followed by an NDA submission in the second half of this year and are diligently preparing for the opportunity to bring bitopertin to market. In addition, we saw momentum across our portfolio, presenting positive clinical data readouts for each of our clinical programs. This included exciting data updates for DISC-0974 in anemias of MF and NDD-CKD, both serious conditions with high unmet patient need and significant opportunity for better treatment options. These latest clinical results strengthen our belief in the potential of our iron homeostasis portfolio assets to address a range of hematological diseases.”

Recent Highlights and Anticipated Milestones:

Bitopertin: GlyTI Inhibitor (Heme Synthesis Modulator)

- Presentation of full results from Phase 2 AURORA and BEACON studies at 2024 ASH Annual Meeting demonstrating significant reductions in PPIX are associated with substantial improvements in time spent in sunlight, measures of quality of life, and reduction in phototoxic reactions
- Positive end-of-phase 2 meeting with FDA providing a path toward potential accelerated approval for bitopertin in EPP with protoporphyrin IX (PPIX) reduction as a surrogate endpoint
- Positive Type C meeting with FDA to achieve regulatory alignment on APOLLO post-marketing confirmatory trial design; on track to initiate trial by mid-year 2025
- Planning to submit NDA under accelerated approval pathway in H2 2025 based on existing clinical data, including results from BEACON and AURORA Phase 2 trials

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

- Presented positive data from the Phase 1b/2 study of DISC-0974 in anemia of myelofibrosis (MF), demonstrating robust and broad hematologic activity across patient segments
 - Results showed substantial and durable improvements in hemoglobin, reductions in transfusion burden, and improvements in fatigue scores
 - Initiated the Phase 2 portion of the study in December 2024, enrolling a broad range of patients after positive discussions with FDA
- Presented data from initial cohorts of ongoing Phase 1b study of DISC-0974 in patients with anemia of NDD-CKD, demonstrating hematologic activity following a single dose
- Presented preclinical data at ASH 2024 demonstrating the potential of DISC-0974 to treat anemia of chronic inflammatory diseases such as IBD
- The Company expects initial data from the ongoing Phase 2 MF anemia trial and multiple-dose data from the ongoing Phase 1b NDD-CKD trial in H2 2025

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

- Presented complete data from the Phase 1 SAD/MAD trial in healthy volunteers, demonstrating proof-of-mechanism with substantial, dose-dependent increases in hepcidin and reductions in serum iron supportive of a once-monthly dosing regimen
- Presented positive preclinical data in sickle cell disease highlighting the potential for DISC-3405 to provide therapeutic benefit in SCD by restricting iron
- The Company plans to initiate a Phase 2 study in PV in H1 2025

Corporate:

- In January 2025, the Company completed an underwritten public offering of 4,533,182 shares of its common stock at \$55.00 per share and 181,818 pre-funded warrants at \$54.9999 per pre-funded warrant. The offering included 615,000 shares which were issued upon the exercise in full by the underwriters of their option to purchase additional shares of common stock.
 - The gross proceeds to the Company from the offering were approximately \$259 million, before deducting underwriting discounts, commissions and offering expenses.
- In the fourth quarter of 2024, the Company closed a \$200 million non-dilutive debt financing with Hercules Capital. An initial \$30 million was drawn at closing. An additional \$80 million is available to be drawn through the second half of 2026 at the Company's discretion. An additional \$65 million is available subject to the Company's achievement of certain performance milestones. The final \$25 million is available subject to Hercules' consent during the interest-only period, which lasts for a minimum of 48 months from closing.

Full Year 2024 Financial Results:

- **Cash Position:** Cash, cash equivalents, and marketable securities were \$489.9 million as of December 31, 2024, compared to \$360.4 million as of December 31, 2023. The increase was largely due to net proceeds of \$172.5 million and \$27.6 million from the follow-on offering in June 2024 and the debt financing in November 2024, respectively. We expect that our existing cash, cash equivalents, and marketable securities as of December 31, 2024, together with the estimated net proceeds of \$243.3 million from our underwritten public offering completed in January 2025, will be sufficient to fund operational plans into 2028.
- **Research and Development Expenses:** R&D expenses were \$96.7 million for the full year ended December 31, 2024, as compared to \$69.3 million for the full year ended December 31, 2023. The increase in R&D expenses was primarily driven by the progression of Disc's portfolio, including bitopertin's clinical studies and drug manufacturing, advancement of DISC-0974 and DISC-3405 programs deeper into development, and increased headcount.
- **Selling, General and Administrative Expenses:** SG&A expenses were \$33.0 million for the full year ended December 31, 2024, as compared to \$21.9 million for the full year ended December 31, 2023. The increase in SG&A expenses was primarily due to increased headcount including establishing infrastructure to support potential commercialization.
- **Net Loss:** Net loss was \$109.4 million for the full year ended December 31, 2024, as compared to \$76.4 million for the full year ended December 31, 2023. 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: 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; the potential of its development programs in new indications; 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,” “opportunity,” 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 our Annual Report on Form 10-K for the year ended December 31, 2024. 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)

	Year Ended December 31,	
	2024	2023
Operating expenses:		
Research and development	\$ 96,671	\$ 69,264
Selling, general and administrative	33,049	21,861
Total operating expenses	<u>129,720</u>	<u>91,125</u>
Loss from operations	(129,720)	(91,125)
Other income (expense), net	20,718	14,795
Income tax expense	(355)	(99)
Net loss	<u>\$ (109,357)</u>	<u>\$ (76,429)</u>
Weighted-average common shares outstanding, basic and diluted	<u>27,606,022</u>	<u>22,315,877</u>
Net loss per share, basic and diluted	<u>\$ (3.96)</u>	<u>\$ (3.42)</u>



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

	<u>December 31,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u>
Assets		
Cash, cash equivalents, and marketable securities	\$ 489,881	\$ 360,382
Other current assets	3,734	5,280
Total current assets	493,615	365,662
Non-current assets	3,158	2,334
Total assets	<u>\$ 496,773</u>	<u>\$ 367,996</u>
Liabilities and Stockholders' Equity		
Current liabilities	\$ 23,316	\$ 21,439
Non-current liabilities	29,870	1,436
Total liabilities	53,186	22,875
Total stockholders' equity	443,587	345,121
Total liabilities and stockholders' equity	<u>\$ 496,773</u>	<u>\$ 367,996</u>

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