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): December 11, 2023

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, MA 02472	**02472**
(Address of principal executive offices)	**(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 7.01 Regulation FD Disclosure.

On December 11, 2023, Disc Medicine, Inc. (the "Company") issued a press release announcing the Company's data presented at the 65th American Society of Hematology ("ASH") Annual Meeting and Exposition. The Company will host a conference call on December 11 at 9:30 p.m. ET to review such data and the Company's operational plans. An archived webcast will be available following the call for 30 days on the Events & Presentations section of the Company's website. A copy of the press is attached as Exhibit 99.1 to this Current Report on Form 8-K. The corporate presentation will also be available in the investor relations section of the Company's website at https://ir.discmedicine.com. Information contained on the Company's website is not incorporated by reference into this Current Report on Form 8-K, and you should not consider any information on, or that can be accessed from, the Company's website as part of this Current Report on Form 8-K.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, 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 provided by specific reference in such filing. The Company undertakes no obligation to update, supplement or amend the material attached hereto as Exhibit 99.1.

Item 8.01 Other Events.

On December 11, 2023, the Company reported initial data from its ongoing Phase 1b/2 study of DISC-0974 in patients with myelofibrosis ("MF").

The Phase 1b/2a multi-center, open-label, ascending-dose study (NCT05320198) is enrolling patients with MF and severe anemia, including both transfusion and non-transfusion dependent patients. The trial also includes patients who may or may not be receiving concomitant janus kinase (JAK) inhibitor therapy. Study assessments include safety and tolerability of DISC-0974, as well as markers of iron regulation, such as hepcidin and iron, and hematologic parameters. In the phase 1b dose-escalation phase, DISC-0974 is administered subcutaneously every 4 weeks for up to 6 treatments. Dose escalation is ongoing and the data presented reflect 11 evaluable subjects from the initial three dose levels (14 mg, 28 mg and 50 mg) as of the October 20, 2023 data cutoff.

Key initial data presented:

- DISC-0974 dosing resulted in meaningful, dose-dependent decreases in hepcidin across all treated patients
- These reductions in hepcidin corresponded to dose-dependent increases in serum iron
    - Patients dosed with 28 mg of DISC-0974 had a >75% reduction in serum hepcidin and >75% increase in serum iron
- Four of seven (57%) evaluable non-transfusion-dependent (NTD) patients at the 28 mg and 50 mg dose levels had a ≥ 1.5 g/dL hemoglobin increase from baseline after starting DISC-0974
- One of two transfusion-dependent (TD) patients achieved transfusion independence by the Gale Criteria
- Hematologic activity was observed in MF patients, regardless of concomitant JAK inhibitor use
- To date, DISC-0974 has been generally well-tolerated. The adverse events (AEs) seen in two or more subjects were fatigue, anemia, diarrhea, and nausea. The majority of AEs were deemed not related to DISC-0974.

Cautionary Statement Regarding Forward-Looking Statements

This Current Report on Form 8-K 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 the Company's expectations with respect to its Phase 1b/2 clinical studies of DISC-0974 in patients with MF and NDD-CKD patients with anemia, projected timelines for the initiation and completion of its clinical trials, anticipated

timing of release of data, and other clinical activities; and the Company's business plans and objectives. 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 the Company's current beliefs, expectations and assumptions regarding the future of the Company'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.

The Company 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 nature, strategy and focus of the Company; the Company's plans to research, develop and commercialize its current and future product candidates; the timing of the availability of data from the Company's clinical trials; the timing and anticipated results of the Company's preclinical studies and clinical trials and the risk that the results of the Company's 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 other risks and uncertainties described in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2022, Quarterly Reports on Form 10-Q for the quarters ended March 31, 2023, June 30, 2023, and September 30, 2023, and other documents filed by the Company from time to time with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in the Company's subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. None of the Company, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Disc Medicine, Inc. on December 11, 2023.
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: December 11, 2023

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

Disc Presents Initial Positive Data from Ongoing Phase 1b/2 Trial of DISC-0974 in Patients with Myelofibrosis (MF) and Anemia at the 65th American Society of Hematology (ASH) Annual Meeting

- *Substantial, dose-dependent reductions in serum hepcidin and increases in serum iron*
- *Hematologic response demonstrated by increased hemoglobin levels and reduction in transfusion burden*
- *DISC-0974 was generally well-tolerated at all evaluated doses*

WATERTOWN, Mass. (December 11, 2023) – 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 announced data from initial dose cohorts of its ongoing phase 1b/2 study of DISC-0974, a monoclonal antibody designed to suppress hepcidin by inhibiting the hemojuvelin (HJV) co-receptor, in MF patients with anemia. The initial data demonstrated that treatment with DISC-0974 substantially decreased serum hepcidin, increased serum iron and resulted in improvements in hemoglobin or reduced transfusion burden across a broad range of MF patients.

“We are thrilled to see this level of hematologic activity so early during dose escalation and in a range of patient types. Elevated hepcidin is an important driver of anemia in patients with MF and the initial data suggest that DISC-0974 has leading activity in suppressing hepcidin,” said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc. “This is the second program in the last six months where Disc has shown proof-of-concept data in patients, and we look forward to advancing DISC-0974 deeper into development and presenting updated data from both this MF and the ongoing CKD anemia study next year.”

The phase 1b/2a multi-center, open-label, ascending-dose study (NCT05320198) is enrolling patients with MF and severe anemia, including both transfusion and non-transfusion dependent patients. The trial also includes patients who may or may not be receiving concomitant janus kinase (JAK) inhibitor therapy. Study assessments include safety and tolerability of DISC-0974, as well as markers of iron regulation, such as hepcidin and iron, and hematologic parameters. In the phase 1b dose-escalation phase, DISC-0974 is administered subcutaneously every 4 weeks for up to 6 treatments. Dose escalation is ongoing and the data presented reflect 11 evaluable subjects from the initial three dose levels (14 mg, 28 mg and 50 mg) as of the October 20, 2023 data cutoff.

Key initial data presented:

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- One of two transfusion-dependent (TD) patients achieved transfusion independence by the Gale Criteria
- Hematologic activity was observed in MF patients, regardless of concomitant JAK inhibitor use
- To date, DISC-0974 has been generally well-tolerated. The adverse events (AEs) seen in two or more subjects were fatigue, anemia, diarrhea, and nausea. The majority of AEs were deemed not related to DISC-0974.

These data were presented at the 65th American Society of Hematology (ASH) Annual Meeting in San Diego, California and the poster is available on the ASH platform. Later today, the company will be presenting updated results from the phase 2 BEACON study of bitopertin in EPP as an oral presentation, December 11th at 5:30 pm PT / 8:30 pm ET.

Management will host a call to review the presented data on Monday, December 11th at 6:30 pm PT / 9:30 pm ET. Please register for the event on the Events and Presentations page of Disc's website (https://ir.discmedicine.com/).

About DISC-0974

DISC-0974 is an investigational monoclonal antibody (mAb) targeting a BMP-signaling co-receptor called hemojuvelin (HJV) and is designed to suppress hepcidin production and increase serum iron levels in patients suffering from anemia of inflammation. DISC-0974 was in-licensed by Disc from AbbVie in 2019. Anemia of inflammation arises from abnormally elevated hepcidin and is the second most common form of anemia, affecting millions of patients in the US across numerous diseases such as chronic kidney disease, myelofibrosis, cancer, autoimmune diseases, and other conditions with an inflammatory component. Disc has established clinical proof-of-mechanism of DISC-0974 in a Phase 1 trial of healthy volunteers and initiated a Phase 1b/2a clinical trial of DISC-0974 in patients with myelofibrosis and anemia, as well as a Phase 1b/2a clinical trial of DISC-0974 in patients with chronic kidney disease and anemia who are not receiving dialysis.

DISC-0974 is an investigational agent and is not approved for use as a therapy in any jurisdiction worldwide.

About Anemia of Myelofibrosis

Myelofibrosis (MF) is a rare, chronic blood cancer that currently affects an estimated 16,000 to 18,500 patients in the United States alone. Severe, progressive, and treatment resistant anemia is the primary clinical manifestation of MF. At diagnosis, over 80% of MF patients have anemia, which progressively worsens and ultimately renders the majority of patients dependent on chronic red blood cell transfusions. Recent studies have shown hepcidin to be a key molecular driver of anemia in myelofibrosis. Hepcidin is elevated by approximately 12-fold in MF patients, and is correlated with disease severity, anemia, and the need for red blood cell transfusions.

About Disc Medicine

Disc Medicine 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 Medicine Cautionary Statement Regarding Forward-Looking Statements

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