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): October 25, 2024

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		**02472**
(Address of Principal Executive Offices)		**(Zip Code)**

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

(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(s)	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 October 25, 2024, Disc Medicine, Inc. (the "Company") issued a press release announcing the Company's data presented at the 2024 American Society of Nephrology (ASN) Kidney Week. A copy of the press release is attached as Exhibit 99.1 to 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 October 25, 2024, the Company reported positive additional data from its ongoing Phase 1b clinical trial of DISC-0974 in patients with non-dialysis-dependent chronic kidney disease ("NDD-CKD") and anemia, including results from the 40 mg and 60 mg single ascending dose ("SAD") cohorts.

In the SAD portion of this trial, participants with Stage 2-5 NDD CKD were given a single dose of placebo (n=7) or DISC-0974 subcutaneously (SC) at 28 mg (n=9), 40 mg (n=6), or 60 mg (n=6). Dose escalation is ongoing in the SAD. This interim data set demonstrated:

- Substantial, durable, dose-dependent reduction in hepcidin from baseline compared to placebo across dose levels, with median reduction greater than 75% from baseline at highest dose level
- Meaningful and sustained increase in transferrin saturation from baseline compared to placebo across dose levels, with median increase up to 3x from baseline at highest dose level
- Early and sustained increase in mean reticulocyte hemoglobin from baseline across all dose groups through Day 22 and beyond
    - Maximal mean values through Day 22 of +1.14 pg at 28 mg, +1.49 pg at 40 mg, and +1.53 pg at 60 mg, compared with +0.21 pg on placebo
- Increase in mean hemoglobin from baseline across dose groups over the study period
    - Change greater than placebo: +0.35 g/dL at 28 mg, +0.54 g/dL at 40 mg, and +0.55 g/dL at 60 mg
- Mean maximal increase in hemoglobin of +0.8 g/dL at 40 mg and +0.7 g/dL at 60 mg compared with +0.2 g/dL on placebo
    - Maximal observed individual increase in hemoglobin up to +0.95 g/dL at 28 mg, +1.5 g/dL at 40 mg, and +1.8 g/dL at 60 mg
- DISC-0974 demonstrated acceptable safety and tolerability at all evaluated dose levels
    - The majority of adverse events were deemed not related to DISC-0974 and all adverse events assessed as treatment-related were Grade 1 or 2

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Disc Medicine, Inc. on October 25, 2024, furnished herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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: October 25, 2024

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

Exhibit 99.1

Disc Medicine Presents Positive Data from SAD Cohorts of a Phase 1b Trial in Patients with Chronic Kidney Disease (CKD) and Anemia at the 2024 American Society of Nephrology (ASN) Kidney Week

WATERTOWN, Mass. October 25, 2024 -- 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 presented positive additional data from an ongoing Phase 1b study of DISC-0974 in patients with non-dialysis-dependent chronic kidney disease (NDD-CKD) and anemia, including results from the 40 mg and 60 mg single ascending dose (SAD) cohorts. The data presented at the 2024 American Society of Nephrology (ASN) Kidney Week in San Diego, CA demonstrated that a single dose of DISC-0974 results in sustained suppression of hepcidin and mobilization of iron, and increased erythropoiesis and levels of hemoglobin in NDD-CKD patients with anemia.

“We are pleased to present these updated results, which provide the first clinical evidence in CKD anemia that reducing hepcidin through hemojuvelin translates into increased erythropoiesis and hemoglobin. Importantly, we were able to observe activity following only a single dose of DISC-0974, which will enable us to efficiently explore dose regimens in the multiple-dose portion of the phase 1b study,” said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc Medicine. “We have now shown that DISC-0974 can improve anemia in the settings of both myelofibrosis and chronic kidney disease. This speaks to the much broader potential for DISC-0974 to address anemia caused by a range of inflammatory and chronic diseases, each of which are associated with elevated hepcidin, and we look forward to providing our plans to access these indications.”

In the SAD portion of this study, participants with stage 2-5 NDD CKD were given a single dose of placebo (n=7) or DISC-0974 subcutaneously (SC) at 28 mg (n=9), 40 mg (n=6), or 60 mg (n=6). Dose escalation is ongoing in the SAD. This interim data set demonstrated:

- Substantial, durable, dose-dependent reduction in hepcidin from baseline compared to placebo across dose levels, with median reduction greater than 75% from baseline at highest dose level
- Meaningful and sustained increase in transferrin saturation from baseline compared to placebo across dose levels, with median increase up to 3x from baseline at highest dose level
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  - Maximal mean values through Day 22 of +1.14 pg at 28 mg, +1.49 pg at 40 mg, and +1.53 pg at 60 mg, compared with +0.21 pg on placebo
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- Mean maximal increase in hemoglobin of +0.8 g/dL at 40 mg and +0.7 g/dL at 60 mg compared with +0.2 g/dL on placebo
  - Maximal observed individual increase in hemoglobin up to +0.95g/dL at 28 mg, +1.5 g/dL at 40 mg, and +1.8 g/dL at 60 mg
- DISC-0974 demonstrated acceptable safety and tolerability at all evaluated dose levels
  - The majority of adverse events were deemed not related to DISC-0974 and all adverse events assessed as treatment-related were Grade 1 or 2

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

About Anemia of Chronic Kidney Disease (CKD)

Chronic kidney disease is a global, widespread disease characterized by progressive loss of kidney function and may lead to end-stage renal disease or kidney failure. CKD affects over 37 million patients in the United States and an estimated 700 million patients worldwide. Anemia is a serious and frequent complication of CKD, as patients are unable to produce sufficient red blood cells and hemoglobin. It affects approximately 5 to 6 million patients in the U.S. alone, may result in fatigue, shortness of breath, and reduced physical and cognitive function, and can be associated with a higher risk of mortality, hospitalization and other complications. Elevated hepcidin is a primary cause of anemia in CKD patients and prevents erythropoiesis by depriving developing red blood cells of iron. Hepcidin accumulates at high levels in CKD patients because its production is stimulated by inflammation and its clearance is reduced due to impaired renal function. Most CKD patients do not receive any treatment for their anemia due to the complexity of outpatient administration and potential safety concerns related to the current treatments. In severe cases, patients may receive blood transfusions, but use may lead to increased administrative burden, safety risks and the potential for immune sensitization which precludes eligibility for kidney transplantation.

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 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 its phase 1b clinical study of DISC-0974 in NDD-CKD patients with anemia, including the multiple dose portion of this clinical study and the results thereof; and the potential for expansion opportunities in anemia associated with other inflammatory diseases. 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 Securities and Exchange Commission, including in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2023, 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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