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): September 09, 2026

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 September 9, 2026, Disc Medicine, Inc. (the “Company”) issued a press release announcing initial results from the RESTORE-PV Phase 2 clinical trial of DISC-3405 in patients with polycythemia vera ("PV"). 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 September 9, 2026, the Company announced initial results from the RESTORE-PV clinical trial of DISC-3405 in patients with PV. The Phase 2, multi-center, open-label RESTORE-PV trial enrolled 40 adult participants with PV, including 20 participants in Cohort A and 20 participants in Cohort B. In the trial, following a 4- to 12-week observation, participants undergo a 12-week dose escalation, then receive DISC-3405 subcutaneously at 300 mg Q2 weeks (Cohort A) or Q4 weeks (Cohort B) for 20 weeks, followed by up to 20 additional weeks of treatment at these respective doses. At the time of the data cut, all 20 participants in Cohort A were dosed and n=13 patients completed 26 weeks of the study, and 18 of 20 participants in Cohort B were dosed. Efficacy data was announced for Cohort A and baseline and safety data were announced for Cohorts A and B. Across escalation and maintenance periods, results demonstrated:

- Dose-proportional PK, elevation of hepcidin, reduction of serum iron, and increase in ferritin (Cohort A)
- Control of hematocrit, with mean hematocrit maintained stably <45% through week 26 which led to initial improvement in symptom burden (Cohort A)
- DISC-3405 significantly reduced phlebotomy events in Cohort A participants. For n=13 patients completing 26 weeks of study:
    - Mean total phlebotomy events significantly decreased from 4.0 in 26 weeks at baseline to 0.6 in 26 weeks post-Day 1 ($p<0.0001$)
    - 61.5% of participants remained entirely phlebotomy-free post-baseline through 26 weeks
    - Of those who completed the first maintenance period (weeks 12-32, n=9), 77.8% of participants remained phlebotomy free during this period
- DISC-3405 was 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 (Cohorts A and B)

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press release issued by Disc Medicine, Inc. on September 9, 2026, 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: September 10, 2026

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

Exhibit 99.1

Disc Medicine Presents Initial Results from RESTORE-PV Phase 2 Trial in Patients with Polycythemia Vera (PV) at the 14th Society of Hematologic Oncology (SOHO) Annual Meeting

- *Initial results from RESTORE-PV show DISC-3405 increased hepcidin and lowered serum iron, translating to controlled hematocrit, reduced phlebotomy, and improved symptoms in PV patients*
- *DISC-3405 is the first monoclonal antibody targeting TMPRSS6 that has demonstrated phlebotomy reduction in patients with PV*
- *Disc also presented an encore of the positive results from the Phase 2 RALLY-MF trial of selcodebart (DISC-0974) in patients with anemia of myelofibrosis (MF) and a new systematic literature review characterizing the burden of anemia associated with MF*

WATERTOWN, Mass. September 9, 2026 -- 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 initial results from the RESTORE-PV Phase 2 trial of DISC-3405 in patients with polycythemia vera (PV). The data, presented in a poster session at the 2026 Society of Hematologic Oncology (SOHO) annual meeting in Houston, TX, demonstrated that treatment with DISC-3405 increased hepcidin and lowered serum iron, translating to reduction in phlebotomy, controlled hematocrit, and improved symptom burden in patients with PV. These data will be featured in an oral presentation at the SOHO conference tomorrow, September 10. Disc also presented an encore of the positive results from the Phase 2 RALLY-MF trial of selcodebart (DISC-0974) in patients with anemia of myelofibrosis (MF) and a new systematic literature review characterizing the humanistic burden of anemia associated with MF through patient reported outcomes.

“This first look at data from the RESTORE-PV trial shows that the established pharmacodynamics of DISC-3405 are translating well on important clinical measures,” said John Quisel, JD, PhD, President and Chief Executive Officer of Disc Medicine. “Iron restriction is proving to be a transformative treatment approach for a large population of patients with polycythemia vera, with the potential to address their crucial need for hematocrit control while managing symptom burden and reducing reliance on phlebotomy. Our goal for DISC-3405 is to deliver an optimal product presentation combining durable disease control with straightforward, controllable, and convenient dosing using a novel antibody approach. Between this update in PV and our earlier progress in MF this year, we have strengthened our commitment to hematologic oncology and now have two programs advancing toward potential pivotal development in myeloproliferative neoplasms.”

The Phase 2 multi-center, open-label RESTORE-PV trial enrolled 40 adult participants with PV, including 20 participants in Cohort A and 20 participants in Cohort B. In the trial, following a 4- to 12-week observation, participants undergo a 12-week dose escalation, then receive DISC-3405 subcutaneously at 300 mg Q2 weeks (Cohort A) or Q4 weeks (Cohort B) for 20 weeks, followed by up to 20 additional weeks of treatment at these respective doses. At the time of the data cut, all 20 participants in Cohort A were dosed and n=13 patients completed 26 weeks of the study, and 18 of 20 participants in Cohort B were dosed. Efficacy data was presented for Cohort A and baseline and safety data were presented for Cohorts A and B. Across escalation and maintenance periods, results demonstrated:

- Dose-proportional PK, elevation of hepcidin, reduction of serum iron, and increase in ferritin (Cohort A)
- Control of hematocrit, with mean hematocrit maintained stably <45% through week 26 which led to initial improvement in symptom burden (Cohort A)

- DISC-3405 significantly reduced phlebotomy events in Cohort A participants. For n=13 patients completing 26 weeks of study:
    - Mean total phlebotomy events significantly decreased from 4.0 in 26 weeks at baseline to 0.6 in 26 weeks post-Day 1 ($p<0.0001$)
    - 61.5% of participants remained entirely phlebotomy-free post-baseline through 26 weeks
    - Of those who completed the first maintenance period (weeks 12-32, n=9), 77.8% of participants remained phlebotomy free during this period
- DISC-3405 was 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 (Cohorts A and B)

Disc plans to provide an update on RESTORE-PV, as well as initial data from the Phase 1b trial of DISC-3405 in sickle cell disease, by the end of 2026.

With respect to selcodebart, the company also expects to share feedback from an end of phase 2 meeting with the U.S. Food and Drug Administration (FDA) and plans for pivotal development in anemia of MF by the end of the year.

About DISC-3405

DISC-3405 is an investigational, anti-TMPRSS6 (Transmembrane Serine Protease 6, also known as Matriptase-2) monoclonal antibody designed to increase hepcidin production and suppress serum iron. Disc in-licensed DISC-3405 from Mabwell Therapeutics in January 2023. The therapeutic potential for hepcidin induction includes treatment of diseases associated with iron overload, diseases of excess red blood cell production, or diseases otherwise enabled by iron availability. Disc has established clinical proof-of-mechanism of DISC-3405 in a Phase 1 study in healthy volunteers and initiated a Phase 2 trial in patients with polycythemia vera and a Phase 1b trial in patients with sickle cell disease.

DISC-3405 is an investigational agent and is not approved for use as a therapy in any jurisdiction worldwide.

About Polycythemia Vera

Polycythemia vera (PV) is a chronic and rare myeloproliferative neoplasm characterized by the abnormal proliferation of red blood cells. PV affects approximately 150,000 patients in the U.S. and has a similar prevalence in Europe. The overproduction of red blood cells alters the viscosity of blood, causing it to thicken and placing patients at an elevated risk of cardiovascular and thromboembolic events, such as heart attack and stroke. Patients also experience complications such as enlarged spleen and symptoms of their disease such as fatigue, pruritis, difficulty concentrating and others. Current therapy involves phlebotomy to physically remove blood and iron to limit erythropoiesis or treatment with cytoreductive agents, with the goal of reducing red blood cell count and managing symptoms.

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 the next stages of its development programs for selcodebart and DISC-3405, including projected timelines for the initiation and completion of its clinical trials, anticipated timing of release of data, other clinical activities, and anticipated discussions with regulatory agencies. 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 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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