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 13, 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** **(Address of Principal Executive Offices)**	**02472** **(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 February 13, 2026, Disc Medicine, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") issued a Complete Response Letter ("CRL") for the New Drug Application ("NDA") for bitopertin as a treatment for patients with erythropoietic protoporphyria ("EPP"). A copy of the press release and a copy of the CRL are attached as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

The information in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 and Exhibit 99.2 attached hereto 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 liability under 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 a filing.

Item 8.01 Other Events.

On February 13, 2026, the Company received a CRL from the FDA for the Company's NDA for bitopertin as a treatment for patients with EPP.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Disc Medicine, Inc. press release, dated February 13, 2026
99.2*	Complete Response Letter, dated February 13, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the Securities and Exchange Commission.

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: February 13, 2026

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

Exhibit 99.1

Disc Medicine Receives Complete Response Letter from FDA for Bitopertin for the Treatment of EPP

- FDA acknowledged that AURORA and BEACON provided sufficient evidence that bitopertin significantly lowers PPIX and that there is a strong mechanistic and biological plausibility supporting the use of the PPIX biomarker in protoporphyria
- FDA indicated a need to see the results of the ongoing Phase 3 APOLLO study before making a decision
- Ongoing Phase 3 APOLLO study potential to serve as basis for traditional approval; topline data anticipated Q4 2026

WATERTOWN, Mass. (February 13, 2026) – Disc Medicine, Inc. (NASDAQ:IRON), a biopharmaceutical company focused on the discovery, development, and commercialization of novel treatments for patients suffering from serious hematologic diseases, announced that the U.S. Food and Drug Administration (FDA) today issued a Complete Response Letter (CRL) for the New Drug Application (NDA) for bitopertin as a treatment for patients with erythropoietic protoporphyria (EPP). Bitopertin has been under review for accelerated approval and as part of the Commissioner's National Priority Voucher (CNPV) pilot program.

Accelerated approval relies on (1) whether there is evidence of an effect on the proposed surrogate endpoint (% change in whole blood metal-free PPIX) and (2) whether the proposed surrogate endpoint, including the magnitude of change, is reasonably likely to predict a clinical benefit. On the first point, the FDA agreed that AURORA and BEACON provided sufficient evidence that bitopertin significantly lowers whole blood metal-free PPIX. On the second, based on review of AURORA and BEACON results, the FDA concluded that the trials did not show evidence of association between percent change in PPIX and sunlight exposure-based endpoints, as measured in the trials, despite the strong mechanistic and biological plausibility supporting the use of the PPIX biomarker in protoporphyria. The FDA indicated results of the APOLLO study could serve as evidence to support traditional approval.

"We are committed to delivering bitopertin to patients, knowing how critical this potentially disease-modifying therapy is to the EPP community. While our efforts at utilizing expedited pathways to get bitopertin to patients quickly have not come to fruition, we are continuing to pursue all avenues in support of FDA approval," said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc Medicine. "The CRL will delay the potential approval of bitopertin, but we have confidence in the ongoing APOLLO trial, for which we are seeing incredible enthusiasm from the EPP community. Confidence in our product and program guides our approach, and we will continue working closely with the FDA to support their review."

Disc believes the issue raised is readily addressable, given the APOLLO study is already well underway with topline data expected in Q4. Disc plans to request a Type A meeting to review our approach with the FDA. A blinded sample size re-estimation of the APOLLO study was conducted in January and no modifications to sample size were needed based on statistical

analysis. There has been significant patient and physician enthusiasm around the APOLLO trial, allowing Disc to complete trial enrollment in March 2026, several months earlier than expected. Upon completion of APOLLO, Disc would then file a response to the CRL and expect an updated FDA decision by mid-2027. Disc has approximately $791 million at December 31, 2025 in unaudited cash, cash equivalents, and marketable securities and maintains guidance of providing runway into 2029.

Disc Medicine will host a call for investors at 8 am ET on Tuesday, February 17th to discuss this outcome. Please register for the event on the Events and Presentations page of Disc's website (https://ir.discmedicine.com/).

A copy of the CRL will be included in a Form 8-K to be filed with the Securities and Exchange Commission, which will be accessible on ir.discmedicine.com.

About Bitopertin

Bitopertin is an investigational, clinical-stage, orally administered inhibitor of glycine transporter 1 (GlyT1) that is designed to modulate heme biosynthesis. GlyT1 is a membrane transporter expressed on developing red blood cells and is required to supply sufficient glycine for heme biosynthesis and support erythropoiesis. Disc is developing bitopertin as a potential treatment for a range of hematologic diseases including erythropoietic porphyrias, where it has potential to be the first disease-modifying therapy. Bitopertin has been studied in multiple clinical trials in patients with EPP, including the Phase 2 open-label BEACON trial, the Phase 2 double-blind, placebo-controlled AURORA trial, an open-label extension HELIOS trial, and the confirmatory Phase 3 double-blind, placebo-controlled APOLLO trial.

Bitopertin is an investigational agent and is not approved for use as a therapy in any jurisdiction worldwide. Disc obtained global rights to bitopertin under a license agreement from Roche in May 2021.

About Disc Medicine
Disc Medicine (NASDAQ:IRON) is a 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: the APOLLO clinical trial, including timing for completion and the results thereof; the future regulatory path for bitopertin with the FDA, including the potential for traditional approval, the timing of any such approval, and the potential for APOLLO to serve as

the basis for any such approval; and our 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 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, 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.

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Exhibit 99.2

Certain identified information has been excluded from this exhibit. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

NDA 220707

COMPLETE RESPONSE

Disc Medicine, Inc.
Attention: Steve Caffé,
MD Chief Regulatory
Officer
321 Arsenal Street, Suite 101
Watertown, MA 02472

Dear Dr. Caffé:

Please refer to your new drug application (NDA) [***] for bitopertin oral tablets.

We have completed our review of this application, as amended, and have determined that we cannot approve this application in its present form. We have described our reasons for this action below and, where possible, our recommendations to address these issues.

CLINICAL/BIOSTATISTICS

On [***], you submitted NDA 220707 for bitopertin for [***]. You seek approval of this application under the provisions of [***], proposing the primary biomarker endpoint of percent change in whole blood metal-free protoporphyrin IX (PPIX) as a surrogate endpoint that is reasonably likely to predict clinical benefit.

In support of approval, you submitted the results of Study DISC-1459-201 (Trial 201) and Study DISC-1459-202 (Trial 202). Trial 201 was a randomized, double-blind, placebo-controlled trial in subjects 18 years of age and older with EPP. The trial included a 28-day screening period and a randomized 120-day treatment period. The trial enrolled [***] subjects, including [***] randomized to bitopertin 20 mg, [***] randomized to bitopertin 60 mg, and [***] randomized to placebo. The trial was conducted at 9 sites in the United States. Trial 202 was a randomized, open-label trial of bitopertin 60 mg vs. 20 mg in subjects 12 years of age and older with EPP or XLP. The trial included a 28-day screening period and a randomized 168-day treatment period. The trial was conducted at 2 sites in Australia. The trial enrolled [***] subjects, including [***] randomized to bitopertin 20 mg and [***] randomized to bitopertin 60 mg. The primary biomarker endpoint was the percent change in whole blood metal-free PPIX levels from baseline to end of the treatment period (Day 121 in Trial 201 and Day 169 in Trial 202). You propose an ongoing trial, DISC-1459-301, as your confirmatory trial.

The approvability of an NDA under the provisions of [***], relies on, in part, two factors: first, whether there is evidence of an effect on the proposed surrogate endpoint; and second, whether the proposed surrogate endpoint, including the magnitude of change, is reasonably likely to predict a clinical benefit.

With respect to the first factor, we agree that Trial 201, one adequate and well-controlled trial, demonstrated an effect on its primary endpoint. In Trial 201, bitopertin 60 mg was superior to placebo for the primary biomarker endpoint of percent change from baseline to Day 121 of whole blood metal-free PPIX in adult patients with EPP ($p<0.001$). Confirmatory evidence was provided from a second, randomized, open-label trial, Trial 202, in which bitopertin 60 mg was superior to bitopertin 20 mg for the primary biomarker endpoint of percent change from baseline to Day 169 of whole blood metal-free PPIX in adult and adolescent patients with EPP or XLP ($p=0.018$).

However, there are uncertainties with respect to the second factor. The percent change in PPIX was relatively modest (about 40% reduction from baseline to Day 121 for the higher 60 mg dose) and whether that magnitude of change in whole blood metal-free PPIX is reasonably likely to predict clinical benefit is unknown. This uncertainty is further exacerbated by the results from Trials 201 and 202 which did not show evidence of association between percent change in whole blood metal-free PPIX and sunlight-exposure based endpoints, as measured in the trials, despite the strong mechanistic and biological plausibility supporting the use of the PPIX biomarker in [***].
This lack of correlation between the changes in PPIX and clinical outcomes measured leaves significant uncertainty that bitopertin will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling.

For this application to be approved, you will need to provide evidence from an adequate and well-controlled trial(s) demonstrating the efficacy of bitopertin for [***] based on clinical endpoint(s). The Division is willing to meet with you to discuss options, such as completing your ongoing trial and, if the trial is successful, submitting the results to support a traditional approval.

PRESCRIBING INFORMATION

We reserve comment on the proposed labeling until the application is otherwise adequate. We encourage you to review the labeling review resources on the Prescription Drug Labeling Resources[1] and Pregnancy and Lactation Labeling Final Rule[2] websites, including regulations and related guidance documents and the Selected Requirements for Prescribing Information (SRPI) − a checklist of important format items from labeling regulations and guidances.

[1] https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labeling-resources

[2] https://www.fda.gov/drugs/labeling-information-drug-products/pregnancy-and-lactation-labeling-drugs-final-rule

CARTON AND CONTAINER LABELING

We reserve comment on the proposed labeling until the application is otherwise adequate.

PROPRIETARY NAME

Please refer to our correspondence dated, [***], which addresses the proposed proprietary name, [***]. This name was found conditionally acceptable pending approval of the application in the current review cycle. Please resubmit the proposed proprietary name when you respond to all of the application deficiencies that have been identified in this letter.

SAFETY UPDATE

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(*b*). The safety update should include data from all nonclinical and clinical studies/trials of the drug under consideration regardless of indication, dosage form, or dose level.

(1) Describe in detail any significant changes or findings in the safety profile.

(2) When assembling the sections describing discontinuations due to adverse events, serious adverse events, and common adverse events, incorporate new safety data as follows:

- Present new safety data from the studies/clinical trials for the proposed indication using the same format as in the original submission.
- Present tabulations of the new safety data combined with the original application data.
- Include tables that compare frequencies of adverse events in the original application with the retabulated frequencies described in the bullet above.
- For indications other than the proposed indication, provide separate tables for the frequencies of adverse events occurring in clinical trials.

(3) Present a retabulation of the reasons for premature trial discontinuation by incorporating the drop-outs from the newly completed trials. Describe any new trends or patterns identified.

(4) Provide case report forms and narrative summaries for each subject who died during a clinical trial or who did not complete a trial because of an adverse event. In addition, provide narrative summaries for serious adverse events.

(5) Describe any information that suggests a substantial change in the incidence of common, but less serious, adverse events between the new data and the original application data.

(6) Provide updated exposure information for the clinical studies/trials (e.g., number of subjects, person time).

(7) Provide a summary of worldwide experience on the safety of this drug. Include an updated estimate of use for drug marketed in other countries.

(8) Provide English translations of current approved foreign labeling not previously submitted.

OTHER

Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 314.65. You may also request an extension of time in which to resubmit the application.

A resubmission must fully address all the deficiencies listed in this letter and should be clearly marked with "**RESUBMISSION**" in large font, bolded type at the beginning of the cover letter of the submission. The cover letter should clearly state that you consider this resubmission a complete response to the deficiencies outlined in this letter. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

You may request a meeting or teleconference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.*

The product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, email [***].

Sincerely,

{See appended electronic signature page}

[***]
Center for Drug Evaluation and Research

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

[***]
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