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): April 1, 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, 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 April 1, 2024, Disc Medicine, Inc. (the "Company") issued a press release announcing the Company's topline results from its Phase 2 AURORA Study of Bitopertin in Patients with Erythropoietic Protoporphyria ("EPP"). The Company hosted a conference call on April 1, 2024 at 8:30 a.m. ET and reviewed such data. 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 release 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 April 1, 2024, the Company reported topline results from its Phase 2 AURORA Study of Bitopertin in Patients with EPP.

Treatment with bitopertin resulted in statistically significant reductions in protoporphyrin IX ("PPIX"), the primary endpoint, and significant improvements in the rate of phototoxic reactions with pain and the Patient Global Impression of Change ("PGIC"). On the key secondary endpoint of cumulative time in sunlight on days without pain, bitopertin patients had a positive response consistent with BEACON results, but the endpoint did not meet statistical significance due to strong placebo performance.

The AURORA study is a randomized, double-blind, placebo-controlled phase 2 study that enrolled 75 adult subjects with EPP. Subjects were randomized 1:1:1 to receive 20 mg of bitopertin, 60 mg of bitopertin, or placebo once daily for 17 weeks.

Summary of topline results

Primary endpoint: Bitopertin resulted in significant, dose-dependent, and sustained reductions in whole blood PPIX levels (-21.6% for 20 mg ($p=0.003$ vs placebo) and -40.7% for 60 mg ($p<0.001$ vs placebo); the placebo group had mean increases of +8.0%).

Secondary endpoints

- Cumulative total time in sunlight between 10 am and 6 pm on days without pain observed over the 4-month treatment period (bitopertin-treated patients recorded a mean of 175.1 hours at 20 mg and 153.1 hours at 60 mg, compared with 133.9 hours for placebo; results were not statistically significant compared to placebo).
    - The magnitude of the improvement in the bitopertin-treated patients was comparable to that observed in the BEACON study, but the benefit in the placebo arm in the AURORA trial was greater than expected.
- Large improvements in light tolerance from baseline in 20 mg and 60 mg bitopertin treatment groups as measured by time to prodrome; results were not statistically significant relative to placebo.
- Substantial and dose-dependent reductions in phototoxic reactions with pain during the 4-month study period:
    - 75% reduction in the incidence rate of new phototoxic reactions with pain at the 60 mg dose group compared to placebo ($p=0.011$); 60% reduction in the 20 mg dose group ($p=0.109$); and
    - Fewer bitopertin-treated patients reported a phototoxic event compared to placebo (19% for 20 mg and 12% for 60 mg compared to 46% for placebo).

- Dose-dependent improvements in PGIC, which were statistically significant for the 60 mg dose (77% of completers at 20 mg and 86% at 60 mg (p=0.022 vs. placebo) reported that their EPP was “much better” compared with 50% for placebo).
- Bitopertin was generally well tolerated in both dose groups with no serious adverse events and stable hemoglobin levels. Two patients discontinued treatment due to treatment-emergent AEs, both in the 60 mg dose group: one due to dizziness and one due to a skin rash. The most common AE reported with bitopertin treatment was dizziness.

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 2 clinical study of bitopertin in patients with EPP, expectations around timing of registrational data endpoints, 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, 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 April 1, 2024.
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: April 2, 2024

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

Disc Reports Topline Results from Phase 2 AURORA Study of Bitopertin in Patients with Erythropoietic Protoporphyria (EPP)

April 1, 2024

- *Met primary endpoint, demonstrating dose-dependent, statistically significant reductions in protoporphyrin IX (PPIX) compared to placebo in both 20 mg and 60 mg dose groups*
- *Improved measures of light tolerance, including the key secondary endpoint, in both 20 mg and 60 mg dose groups, but did not meet statistical significance compared to placebo*
- *Dose-dependent reductions in the rate of phototoxic reactions with pain, with statistical significance at the 60 mg dose group compared to placebo*
- *Dose-dependent improvements in the Patient Global Impression of Change (PGIC), with statistical significance at the 60 mg dose group compared to placebo*
- *Investor webcast at 8:30 am ET to discuss top-line data*

WATERTOWN, Mass., April 01, 2024 (GLOBE NEWSWIRE) – 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 topline data from AURORA, a phase 2 study of bitopertin in patients with EPP. Treatment with bitopertin resulted in statistically significant reductions in PPIX, the primary endpoint, and significant improvements in the rate of phototoxic reactions with pain and the Patient Global Impression of Change (PGIC). On the key secondary endpoint of cumulative time in sunlight on days without pain, bitopertin patients had a positive response consistent with BEACON results, but the endpoint did not meet statistical significance due to strong placebo performance.

“This study has confirmed that bitopertin significantly reduces the toxic metabolite, PPIX, in patients with EPP, and we have shown that bitopertin-treated patients experience improvements in the clinically meaningful outcomes of Patient Global Impression of Change and the number and rate of phototoxic reactions with pain, with the 60 mg dose reaching statistical significance compared to placebo. Despite the strong performance of bitopertin on the key secondary endpoint of cumulative time in light, consistent with results seen in BEACON, statistical significance was not met due to an outsized placebo response,” said John Quisel, J.D., Ph.D., President and Chief Executive Officer. “Given that, we will need to conduct an analysis of our final data set and work with investigators, regulators, and patient advocacy groups to define the optimal registrational endpoints moving forward. While we do this additional work, we continue to be excited about the upcoming readouts from our other programs, including updated data from our DISC-0974 study in anemia of myelofibrosis in Q2.”

The AURORA study is a randomized, double-blind, placebo-controlled phase 2 study that enrolled 75 adult subjects with EPP. Subjects were randomized 1:1:1 to receive 20 mg of bitopertin, 60 mg of bitopertin, or placebo once daily for 17 weeks.

Summary of topline results

Primary endpoint

- Bitopertin resulted in significant, dose-dependent, and sustained reductions in whole blood PPIX levels: -21.6% for 20 mg ($p=0.003$ vs placebo) and -40.7% for 60 mg ($p<0.001$ vs placebo); the placebo group had mean increases of +8.0%

Secondary endpoints

- Cumulative total time in sunlight between 10 am and 6 pm on days without pain observed over the 4-month treatment period: bitopertin-treated patients recorded a mean of 175.1 hours at 20 mg and 153.1 hours at 60 mg, compared with 133.9 hours for placebo; results were not statistically significant compared to placebo
  - The magnitude of the improvement in the bitopertin-treated patients was comparable to that observed in the BEACON study, but the benefit in the placebo arm in the AURORA trial was greater than expected
- Large improvements in light tolerance from baseline in 20 mg and 60 mg bitopertin treatment groups as measured by time to prodrome; results were not statistically significant relative to placebo.
- Substantial and dose-dependent reductions in phototoxic reactions with pain during the 4-month study period:
  - 75% reduction in the incidence rate of new phototoxic reactions with pain at the 60 mg dose group compared to placebo ($p=0.011$); 60% reduction in the 20 mg dose group ($p=0.109$)
  - Fewer bitopertin-treated patients reported a phototoxic event compared to placebo: 19% for 20 mg and 12% for 60 mg compared to 46% for placebo
- Dose-dependent improvements in PGIC, which were statistically significant for the 60 mg dose: 77% of completers at 20 mg and 86% at 60 mg ($p=0.022$ vs placebo) reported that their EPP was “much better” compared with 50% for placebo

- Bitopertin was generally well tolerated in both dose groups with no serious adverse events and stable hemoglobin levels. Two patients discontinued treatment due to treatment-emergent AEs, both in the 60 mg dose group: one due to dizziness and one due to a skin rash. The most common AE reported with bitopertin treatment was dizziness: n=4 in the 20 mg dose group, n=11 in the 60 mg dose group compared with n=4 in the placebo group (median durations of 4.5, 5, and 2 days, respectively)

Webcast Conference Call Information

Management will host a call on Monday, April 1 at 8:30 am ET to review the data. Please register for management's webcast on the Events and Presentations page of Disc's website (https://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 planning to develop 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. There are currently two ongoing phase 2 clinical trials of bitopertin in patients with EPP that have fully enrolled and have had key data readouts: the open-label trial called BEACON and a randomized, double-blind placebo-controlled trial called AURORA.

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 Erythropoietic Protoporphyria (EPP) and X-linked Protoporphyria (XLP)

Erythropoietic protoporphyria (EPP) and X-linked Protoporphyria (XLP) are rare, debilitating and potentially life-threatening diseases caused by mutations that affect heme biosynthesis, resulting in the accumulation of a toxic, photoactive intermediate called protoporphyrin IX (PPIX). This causes severe reactions when patients are exposed to sunlight, characterized by excruciating pain, edema, burning sensations and potential blistering and disfigurement. PPIX also accumulates in the hepatobiliary system and can result in complications including gallstones, cholestasis, and liver damage in 20-30% of patients and in extreme cases liver failure. Current standard of care involves extreme measures to avoid sunlight, including restricting outdoor activities to nighttime, use of protective clothing and opaque shields, and pain management. This has a significant impact on the psychosocial development, quality of life, and daily activities of patients, particularly in young children and families. There is currently no cure for EPP and only one FDA-approved therapy, a surgically implanted synthetic hormone designed to stimulate melanin production called Scenesse® (afamelanotide).

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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Media Contact

Peg Rusconi
Verge Scientific Communications
prusconi@vergescientific.com

Investor Relations Contact

Christina Tartaglia

Stern Investor Relations
christina.tartaglia@sternir.com