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): November 9, 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© under the Exchange Act (17 CFR 240.13e-4©)

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 2.02 Results of Operations and Financial Condition.

On November 9, 2023, Disc Medicine, Inc. announced its financial results for the quarter ended September 30, 2023 and provided a corporate update. A copy of the press release in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) 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 set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 of this Current Report on Form 8-K shall be deemed to be furnished and not filed:

Exhibit No.	Description
99.1	Press Release issued by Disc Medicine, Inc. on November 9, 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: November 9, 2023

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

Disc Medicine Reports Third Quarter 2023 Financial Results and Provides Business Update

- *Completed enrollment of BEACON and AURORA trials of bitopertin in erythropoietic protoporphyria (EPP); BEACON expanded to include adolescents*
- *Data from all adult patients in BEACON to be presented in an oral presentation at the 65th American Society of Hematology Annual Meeting and Exposition (ASH 2023), including the preliminary analysis of the precedented pivotal endpoint, cumulative time in sunlight over 6 months on days without pain*
- *Preliminary pharmacodynamic data from the ongoing phase 1b/2 study of DISC-0974 in patients with myelofibrosis (MF) and anemia to be presented in a poster at ASH 2023, including changes in hemoglobin levels*
- *Data from the first 28 mg cohort of the phase 1b/2 study of DISC-0974 in patients with anemia of chronic kidney disease who are not receiving dialysis (NDD-CKD) to be presented as a part of a management call during ASH 2023*
- *Initiated a Phase 1 trial of DISC-3405, an anti-TMPRSS6 antibody, in healthy volunteers and received fast track designation by the U.S. Food and Drug Administration (FDA) for the treatment of polycythemia vera (PV)*

WATERTOWN, Mass. (November 9, 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 reported financial results for the third quarter ended September 30, 2023, and provided an update on recent program and corporate developments.

“We made tremendous progress this quarter in advancing our portfolio, including a major milestone of completing enrollment of both BEACON and AURORA studies within a year, as well as advancing our third development program into the clinic,” said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc. “We’re looking forward to the ASH 2023 meeting in December, when we will be presenting updated interim data from BEACON, as well as initial data for DISC-0974 in MF and CKD.”

Recent Business Highlights and Upcoming Milestones:

Bitopertin: GlyT1 Inhibitor (Heme Synthesis Modulator)

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.

- Completed enrollment for both BEACON, an open-label Phase 2 clinical study of bitopertin in patients with EPP and X-linked protoporphyria (XLP), and AURORA a Phase 2 randomized, placebo-controlled clinical study of bitopertin in adults with EPP
- Expanded enrollment of BEACON to include adolescents (ages 12-18)
- Updated BEACON data from all patients and with longer duration of therapy will be presented at ASH 2023, including measures of protoporphyrin IX (PPIX), photosensitivity, quality of life, safety, and tolerability, as well as preliminary analysis of the precedented pivotal endpoint, cumulative time in light over 6 months on days without pain

- Topline AURORA data is expected to be presented in early 2024

DISC-0974: Anti-Hemojuvelin Antibody (Hepcidin Suppression)

DISC-0974 is an investigational anti-hemojuvelin monoclonal antibody and is designed to suppress hepcidin production and increase serum iron levels in patients suffering from anemia of inflammation.

- Ongoing enrollment and dose escalation in a Phase 1b/2 clinical study in MF patients with severe anemia on stable background therapy; initial data from 10-20 patients in the dose-escalation phase of the study, including safety and changes in hepcidin, iron, and hemoglobin levels, will be presented at ASH 2023
- Ongoing enrollment and dose escalation in a Phase 1b/2 clinical study of patients with anemia of chronic kidney disease who are not receiving dialysis (NDD-CKD); initial data from the 28 mg cohort will be presented as part of a management call in December

DISC-3405: Anti-TMPRSS6 Antibody (Hepcidin Induction)

DISC-3405 is an investigational, anti-TMPRSS6 (Transmembrane Serine Protease 6, also known as Matriptase-2) monoclonal antibody designed to increase hepcidin production and restrict serum iron.

- Initiated a Phase 1 study in healthy volunteers in October 2023
- Received FDA fast track designation in September 2023 for DISC-3405 for the treatment of PV

Third Quarter 2023 Financial Results:

- **Cash Position:** Cash and cash equivalents were $370.5 million as of September 30, 2023, which are expected to fund our operational plans well into 2026.
- **Research and Development Expenses:** R&D expenses were $14.4 million for the quarter ended September 30, 2023, as compared to $7.9 million for the quarter ended September 30, 2022. The increase in R&D expenses were primarily driven by the progression of Disc's portfolio, including bitopertin's ongoing two Phase 2 clinical studies and drug manufacturing, study initiation for DISC-3405, and increased headcount.
- **General and Administrative Expenses:** G&A expenses were $4.5 million for the quarter ended September 30, 2023, as compared to $2.6 million for the same period in 2022. The increase in G&A expenses was primarily due to increased headcount.
- **Net Loss:** Net loss was $14.1 million for the quarter ended September 30, 2023, as compared to $16.2 million for the third quarter of 2022. Although operating expenses increased in the current period relative to the prior period due to increased product development activities, these increases were offset by increased interest income and the absence of the change in fair value of the derivative liability related to a one-time share issuance obligation to F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. in connection with the bitopertin license agreement which was settled in late 2022.

About Disc Medicine

Disc Medicine (NASDAQ:IRON) 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.

Available Information

Disc announces material information to the public about the Company, its products and services, and other matters through a variety of means, including filings with the U.S. Securities and Exchange Commission (SEC), press releases, public conference calls, webcasts and the investor relations section of the Company website at ir.discmedicine.com in order to achieve broad, non-exclusionary distribution of information to the public and for complying with its disclosure obligations under Regulation FD.

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 AURORA Phase 2 and BEACON Phase 2 clinical studies of bitopertin and the results thereof, and its Phase 1b/2 study of bitopertin in Diamond-Blackfan Anemia, its Phase 1b/2 clinical studies of DISC-0974 in patients with MF and NDD-CKD patients with anemia, its Phase 1 clinical study of DISC-3405 in healthy volunteers; projected timelines for the initiation and completion of its clinical trials, anticipated timing of release of data, and other clinical activities; and Disc's business plans and objectives; and Disc's beliefs about operating expenses and that it will have capital to fund Disc well into 2026. 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; that enrollment timelines of both the BEACON and AURORA studies may not necessarily be predictive of future enrollment timelines; the timing of initiation of Disc's planned clinical trials; Disc's ability to retain and recognize the intended incentives conferred by Fast Track Designation for its product candidates including DISC-3405; 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 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 and June 30, 2023, and other documents filed by Disc from time to time with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in Disc’s subsequent filings with the SEC. 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.

DISC MEDICINE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 14,419	$ 7,886	$ 46,699	$ 23,421
General and administrative	4,539	2,593	14,712	9,033
Total operating expenses	18,958	10,479	61,411	32,454
Loss from operations	(18,958)	(10,479)	(61,411)	(32,454)
Other income (expense), net	4,856	(5,671)	8,628	(3,129)
Income tax expense	(20)	—	(67)	—
Net loss	$ (14,122)	$ (16,150)	$ (52,850)	$ (35,583)
Weighted-average common shares outstanding-basic and diluted	24,316,817	960,317	21,605,202	943,058
Net loss per share-basic and diluted	$ (0.58)	$ (16.82)	$ (2.45)	$ (37.73)

DISC MEDICINE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	September 30, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 370,541	$ 194,611
Other current assets	3,722	3,880
Total current assets	374,263	198,491
Non-current assets	2,234	1,714
Total assets	$ 376,497	$ 200,205
Liabilities and Stockholders' Equity		
Current liabilities	$ 14,416	$ 22,578
Non-current liabilities	3,107	1,027
Total liabilities	17,523	23,605
Total stockholders' equity	358,974	176,600
Total liabilities and stockholders' equity	$ 376,497	$ 200,205

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