

**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): March 31, 2023

DISC MEDICINE, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39438
(Commission
File Number)

85-1612845
(IRS Employer
Identification No.)

321 Arsenal Street, Suite 101, Watertown, MA 02472
(Address of principal executive offices)

02472
(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 March 31, 2023, Disc Medicine, Inc. (the “Company”) announced its financial results for the quarter and fiscal year ended December 31, 2022 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 5.08 Shareholder Director Nominations.

On March 31, 2023, the Company announced that its 2023 Annual Meeting of Stockholders (the “2023 Annual Meeting”) is scheduled to be held at 9:00 a.m. Eastern Time on Friday, June 9, 2023. The record date for the 2023 Annual Meeting will be April 14, 2023. Only stockholders of record as of the close of business on the record date will be entitled to vote at the 2023 Annual Meeting, or any adjournment or postponement thereof. The 2023 Annual Meeting will be a virtual meeting, conducted as a live webcast.

Pursuant to the provisions of the Company’s Amended and Restated Bylaws (the “Bylaws”), for any stockholder to propose business (other than pursuant to and in compliance with Exchange Act Rule 14a-8) or make a nomination before the 2023 Annual Meeting, the stockholder must have given timely notice in writing to the secretary of the Company and any such nomination or proposed business must constitute a proper matter for stockholder action. Under our Bylaws, because no annual meeting was held last year, any stockholder notice for purposes of the 2023 Annual Meeting must be received by the secretary of the Company not later than the close of business on the tenth (10th) day following the filing of this Current Report on Form 8-K, which is April 10, 2023.

Pursuant to Rule 14a-8, for a stockholder to submit a proposal for inclusion in our proxy materials for the 2023 Annual Meeting, the stockholder must comply with the requirements set forth in Rule 14a-8, including with respect to the subject matter of such proposal, and must deliver the proposal and all required documentation to us a reasonable time before we begin to print and send our proxy materials for the meeting. For the 2023 Annual Meeting, we have determined such deadline to be April 10, 2023.

Further details regarding the 2023 Annual Meeting will be provided at a later date.

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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Disc Medicine, Inc. on March 31, 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: March 31, 2023

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



Disc Medicine Reports Full Year 2022 Financial Results and Provides Business Update

- Completed reverse merger with Gemini Therapeutics, debuting on Nasdaq as “IRON” and ending 2022 with approximately \$194.6 million in cash and cash equivalents
- Initiated two Phase 2 trials, AURORA and BEACON, for bitopertin in erythropoietic protoporphyria (EPP); initial BEACON data to be shared 1H 2023 and topline AURORA data expected by end of 2023
- Completed a Phase 1 study of DISC-0974 in healthy volunteers, which demonstrated clinical proof of mechanism
- Initiated a Phase 1b/2 study of DISC-0974 in myelofibrosis (MF) patients with anemia, as well as a Phase 1b/2 study in patients with anemia of chronic kidney disease who are not receiving dialysis (NDD-CKD); interim data from both studies expected by end of 2023

WATERTOWN, Mass. (March 31, 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 full year ended December 31, 2022 and business highlights.

“2022 was a year of transformation and tremendous achievement for Disc. During the past year, we became a publicly-traded company through our reverse merger with Gemini Therapeutics, strengthened our balance sheet, and advanced both bitopertin and DISC-0974 into patient studies. This puts us in a strong position for growth in 2023, when we anticipate our first data readouts in patients and will continue to execute on our vision of building a leading hematology franchise,” said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc. “In this past quarter, we have already expanded our pipeline by in-licensing a third, Phase 1-ready program, further strengthened our financial position with a registered direct offering led by Bain Capital Life Sciences, and initiated a Phase 1b/2 study of DISC-0974 in patients with CKD anemia. I want to thank the Disc team for their tireless efforts as we look forward to another exciting year in 2023.”

Business Highlights and Anticipated 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.

- In August 2022, Disc initiated BEACON, an open-label Phase 2 clinical study of bitopertin in patients with EPP and X-linked protoporphyria (XLP). Disc expects to present interim data in the first half of 2023.
- In October 2022, Disc initiated AURORA, a Phase 2 randomized, placebo-controlled clinical study of bitopertin in adults with EPP. Disc expects topline data by year-end 2023.
- In December 2022, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to bitopertin for the treatment of EPP. In January 2023, the European Committee for Orphan Medical Products adopted a positive opinion on Orphan Designation for bitopertin for treatment of EPP.
- In March 2023, Disc announced a collaboration with NIH to study bitopertin in patients with Diamond-Blackfan Anemia; the study is expected to initiate in mid-year 2023.

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

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

- Successful completion of the first-in-human, Phase 1 SAD study in healthy volunteers, demonstrating suppressed hepcidin and improvements in serum iron, hemoglobin, and other hematologic parameters.
- Data from the Phase 1 study were presented at the European Hematology Association Annual Congress and the American Society of Hematology Annual Meeting.
- Initiated a Phase 1b/2 clinical study in MF patients with severe anemia who may or may not be receiving concomitant treatment with JAK inhibitors; interim data expected at the end of 2023.
- In February 2023, Disc initiated a Phase 1b/2 clinical study of patients with anemia of chronic kidney disease who are not receiving dialysis (NDD-CKD); interim data expected at the end of 2023.

MWTX-003: Anti-TMPRSS6 Antibody (Hepcidin Induction)

MWTX-003 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.

- In January 2023, Disc entered into an exclusive licensing agreement with Mabwell Therapeutics to obtain an exclusive license to rights outside of Greater China for a portfolio of monoclonal antibodies targeting TMPRSS6 including a Phase 1-ready drug candidate, MWTX-003.
- Preclinical studies of MWTX-003 have demonstrated an increase in hepcidin production and suppression of serum iron levels in various animal models of beta-thalassemia and polycythemia vera.
- The IND was accepted in November 2022 and Disc plans to initiate a Phase 1 study of MWTX-003 in healthy volunteers during the second half of 2023.
- Disc plans to develop MWTX-003 initially as a treatment for polycythemia vera as well as other indications.

Corporate:

- Disc completed a reverse merger with Gemini Therapeutics in December 2022, which resulted in Disc becoming publicly listed on NASDAQ, and raised approximately \$90 million in operating capital. Concurrent with the merger, Disc completed a financing of \$53.5 million from a syndicate of healthcare investors led by Access Biotechnology and including OrbiMed, Atlas Venture, 5AM Ventures, Novo Holdings A/S, Arix Bioscience, Rock Springs Capital, and Janus Henderson Investors.
- In February 2023, Disc completed a \$62.5 million registered direct offering led by Bain Capital Life Sciences, with participation from Access Biotechnology and OrbiMed.

Full Year 2022 Financial Results:

- **Cash Position:** Cash and cash equivalents were \$194.6 million as of December 31, 2022 compared to \$88.0 million as of December 31, 2021. The increase was due to the completion of the reverse merger with Gemini Therapeutics and the concurrent financing, which was completed on December 29, 2022. In February 2023, Disc subsequently completed a registered direct offering in the amount of \$62.5 million led by Bain Capital Life Sciences. Disc expects these combined cash and cash equivalents to fund its operational plans into 2025.

- **Research and Development Expenses:** R&D expenses were \$33.4 million for the full year ending December 31, 2022, as compared to \$25.2 million for the full year ending December 31, 2021. The increase in R&D expenses were primarily driven by the progression of Disc's portfolio, including increased headcount, the advancement of DISC-0974 into a Phase 1b/2 clinical study, and bitopertin into two Phase 2 clinical studies.
- **General and Administrative Expenses:** G&A expenses were \$14.0 million for the full year ending December 31, 2022, as compared to \$5.8 million for the full year ending December 31, 2021. The increase in G&A expenses was primarily due to increased headcount and costs associated with a planned equity financing that was superseded by the Gemini reverse merger.
- **Net Loss:** The net loss was \$46.8 million for the year ended December 31, 2022, as compared to \$36.0 million for the full year ending December 31, 2021. The increase was primarily due to higher operating costs in the current period to support the continued advancement of the Company's pipeline.

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 anticipated study of bitopertin in Diamond-Blackfan Anemia, its Phase 1b/2 clinical study of DISC-0974 in NDD-CKD patients with anemia, its anticipated Phase 1 study of MWTX-003 and potential development of MWTX-003 as a treatment for polycythemia vera and other indications, projected timelines for the initiation and completion of its clinical trials, anticipated timing of release of data, and other clinical activities; Disc's business plans and objectives; and Disc's beliefs about operating expenses and that it will have capital to fund Disc into 2025. 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; 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 and other documents filed by Disc from time to time with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in Disc's subsequent filings with the Securities and Exchange Commission. 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)

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 33,437	\$ 25,170
General and administrative	14,038	5,763
Total operating expenses	<u>47,475</u>	<u>30,933</u>
Loss from operations	(47,475)	(30,933)
Other income (expense), net	648	(5,036)
Net loss	<u>\$ (46,827)</u>	<u>\$ (35,969)</u>
Weighted-average common shares outstanding-basic and diluted	<u>1,039,490</u>	<u>878,407</u>
Net loss per share-basic and diluted	<u>\$ (45.05)</u>	<u>\$ (40.95)</u>



DISC MEDICINE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	December 31,	
	2022	2021
Assets		
Cash and cash equivalents	\$ 194,611	\$ 88,036
Other current assets	3,880	2,448
Total current assets	198,491	90,484
Other assets	1,714	1,927
Total assets	<u>\$200,205</u>	<u>\$ 92,411</u>
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities	22,578	13,424
Non-current liabilities	1,027	1,334
Total liabilities	23,605	14,758
Total convertible preferred stock	—	141,856
Total stockholders' equity (deficit)	176,600	(64,203)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$200,205</u>	<u>\$ 92,411</u>

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