Disc Medicine Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

March 21, 2024

- *Top-line results from AURORA, the placebo-controlled phase 2 study of bitopertin in erythropoietic porphyrias (EPP), expected March / April 2024*
- *On track to deliver multiple read-outs in 2024, including updated results from phase 1b/2 study of DISC-0974 in anemia of myelofibrosis (MF) 1H'24*
- *Strengthened leadership team with the appointments of Jean Franchi as Chief Financial Officer and Pamela Stephenson as Chief Commercial Officer, and the promotion of Jonathan Yu to Chief Operating Officer*
- *Well-capitalized, ending 2023 with approximately $360M in cash and cash equivalents, which provides runway well into 2026*

WATERTOWN, Mass., March 21, 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 reported financial results for the fourth quarter and full year ended December 31, 2023, and provided an update on recent program and corporate developments.

"The past year has been truly remarkable for Disc and marks another important chapter in our company's story. During 2023, we provided the first evidence of the therapeutic potential of our programs, with positive read-outs in patients for both bitopertin and DISC-0974. In addition, we advanced a third program, DISC-3405, into the clinic and fortified our balance sheet, so we can execute our strategy with confidence," said John Quisel, J.D., Ph.D., President and Chief Executive Officer of Disc. "These achievements have positioned us well for 2024, which promises to be another transformational year, and I want to express my deep gratitude to our team for their determination and hard work. We're looking forward to sharing AURORA data in the coming weeks, as well as updated data for DISC-0974 in MF and initial data for DISC-3405 in healthy volunteers in the first half of this year."

Recent Business Highlights and Upcoming Milestones:

Bitopertin: GlyT1 Inhibitor (Heme Synthesis Modulator)

- Completed enrollment of its phase 2 program of bitopertin in erythropoietic porphyrias:
  - BEACON, an open-label phase 2 clinical study of bitopertin in patients with EPP and X-linked protoporphyria (XLP), which was expanded to include adolescents
  - AURORA a phase 2 randomized, placebo-controlled clinical study of bitopertin in adults with EPP
- Presented positive results from the phase 2 BEACON trial at ASH 2023, showing:
  - Significant, sustained reductions in whole blood protoporphyrin IX (PPIX) levels >40%
  - Robust and consistent improvements across all measures of sunlight tolerance, including >3x improvement over historical control of precedented pivotal endpoint
  - Bitopertin was generally well-tolerated with stable hemoglobin at both dose levels
- Topline AURORA data planned for press release and corporate presentation in March/April 2024

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

- Presented positive, initial data from ongoing phase 1b/2 clinical study in MF patients with severe anemia at ASH 2023:
  - Treatment at initial dose levels (14 mg, 28 mg, 50 mg) resulted in substantial, dose-dependent decreases in hepcidin and increases in serum iron
  - Hematologic activity was observed in MF patients, regardless of concomitant JAK inhibitor use. Four of seven (57%) evaluable non-transfusion-dependent (NTD) patients reached a >1.5g/dL hemoglobin increase and one of two transfusion-dependent (TD) patients achieved transfusion independence.
  - DISC-0974 was generally well-tolerated
  - Enrollment and dose escalation is ongoing
- Presented initial data from the 28 mg cohort of the ongoing phase 1b/2 clinical study of patients with anemia of chronic kidney disease who are not receiving dialysis (NDD-CKD)
  - Data demonstrated meaningful reductions in serum hepcidin and corresponding increases in serum iron with a similar PK/PD profile as seen in Disc's healthy volunteer study
  - Enrollment and dose escalation is ongoing

- Updated phase 1b/2 data from DISC-0974 in anemia in MF patients is expected to be presented in the first half of 2024
- Updated phase 1b/2 data from DISC-0974 in anemia in NDD-CKD is expected to be shared in the second half of 2024
- Received FDA fast track designation in February 2024 for DISC-0974 for the treatment of anemia in NDD-CKD

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

- Initiated a phase 1 SAD / MAD study in healthy volunteers in October 2023
- Initial SAD data expected to be presented in the first half of 2024
- Received FDA orphan drug designation in February 2024 for DISC-3405 for the treatment of PV

Corporate:

- As the company enters late-stage development and begins planning for commercialization, Disc expanded its leadership team with the appointments of industry veterans Jean Franchi as Chief Financial Officer and Pamela Stephenson as Chief Commercial Officer, and the promotion of Jonathan Yu to Chief Operating Officer

Full Year 2023 Financial Results:

- **Cash Position:** Cash and cash equivalents were $360.4 million as of December 31, 2023, which are expected to fund our operational plans well into 2026, compared to $194.6 million as of December 31, 2022. The increase was primarily due to the completion of a registered direct offering in February 2023 and a publicly marketed follow-on offering in June 2023.
- **Research and Development Expenses:** R&D expenses were $69.3 million for the full year ended December 31, 2023, as compared to $33.4 million for the full year ended December 31, 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, phase 1 study initiation for DISC-3405, and increased headcount.
- **General and Administrative Expenses:** G&A expenses were $21.9 million for the full year ended December 31, 2023, as compared to $14.0 million for the full year ended December 31, 2022. The increase in G&A expenses was primarily due to increased headcount and increased costs as a public company.
- **Net Loss:** Net loss was $76.4 million for the full year ended December 31, 2023, as compared to $46.8 million for the full year ended December 31, 2022. The increase was primarily due to higher operating costs in the current period to support the continued advancement of our 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 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; Disc's business plans, objectives and expected contributions of management; 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 and DISC-0974; Disc's ability to retain and recognize the intended incentives conferred by Orphan Drug Designation for DISC-3405 and bitopertin; 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, 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)

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 69,264	$ 33,437
General and administrative	21,861	14,038
Total operating expenses	91,125	47,475
Loss from operations	(91,125)	(47,475)
Other income (expense), net	14,795	648
Income tax expense	(99)	—
Net loss	$ (76,429)	$ (46,827)
Weighted-average common shares outstanding-basic and diluted	22,315,877	1,039,490
Net loss per share-basic and diluted	$ (3.42)	$ (45.05)

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

	December 31,	December 31,
	2023	**2022**
Assets		
Cash and cash equivalents	$ 360,382	$ 194,611
Other current assets	5,280	3,880
Total current assets	365,662	198,491
Non-current assets	2,334	1,714
Total assets	$ 367,996	$ 200,205
Liabilities and Stockholders' Equity		
Current liabilities	$ 21,439	$ 22,578
Non-current liabilities	1,436	1,027
Total liabilities	22,875	23,605
Total stockholders' equity	345,121	176,600
Total liabilities and stockholders' equity	$ 367,996	$ 200,205

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