Disc Medicine Reports Third Quarter 2024 Financial Results and Provides Business Update

November 12, 2024

- *Completed a successful end of Phase 2 meeting with the FDA for bitopertin in erythropoietic protoporphyria (EPP), reaching alignment on all proposed study parameters with the potential for accelerated approval based on existing data*
- *Presented proof-of-mechanism data for Phase 1b trial of DISC-0974 in patients with non-dialysis-dependent chronic kidney disease (NDD-CKD) and anemia at the American Society of Nephrology (ASN) Kidney Week 2024*
- *Eight posters and an oral presentation across all three clinical-stage assets to be presented at the 66th American Society of Hematology (ASH) Annual Meeting and Exposition*
- *Strong financial position ending Q3 with $487 million in cash, cash equivalents, and marketable securities, further strengthened by closing a $200 million non-dilutive debt financing in November 2024 increasing future financing optionality*

WATERTOWN, Mass., Nov. 12, 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 third quarter ended September 30, 2024.

“This is an exciting time for Disc as we have made significant progress in advancing our pipeline in recent months and remain keenly focused on execution as we prepare for multiple upcoming catalysts. We now have clarity on the path forward for bitopertin in EPP, with the potential for accelerated approval, and added to the data set supporting the potential of DISC-0974 in treating anemias of inflammation with positive SAD data in NDD-CKD,” said John Quisel, J.D., Ph.D., Chief Executive Officer and President of Disc. “Additionally, with the recent completion of a debt financing with Hercules Capital, we have further solidified our strong financial position, enabling us to achieve our upcoming catalysts and to continue to work toward our goal of developing therapies with the potential to address a range of hematologic diseases.”

Recent Highlights and Anticipated Milestones:

Bitopertin: GlyTI Inhibitor (Heme Synthesis Modulator)

- Announced positive End of Phase 2 meeting with the FDA, reflecting alignment with the FDA on all proposed attributes of the APOLLO study, as well as the potential to pursue accelerated approval based on existing data using reduction of PPIX as a surrogate endpoint
- The Company will provide an update on discussions with the FDA around the design of a confirmatory trial in Q1 2025 and plans to initiate this trial by mid-2025.
- Announced four posters at ASH 2024:
  - Additional clinical data from the AURORA and BEACON Phase 2 trials
  - Preclinical data on bitopertin’s effects on PPIX and phototoxicity
  - Real-world evidence from the EPP LIGHT survey study on the burden of disease in EPP

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

- Presented proof of mechanism data from its ongoing Phase 1b single-ascending dose (SAD) study of DISC-0974 in non-dialysis-dependent chronic kidney disease (NDD-CKD) patients with anemia at ASN Kidney Week 2024, demonstrating that a single dose of DISC-0974 leads to consistent reductions in hepcidin and increases in transferrin saturation (TSAT), resulting in an increase in reticulocyte hemoglobin and hemoglobin Announced several data updates at ASH 2024:
  - Oral presentation of final clinical data from the Phase 1b trial of DISC-0974 in anemia of myelofibrosis (MF)
  - Pre-clinical data for DISC-0974 in anemia of inflammatory bowel disease (IBD)
  - Pre-clinical data for DISC-0974 in combination with ruxolitinib
- The Company expects to initiate a Phase 2 study in anemia of myelofibrosis (MF) by the end of 2024

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

- Announced two posters to be presented at ASH 2024:
  - Data from the ongoing Phase 1 SAD/MAD study in healthy volunteers will be presented at ASH 2024
  - Preclinical data for DISC-3405 in a mouse model of sickle cell disease

- The Company plans to initiate a Phase 2 study in polycythemia vera (PV) in 2025

Corporate:

- Successfully completed $200 million non-dilutive debt financing deal with Hercules Capital in November. An initial $30 million was funded at closing with an additional $80 million available to be drawn through the second half of 2026 at the Company's discretion. An additional $65 million is available subject to milestones and at the Company's option. The financing provides minimum 48 months of interest-only.
- Expanded leadership team with the appointment of Steve Caffé, MD as Chief Regulatory Officer and Rahul Kaushik, Ph.D. as Chief Technical Officer

Third Quarter 2024 Financial Results:

- **Cash Position:** Cash, cash equivalents and marketable securities were $487.4 million as of September 30, 2024. The Company is sufficiently financed to fund operational plans well into 2027.
- **Research and Development Expenses:** R&D expenses were $24.7 million for the quarter ended September 30, 2024, as compared to $14.4 million for the quarter ended September 30, 2023. The increase in R&D expenses were primarily driven by the progression of Disc's portfolio, including bitopertin's clinical studies and drug manufacturing, advancement of DISC-0974 and DISC-3405 programs deeper into development, and increased headcount.
- **General and Administrative Expenses:** G&A expenses were $8.2 million for the quarter ended September 30, 2024, as compared to $4.5 million for the quarter ended September 30, 2023. The increase in G&A expenses was primarily due to increased headcount.
- **Net Loss:** Net loss was $26.6 million for the quarter ended September 30, 2024, as compared to $14.1 million for the quarter ended September 30, 2023.

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 anticipated use of net proceeds from the debt financing; the potential for accelerated approval and conducting a confirmatory trial for bitopertin; and future product development plans and projected timelines for the initiation and completion of preclinical and clinical trials and other activities. 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 offering may not be completed on the timeline expected or at all; 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 SEC, including in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2023, 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.

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,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 24,685	$ 14,419	$ 71,874	$ 46,699
General and administrative	8,171	4,539	23,296	14,712
Total operating expenses	32,856	18,958	95,170	61,411
Loss from operations	(32,856)	(18,958)	(95,170)	(61,411)
Other income (expense), net	6,371	4,856	15,449	8,628
Income tax expense	(114)	(20)	(179)	(67)
Net loss	$ (26,599)	$ (14,122)	$ (79,900)	$ (52,850)
Weighted-average common shares outstanding-basic and diluted	29,935,551	24,316,817	26,809,605	21,605,202
Net loss per share-basic and diluted	$ (0.89)	$ (0.58)	$ (2.98)	$ (2.45)

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

	September 30, 2024	December 31, 2023
Assets		
Cash, cash equivalents, and marketable securities	$ 487,363	$ 360,382
Other current assets	5,789	5,280
Total current assets	493,152	365,662
Non-current assets	1,993	2,334
Total assets	$ 495,145	$ 367,996
Liabilities and Stockholders' Equity		
Current liabilities	$ 25,473	$ 21,439
Non-current liabilities	1,712	1,436
Total liabilities	27,185	22,875
Total stockholders' equity	467,960	345,121
Total liabilities and stockholders' equity	$ 495,145	$ 367,996

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