

**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): January 19, 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^(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 1.01 Entry into a Material Definitive Agreement.

Exclusive License Agreement with Mabwell Therapeutics, Inc.

On January 19, 2023, Disc Medicine, Inc. ("Disc") entered into an exclusive license agreement with Mabwell Therapeutics, Inc. ("Mabwell") (a wholly-owned subsidiary of Mabwell (Shanghai) Bioscience Co., Ltd), pursuant to which Mabwell granted Disc an exclusive and sublicensable license under certain patent rights, know-how, and materials to develop and commercialize antibody products containing Mabwell's MWTX-001, MWTX-002, and MWTX-003 antibodies, along with limited variants thereof, in all fields of use, in all territories other than Greater China (Mainland China, Hong Kong, Macau and Taiwan) and Southeast Asia (Brunei, Myanmar, Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, Philippines, Singapore, Thailand and Vietnam). Disc also granted Mabwell an exclusive, sublicensable, royalty-free license under Disc's patents and know-how arising under the agreement to develop and commercialize licensed antibody products in Greater China and Southeast Asia.

The license agreement requires Disc to pay Mabwell an upfront payment of \$10 million dollars, and certain development and regulatory milestone payments for the licensed antibody products, for up to three indications, up to a maximum aggregate amount of \$127.5 million dollars, as well as certain commercial milestone payments for certain licensed antibody product net sales achievements, up to a maximum aggregate amount of \$275 million dollars. Disc is further obligated to pay a tiered percentage of revenue that Disc receives from its sublicensees (excluding revenue that is attributable to net sales on which royalty payments are due), ranging from a low third decile percentage if the sublicense is granted prior to the initiation of a phase 1 clinical trial of the licensed antibody product, to a low first decile percentage if the sublicense is granted after regulatory approval of the licensed antibody product. No sublicense revenue is due if the sublicense is granted after the first commercial sale of the licensed antibody product.

In addition, Disc is obligated to pay Mabwell a royalty on annual net sales of all licensed antibody products at a tiered rate ranging from low single-digits to high single-digits, subject to customary royalty reductions for (i) lack of a valid patent claim covering the licensed antibody product generating such sales, (ii) entry of a biosimilar product that equals or exceeds 20% of the total market share of the licensed antibody product, and (iii) a portion of any royalties paid to a third party for patents that claim the composition of matter or method of use of the licensed antibodies. Further, royalties are subject to customary apportionment calculations where the licensed antibodies are commercialized in combination products. The obligation to pay royalties under the Mabwell license expires on a licensed antibody product-by-licensed antibody product and country-by-country basis upon the later of (a) expiration of the last valid patent claim of the licensed patents that cover such licensed antibody product in such country, (b) expiration of regulatory exclusivity for such licensed antibody product in such country, and (c) ten years from the first commercial sale of such licensed antibody product in such country.

Disc's license grant expires upon expiration of the last remaining royalty obligation for the last licensed antibody product in the last country. Either party may terminate the agreement prior to its expiration upon the other party's uncured material breach, insolvency, or a challenge of the validity or enforceability of the patents licensed to such other party under the agreement. Disc may also terminate the agreement for convenience on 60 days' written notice to Mabwell. In the event the agreement is terminated other than by Disc for cause, Disc has agreed to grant Mabwell an exclusive, sublicensable, worldwide license under Disc's patent rights and know-how arising under the license agreement to develop and commercialize products containing the licensed antibodies. In such circumstances, Disc and Mabwell will negotiate a royalty to be paid by Mabwell on the net sales of such products in the licensed territory.

The forgoing description of the license agreement between Disc and Mabwell does not purport to be complete and is qualified in its entirety by the full text of the agreement, a copy of which is expected to be filed as an exhibit to Disc's annual report on Form 10-K for the year ending December 31, 2022.

Item 7.01 Regulation FD Disclosure.

On January 20, 2023, Disc issued a press release, a copy of which is furnished herewith as Exhibit 99.1.

In addition, on January 20, 2023, Disc posted to its website a slide presentation regarding the transaction with Mabwell and its current development plans for the licensed anti-TMPRSS6 monoclonal antibody portfolio. Such slide presentation is being furnished as Exhibit 99.2 to this Current Report on Form 8-K. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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, except as expressly set forth by specific reference in such filing.

Item 9.01. Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Disc Medicine, Inc. on January 20, 2023, furnished herewith.
99.2	Disc Medicine, Inc. Corporate Presentation, dated January 20, 2023, furnished herewith.
104	Cover Page Interactive Data (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: January 23, 2023

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



Disc Medicine Announces Exclusive Licensing Agreement with Mabwell Therapeutics for Novel Anti-TMPRSS6 Monoclonal Antibodies to Modulate Iron Homeostasis

- *Disc will obtain exclusive rights to MWTX-003 and other novel anti-TMPRSS6 antibodies in the United States, Europe and other territories excluding Greater China and certain other territories in Southeast Asia*
- *MWTX-003 demonstrated potent and durable suppression of serum iron and efficacy in animal models of beta-thalassemia and polycythemia vera (PV)*
- *FDA has accepted the IND for MWTX-003 and Disc plans to initiate a phase 1 study of MWTX-003 in healthy volunteers during 2H'23*

WATERTOWN, Mass. (January 20, 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, announced today that it has entered into an agreement with Mabwell Therapeutics to obtain an exclusive license to a portfolio of monoclonal antibodies targeting TMPRSS6 (Transmembrane Serine Protease 6, also known as Matriptase-2) including the phase 1-ready drug candidate MWTX-003. Disc plans to initiate a phase 1 trial in healthy volunteers in the second half of 2023.

MWTX-003 has the potential to address a wide range of hematologic disorders including polycythemia vera and beta-thalassemia by controlling iron homeostasis. Genetic studies show that TMPRSS6 affects red blood cell formation by controlling the level of iron that is available for erythropoiesis. Clinical and non-clinical evidence has shown that reducing iron levels by inhibiting TMPRSS6 has potential to treat hematologic disorders.

“Disc has built deep expertise in the role of iron homeostasis in hematologic disorders, and I am thrilled to expand our portfolio with these highly complementary antibody programs,” said John Quisel, J.D., Ph.D., Chief Executive Officer and President of Disc. “We are delighted to be partnering with Mabwell, a company with a strong antibody technology platform that is led by Dr. Xin Du, a leading expert on TMPRSS6 biology. This program is in perfect alignment with our strategy and we look forward to advancing MWTX-003 into phase 1 studies later this year.”

Under the terms of the agreement, Disc will obtain exclusive rights to develop and commercialize MWTX-003 and other anti-TMPRSS6 monoclonal antibodies discovered by Mabwell, in the United States, Europe, and other territories outside of China and Southeast Asia. MWTX-003 is phase 1-ready and received acceptance of an Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) in November 2022. Mabwell will receive an upfront cash payment of \$10.0 million, in addition to development and commercial milestones for a total of up to \$412.5 million in eligible payments, and tiered, mid to high single digit royalties on net sales.

The transaction is subject to customary closing conditions and approval by the shareholders of the parent company of Mabwell Therapeutics, Mabwell (Shanghai) Bioscience Co., Ltd.

About Disc

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, 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.

About Mabwell Therapeutics

Mabwell Therapeutics, Inc. is a San Diego-based biotechnology company focusing on the discovery and development of antibody and protein-based drugs in multiple therapeutic areas including hematological disorders, liver disease, and neurodegenerative diseases. Mabwell Therapeutics is a wholly-owned subsidiary of Mabwell (Shanghai) Bioscience Co., Ltd., a global integrated biopharmaceutical company primarily engaged in the discovery, development, manufacturing, and commercialization of biotherapeutics.

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: future product development plans and projected timelines for the initiation and completion of preclinical and clinical trials and other activities; the potential for the results of ongoing preclinical or clinical trials and the efficacy of Disc’s product candidates; future product development and regulatory strategies, including with respect to specific indications; Disc’s plans for Gemini’s assets; Disc’s plans for its hematology portfolio; interactions with regulatory authorities; and Disc’s financial position. 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: (i) the outcome of any legal proceedings that may be instituted against the parties and others related to the merger agreement; (ii) unanticipated difficulties or expenditures relating to the merger, the response of business partners and competitors to the announcement or completion of the merger, and/or potential difficulties in employee retention as a result of the announcement or completion of the merger; (iii) Disc’s listing on the Nasdaq Capital Market and operating as a public company; (iv) the adequacy of Disc’s capital to support its future operations and its ability to successfully initiate and complete clinical trials; (v) the nature, strategy and focus of Disc; (vi) the difficulty in predicting the time and cost of development of Disc’s product candidates; (vii) Disc’s plans to research, develop and commercialize its current and future product candidates; (viii) the timing of initiation of Disc’s planned preclinical studies and clinical trials; (ix) the timing of the availability of data from Disc’s clinical trials; (x) the timing of any planned investigational new drug application or new drug application; (xi) the risk of cessation or delay of any ongoing or planned clinical trials of Disc or its collaborators; (xii) the clinical utility, potential benefits and market acceptance of Disc’s product candidates; (xiii) Disc’s commercialization, marketing and manufacturing capabilities and strategy; (xiv) Disc’s ability to identify additional product candidates with significant commercial potential and to expand its pipeline in hematological diseases; (xv) the risk that Disc may not realize the intended benefits of its drug discovery platform; (xvi) developments and projections relating to Disc’s competitors and its industry; (xvii) the impact of government laws and regulations; (xviii) the impact of public health epidemics affecting countries or regions in which Disc has operations or does business, such as the COVID-19 pandemic, (xix) 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; (xx) the timing and outcome of Disc’s planned interactions with regulatory authorities; (xxi) findings from investigational review boards at clinical trial sites and publication review bodies; (xxii) Disc’s ability to protect its intellectual property position; (xxiii) Disc’s estimates regarding future revenue, expenses, capital requirements and need for additional financing; (xxiv) the other risks and uncertainties described in the “Risk Factors” section of the definitive



proxy statement/prospectus dated December 2, 2022 and filed with the SEC under Rule 424(b) 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 Securities and Exchange Commission; and (xxv) the post-closing integration of Disc and Gemini. 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.

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**Novel Anti-TMPRSS6
Monoclonal Antibody Portfolio**
Exclusive In-Licensing Agreement with
Mabwell Therapeutics

January 20, 2023



Confidential

Disclaimer and FLS

This presentation 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: future product development plans and projected timelines for the initiation and completion of preclinical and clinical trials and other activities; the potential for the results of ongoing preclinical or clinical trials and the efficacy of Disc's product candidates; future product development and regulatory strategies, including with respect to specific indications; Disc's plans for Gemini's assets; Disc's plans for its hematology portfolio; interactions with regulatory authorities; and Disc's financial position. 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.

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Disc is Building a Leading Company Dedicated to Treating Hematologic Diseases

Focus on Hematologic Disorders

Immense medical need across a wide spectrum of disorders

Predictive, objective endpoints

Fundamental & Validated Pathways

Fundamental to red blood cell biology: iron and heme

Clinical and genetic evidence of target mechanism in humans

Multiple Clinical Programs with Broad Potential

Bitopertin in Phase 2
DISC-0974 in Phase 1b/2
New Program: MWTX-003 is Phase 1-Ready

Multiple Near-Term Catalysts

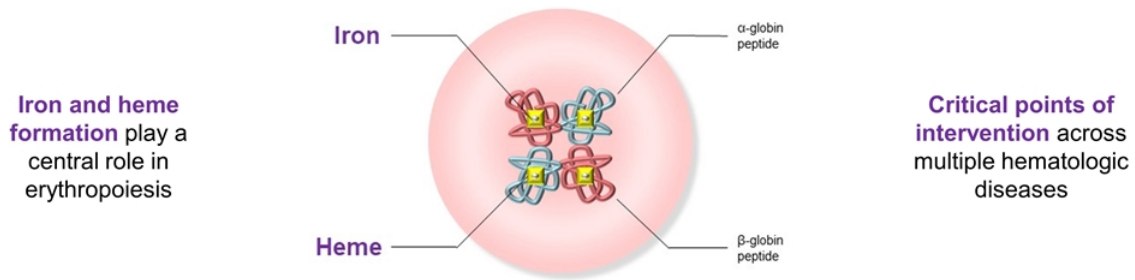
Data expected 2023:
Bitopertin in EPP
DISC-0974 in MF and CKD
Initiate Ph 1 MWTX-003

EPP (Erythropoietic Protoporphria); XLP (X-linked Protoporphria); MF (myelofibrosis); CKD (chronic kidney disease)

3

discmedicine

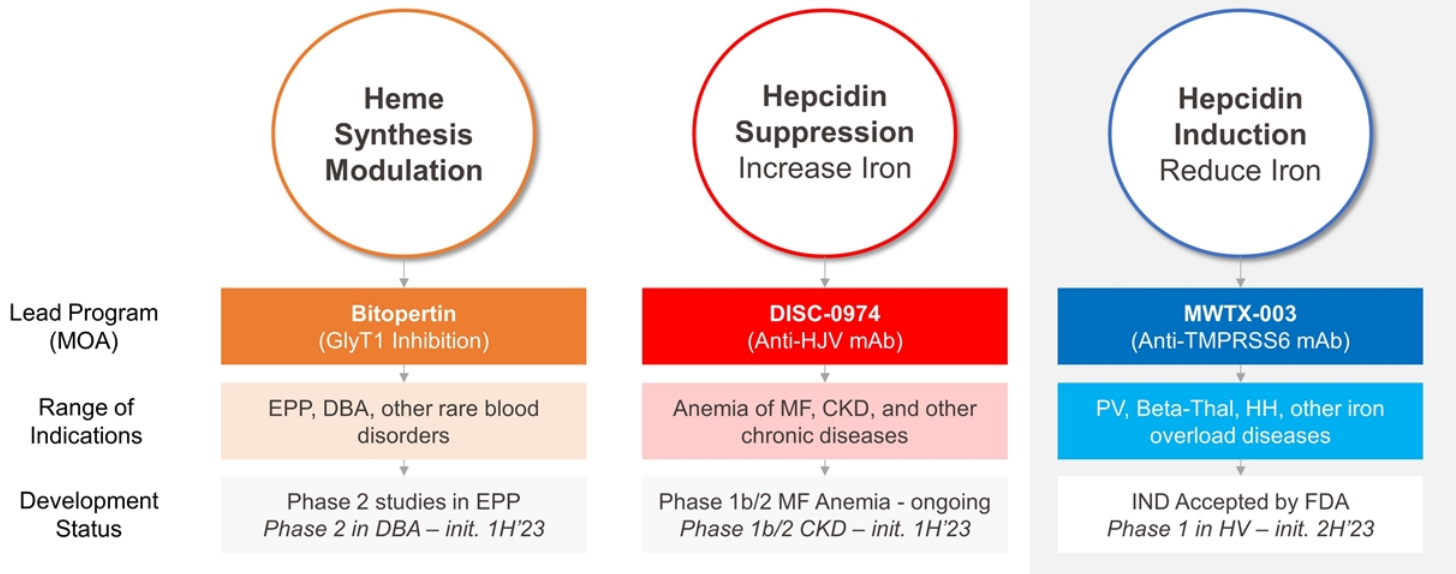
Disc Targets Fundamental Pathways that Impact the Biology of Red Blood Cells



Wide Spectrum of Hematologic Diseases Addressable by Disc Portfolio






Severe Rare (000s)		Moderate Prevalence (100K+)				Widely Prevalent (MMs)			
Diamond-Blackfan Anemia	Erythropoietic Porphyrrias	Beta-Thalassemia	Anemia of Myelofibrosis	Myelodysplastic Syndromes	Sickle Cell Disease	Polycythemia Vera	Hereditary Hemochromatosis	IBD Anemia	CKD Anemia

Disc's Portfolio Addresses Broad Spectrum of Hematologic Disorders



Disc's Hematology-Focused Pipeline

Multiple programs in development with pipeline-in-a-product potential

Portfolio	Program	Preclinical	Phase 1	Phase 2	Near-Term Milestones
Iron Modulation	Heme Biosynthesis Modulator Bitopertin [†] GlyT1 Inhibitor Oral, once-daily	Erythropoietic Porphyrias (EPP and XLP) – <i>Initiated July '22</i>  Diamond-Blackfan Anemia (planned) and other indications 			EPP / XLP <ul style="list-style-type: none"> Phase 2 BEACON Trial in EPP / XLP (open-label, initiated July '22) Phase 2 AURORA Trial in EPP (placebo-controlled, expected to initiate 2H '22) Interim open-label data expected by 1H'23
	Hepcidin Suppression Increase Iron DISC-0974 [‡] Anti-HJV monoclonal antibody Subcutaneous, once-monthly	Anemia of Myelofibrosis (MF) – <i>Initiated June '22</i>  Anemia of Chronic Kidney Disease (CKD) – <i>Initiation expected 1H'23</i> 			Proof-of-Mechanism <ul style="list-style-type: none"> Phase 1 SAD data presented June '22 Myelofibrosis Anemia <ul style="list-style-type: none"> Initiated Phase 1b / 2 trial in 1H'22 Interim open-label data expected in '23 CKD Anemia <ul style="list-style-type: none"> Expect to initiate Phase 1b / 2 trial 1H'23 Interim data expected in '23
	Hepcidin Induction Reduce Iron MWTX-003 Anti-TMPRSS6 Monoclonal antibody	Polycythemia Vera and Diseases of Iron Overload / Ineffective Erythropoiesis  New program in-licensed from Mabwell is phase 1-ready and strategically aligned with portfolio			Phase 1 Proof-of-Mechanism <ul style="list-style-type: none"> IND accepted by FDA Initiation of Phase 1 study 2H'23 Interim proof-of-mechanism data '24

6 [†] Bitopertin in-licensed from Roche; [‡] DISC-0974 and DISC-0998 in-licensed from Abbvie

Expanding Disc's Portfolio in Benign Hematology

In-licensing anti-TMPRSS6 mAbs underscores Disc's leadership in hepcidin biology and iron homeostasis

Strategic Rationale	<ul style="list-style-type: none">• TMPRSS6 is an increasingly important target in benign hematology: there is burgeoning clinical and preclinical evidence validating TMPRSS6 and role of iron restriction in key diseases• Highly complementary mechanism and builds on Disc's expertise in hepcidin biology• Phase 1-ready MWTX-003 means capital-efficient path to clinical proof-of mechanism; Disc maintains guidance on operating runway into 2025
Mabwell Therapeutics	<ul style="list-style-type: none">• Based in San Diego; innovation center of fully-integrated biopharmaceutical company Mabwell (Shanghai) Bioscience; focused on discovery and development of antibody and protein-based drugs• Led by CEO Xin Du, PhD (formerly Scripps, UCSD, Silarus Therapeutics) and expert in TMPRSS6
Lead Antibody MWTX-003	<ul style="list-style-type: none">• Highly potent and durable effects in preclinical studies: ↑ hepcidin and ↓ iron; excellent non-clinical safety• Demonstrated efficacy in disease models of beta-thalassemia (presented ASH 2021) and polycythemia vera• IND accepted by U.S. FDA in November 2022 – expect to initiate phase 1 study 2H'23
Transaction Summary	<ul style="list-style-type: none">• Disc receives an exclusive license to Mabwell's portfolio of anti-TMPRSS6 antibodies• Financial terms \$10 million upfront and eligible milestone payments up to \$402.5 million; mid-to-high single digit tiered royalties on net sales• Disc territories: US, Europe and ROW excluding Greater China and Southeast Asia

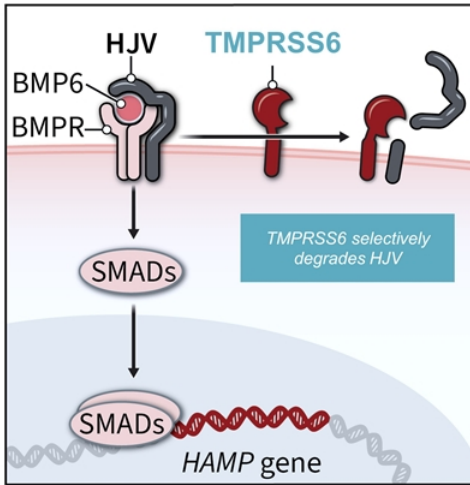
Anti-TMPRSS6 mAb Induces Hepcidin

Designed to limit iron levels with potential to address a wide range of hematologic disorders



Targeting TMPRSS6 to Increase Hepcidin

Potent, specific target controls endogenous hepcidin production



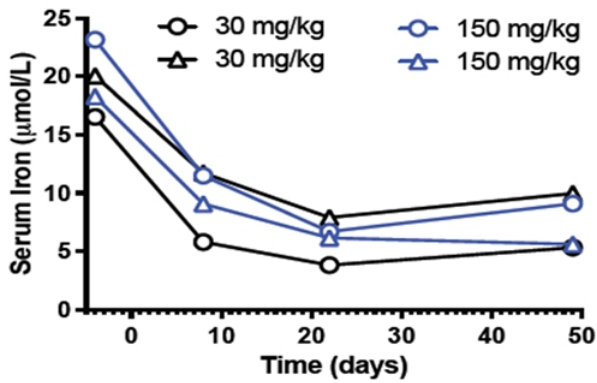
Inhibiting TMPRSS6 with an Antibody Enables Hepcidin Production to Suppress Iron

- **Genetic validation** in patients with IRIDA (Iron-Refractory Iron Deficiency Anemia)
 - LOF TMPRSS6 mutation increases hepcidin and reduces iron availability
- **Functionally specific** to hepcidin / iron
- **Tissue specific** expression primarily in the liver

MWTX-003 Effects in Non-Human Primates

Results in deep and sustained suppression of serum iron levels

Single dose of MWTX-003 resulted in ~ 70% suppression of serum iron lasting 3 weeks

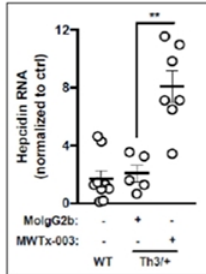
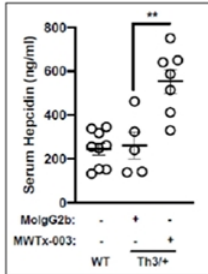


- Potent PD effects observed across multiple preclinical studies consistent with Tmprss6 inhibition
 - Hepcidin: 3-4 fold induction
 - Serum iron: ~ 60-70% suppression
- MWTX-003 demonstrated excellent safety profile in non-clinical GLP safety studies

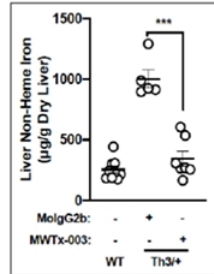
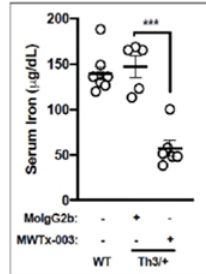
Effects in Hbb^{Th3/+} Model of Beta-Thalassemia

Significant effects on hallmarks of disease including iron overload, ineffective erythropoiesis and splenomegaly

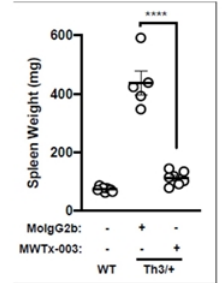
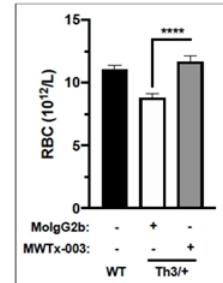
↑ **Hepcidin Production**
Up to 4-fold (mRNA)



↓ **Serum and Liver Iron**
60-65% Reduction



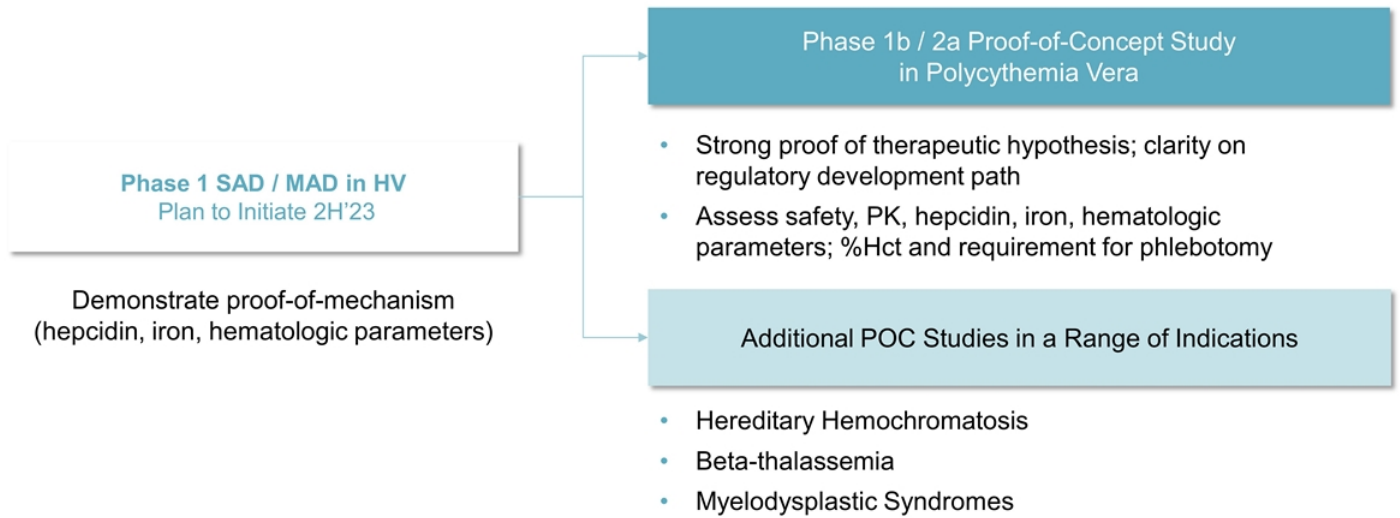
↑ **RBC Production**
↓ **Spleen Weight**




Hbb^{Th3/+} mice were treated with the lead anti-TMPRSS6 antibody at 10 mg/kg IP for 4 weeks

MTWX-003 Development Plans

Establish phase 1 proof-of-mechanism and advance program into POC studies with focus on Polycythemia Vera





**Novel Anti-TMPRSS6
Monoclonal Antibody Portfolio**
Exclusive In-Licensing Agreement with
Mabwell Therapeutics

January 20, 2023



Confidential