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DELTA REPORT

10-K

DISC MEDICINE, INC.

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	4187
CHANGES	304
DELETIONS	2126
ADDITIONS	1757

REFINITIV

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____to_____

Commission file number: 001-39438

Disc Medicine, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**82-3220679 85-1612845**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
321 Arsenal Street, Suite 101 Watertown, Massachusetts	**02472**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 674-9274

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 Par Value	**IRON**	**The Nasdaq Global Market**

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐No Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of Common Stock held by non-affiliates of the registrant computed by reference to the price of the registrant’s Common Stock as of June 30, 2022 June 30, 2023, the last business day of the registrant’s most recently completed second fiscal quarter, was approximately $29.0 507.8 million (based on the last reported sale price on the Nasdaq Global Market as of such date). For this computation, the registrant has excluded the market value of all shares of Common Stock reported as beneficially owned by its executive officer and directors; such exclusion shall not be deemed to constitute an admission that any such person is an affiliate of the registrant.

As of February 28, 2023 February 29, 2024, there were 18,998,025 24,681,028 shares of the registrant’s Common Stock, $0.0001 par value per share, outstanding.

Auditor Firm Id:	42	Auditor Name:	Ernst & Young LLP	Auditor Location:	Boston, Massachusetts

Disc Medicine, Inc.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K of Disc Medicine, Inc., or the Company, contains or incorporates statements that constitute forward-looking statements within the meaning of the federal securities laws. Our forward-looking statements include, but are not limited to, statements regarding our or our management team's expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intends," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements in this Annual Report on Form 10-K may include, for example, statements about:

- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studie and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work the period during which the results of the trials will become available, and our research and development programs;
- our ability to efficiently discover and develop product candidates;
- our ability and the potential to successfully manufacture our drug substances and product candidates for preclinical use, for clinical trial and on a larger scale for commercial use, if approved;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to commercialize our products, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model, and strategic plans for our business and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- estimates of our future expenses, revenues, capital requirements, and our needs for additional financing;
- the potential benefits of strategic collaboration agreements, our ability to enter into strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the commercialization of product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our financial performance;
- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to produce our products or product candidates with advantages in turnaround times or manufacturing cost;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the impact of laws and regulations;
- developments relating to our competitors and our industry;
- the impact of global economic and political developments on our business, including rising inflation and capital market disruptions, the current conflict in Ukraine, economic sanctions and economic slowdowns or recessions that may result from such developments which could harm our research and development efforts as well as the value of our common stock and our ability to access capital markets; a

- other risks and uncertainties, including those listed under the caption “Risk Factors.”

These forward-looking statements are based on information available to us at the time of this Annual Report on Form 10-K and current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties, and other factors. As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. Some factors that could cause actual results to differ include:

- the ability to maintain the listing of our common stock on Nasdaq;
- the price of our securities may be volatile due to a variety of factors, including the volatility in capital markets, changes in the competitiv and highly regulated industries in which we operate, variations in performance across competitors, changes in laws and regulations affecting our business and changes in our capital structure;
- the risk of downturns in the economy and the possibility of rapid change in the highly competitive industry in which we operate;
- the risk that we will need to raise additional capital to execute our business plan, which may not be available on acceptable terms or at and
- the risk that we experience difficulties in managing our growth and expanding operations.

RISK FACTOR SUMMARY

The risk factors detailed in Item 1A entitled “Risk Factors” in this Annual Report on Form 10-K are the risks that we believe are material to our investors and a reader should carefully consider them. Those risks are not all of the risks we face and other factors not presently known to us or that we currently believe are immaterial may also affect our business if they occur. The following is a summary of the risk factors detailed in Item 1A:

- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant net losses since our inception and anticipate that we will continue to incur losses for the foreseeable fu
- We have no products approved for commercial sale and have not generated any revenue from product sales.
- We will need to raise substantial additional funding. If we are unable to raise capital when needed or on terms acceptable to us, we would may be forced to delay, reduce, or eliminate some of our product development programs or commercialization efforts.

- We have only successfully completed one Phase 1 clinical trial, and may be unable to successfully complete any additional clinical t for any product candidates we develop. Certain of our programs are still in preclinical development and may never advance to clinic development.
- Our programs are focused on the development of therapeutics for patients with hematologic diseases, which is a rapidly evolving ar of science, and the approach we are taking to discover and develop product candidates is novel and may never lead to approved or marketable products.
- Interim, top-line, initial and preliminary data from our clinical trials that we announce or publish from time to time may change as mo patient data become available and are subject to confirmation, audit, and verification procedures that could result in material change the final data.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals cou delayed or prevented.
- Results from early preclinical studies and clinical trials of our programs and product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our programs and product candidates. If we cannot replicate the results from earlier preclinical studies and clinical trials of our programs and product candidates in our later preclinical studies and clinical trials, may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.
- Our clinical trials or those of our future collaborators may reveal significant adverse events not seen in prior preclinical studies or cli trials and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, which may res greater research and development expenses, regulatory issues that could delay or prevent approval, or discovery of unknown or unanticipated adverse effects on safety or efficacy.
- We are currently conducting a Phase 2 clinical trial for bitopertin in Australia and may in the future conduct additional clinical trials o product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not b able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.
- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.
- If our current product candidates or any future product candidates do not achieve broad market acceptance, the revenue that we generate from our sales may be limited, and we may never become profitable.

- We rely on third parties to conduct our Phase 2 clinical trials of bitopertin, Phase 1b/2 clinical trials of Disc-0974 DISC-0974 and plan Phase 1 clinical trial of MWTX-003 DISC-3405 (formerly MWTX-003) and expect to rely on third parties to conduct other clinical trial our product candidates, as well as potential investigator-sponsored clinical trials of our product candidates. If these third parties do n successfully carry out their contractual duties, comply with regulatory requirements, or meet expected deadlines, or if the prior work conducted by these third parties is incomplete, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- We might not realize the anticipated benefits of our current collaborations with Mabwell or NIH, or any other collaborations we enter in the future.
- We contract with third parties for the manufacture of our product candidates for preclinical development and clinical testing, and exp to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities

our product candidates or products or such quantities at an acceptable cost, which could delay, prevent, or impair our development commercialization efforts.

- If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates, the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired, and we may not be able to compete effectively in our market.
- We may not obtain or grant licenses or sublicenses to intellectual property rights in all markets on equally or sufficiently favorable te with third parties.
- Intellectual property rights do not guarantee commercial success of current or future product candidates or other business activities. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.
- Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successfu obtaining regulatory approval of our product candidates in other jurisdictions.
- Our future success depends on our ability to retain key executives and experienced scientists and to attract, retain, and motivate qualified personnel.
- Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or nor performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations.
- Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.
- The market price of our common stock is expected to be volatile.
- We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.
- Once we are no longer an emerging growth company, a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.
- Provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may discourage any takeover attempts our stockholders may consider favorable, and may lead to entrenchment of management.

This section contains forward-looking statements. You should refer to the explanation of the qualifications and limitations on forward-looking statements beginning on page ii.

PART I

Except where the context otherwise requires or where otherwise indicated, the terms "Disc," "we," "us," "our," "our company," "the company," and "our business" refer to Disc Medicine, Inc. and its consolidated subsidiaries.

ITEM 1. BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of novel treatments for patients suffering from serious hematologic diseases. We have assembled a portfolio of clinical and preclinical product candidates that aim

to modify fundamental biological pathways associated with the formation and function of red blood cells, specifically heme biosynthesis and iron homeostasis. Our current pipeline includes bitopertin for the treatment of erythropoietic porphyrias, or EPs, including erythropoietic protoporphyria, or EPP, and X-linked protoporphyria, or XLP, and Diamond-Blackfan Anemia, or DBA; DISC-0974 for the treatment of anemia of myelofibrosis, or MF, and anemia of chronic kidney disease, or CKD; and MWTX-003 DISC-3405 (formerly MWTX-003) for the treatment of polycythemia vera, or PV, and other hematologic disorders. In addition, our preclinical programs also include DISC-0998, for the treatment of anemia associated with inflammatory diseases. Our approach to product candidate development leverages well-understood molecular mechanisms that have been validated in humans. We believe that each of our product candidates, if approved, has the potential to improve the lives of patients suffering from hematologic diseases.

Bitopertin is the lead product candidate in our heme biosynthesis modulation portfolio. Bitopertin was previously evaluated by F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or collectively, Roche, in a comprehensive clinical program in over 4,000 individuals in other indications which demonstrated the activity of bitopertin as a glycine transporter 1, or GlyT1, inhibitor and its effect on heme biosynthesis. We are planning to initially develop developing bitopertin for the treatment of EPs, including EPP and XLP. In July 2022, we initiated BEACON, a Phase 2 open-label, parallel-dose clinical trial of bitopertin in EPP and XLP patients that is being conducted at sites in Australia. Separately, in July 2022, we received clearance of our Investigational New Drug application, or IND, from the U.S. Food and Drug Administration, or FDA, for, and in In October 2022, we initiated AURORA, a Phase 2, randomized, double-blind, placebo-controlled clinical trial of bitopertin in EPP patients that is being conducted at sites in the United States. We expect presented interim data from BEACON in the first half of June and December 2023, and we expect topline data from AURORA by year-end 2023. in March or April 2024. Additional analysis of the full population in the BEACON trial is anticipated to be presented in 2024. We entered into a collaborative research and development agreement with the National Institutes of Health, or NIH, to conduct an NIH-sponsored clinical trial of bitopertin in DBA. The FDA authorized the clinical trial to proceed and we expect the trial to begin by mid-year began in July 2023. We are planning additional trials of bitopertin in other indications.

DISC-0974 is the lead product candidate in our iron homeostasis portfolio. portfolio and was in-licensed from AbbVie Deutschland GmbH & Co. KG, or AbbVie. DISC-0974 is designed to suppress hepcidin production and increase serum iron levels. We submitted an IND to the FDA for DISC-0974 in June 2021, received clearance in July 2021, and participants completed a Phase 1 clinical trial in healthy volunteers in the U.S. in June 2022 with results showing an acceptable tolerability profile and evidence of target engagement, iron mobilization and augmented erythropoiesis. We initiated a Phase 1b/2 clinical trial in June 2022 in patients with anemia of MF, and initiated a separate Phase 1b/2 clinical trial in February 2023 in patients with non-dialysis dependent CKD and anemia. We expect presented interim data from both of these trials in 2023. December 2023 and anticipate additional interim data presentations in 2024. In addition, we are developing a preclinical anti-hemojuvelin, or HJV, monoclonal antibody, DISC-0998, which also targets hepcidin suppression and was in-licensed from AbbVie Deutschland GmbH & Co. KG, or AbbVie. DISC-0998 is designed to increase serum iron levels and has an extended serum half-life as compared to DISC-0974. We believe this profile may be desirable in certain subsets of patients with anemia associated with inflammatory diseases.

Lastly, we are developing MWTX-003, DISC-3405, a monoclonal antibody against Transmembrane Serine Protease 6, or TMPRSS6, that we licensed from Mabwell Therapeutics, Inc., or Mabwell. MWTX-003 DISC-3405 is part of our iron homeostasis portfolio and is designed to induce hepcidin production and reduce serum iron levels. An IND for MWTX-003 has been DISC-3405 was cleared by the FDA, and we plan to initiate a Phase 1 clinical trial in healthy adult volunteers was initiated in October 2023. Interim data is anticipated to be presented in the first and second half halves of 2023. 2024. We expect to develop MWTX-003 DISC-3405 for the treatment of PV and other hematologic disorders.

Heme Biosynthesis Modulation: Bitopertin

Our first therapeutic approach is focused on the modulation of heme biosynthesis, a multistep enzymatic process that is highly active in the formation of new red blood cells. We believe this approach has the potential to address a wide range of hematologic diseases where red blood cell formation becomes dysregulated. This includes a family of rare diseases called porphyrias, which are caused by genetic or acquired defects in the enzymes that mediate heme biosynthesis and result in the accumulation of toxic metabolites called porphyrins. Bitopertin is the

most advanced product candidate in our heme biosynthesis portfolio. It is designed to be an oral, selective inhibitor of GlyT1, a key membrane transporter required to supply developing red blood cells with sufficient amounts of the amino acid glycine to support erythropoiesis. Glycine is necessary for the first step of

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heme biosynthesis, and by limiting glycine uptake in newly forming red blood cells, bitopertin has the potential to reduce the activity of the heme biosynthesis pathway, thereby reducing the pathological accumulation of toxic metabolites.

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In May 2021, we licensed the worldwide rights to develop and commercialize bitopertin from Roche, a pharmaceutical company that had previously evaluated bitopertin in a comprehensive clinical program in over 4,000 individuals, originally with a focus on treating certain neurologic disorders. The data generated in these clinical trials failed to establish the efficacy of bitopertin in neurologic disorders. However, the data did demonstrate that by limiting glycine uptake in newly forming red blood cells, bitopertin reduced the activity of the heme biosynthesis pathway, and we believe that this effect has the potential to treat many hematologic disorders. In addition, bitopertin was observed to be well tolerated in humans, with adverse events reported to be generally mild and infrequent across all trials conducted by Roche including at daily oral doses well above those that we plan to use in our clinical trials. We are initially focused on developing bitopertin for the treatment of EPP and XLP which are both diseases marked by severe photosensitivity and damage to the hepatobiliary system caused by the accumulation of protoporphyrin IX, or PPIX, a toxic metabolite of the heme biosynthesis pathway. Based on the demonstrated activity of bitopertin as a GlyT1 inhibitor and suppressor of heme biosynthesis in the clinical trials conducted by Roche, as well as the preclinical data we have generated in disease-relevant animal models and human cellular models, we have initiated a clinical program of bitopertin for EPP and XLP. In July 2022, we initiated BEACON, a Phase 2 open-label, parallel-dose clinical trial of bitopertin in EPP and XLP patients that is being conducted at sites in Australia. Interim data is expected was presented in the first half of 2023. Separately, in October 2022, we initiated AURORA, a Phase 2, randomized, double-blind, placebo-controlled clinical trial of bitopertin in EPP patients that is being conducted at sites in the United States. In July 2022, we received IND clearance from the FDA. Topline data from AURORA is expected by year-end 2023. March or April 2024. We also plan to explore the potential of bitopertin to treat other hematologic diseases, and entered into a collaborative research and development agreement with the NIH to conduct an NIH-sponsored clinical trial of bitopertin in DBA. The FDA authorized the clinical trial to proceed and we expect the trial to begin by mid-year began in July 2023.

Targeting the Hepcidin Pathway to Modulate Iron Homeostasis: Anti-Hemojuvelin mAbs and TMPRSS6 inhibitor Programs

We are also developing a portfolio of product candidates focused on modulating iron homeostasis. Our initial product candidates aim to control the production of hepcidin, which is the master regulator of iron homeostasis. Iron is an essential element that is required for erythropoiesis as well as other important biological functions, and when iron homeostasis becomes dysregulated, it can cause a wide range of diseases. We believe that modulating the production of hepcidin to correct pathologic alterations in iron homeostasis has the potential to be a powerful therapeutic strategy. We are leveraging two approaches that are designed to either suppress or induce hepcidin production in order to increase or decrease serum iron levels, respectively.

The lead product candidate in our iron homeostasis portfolio, DISC-0974, is designed to suppress hepcidin production and is in development for the treatment of anemia associated with inflammatory diseases. DISC-0974, an antibody that we in-licensed from AbbVie, is designed to inhibit HJV, a critical regulator of hepcidin production. We selected this target because the effects of inhibiting HJV, namely

decreased hepcidin and increased serum iron levels, have been genetically demonstrated in both animal knockout studies and in patients with juvenile hemochromatosis who lack fully functional genes encoding HJV. We have completed our Phase 1, placebo-controlled, single-ascending dose clinical trial of DISC-0974 in healthy volunteers. Data from the Phase 1 clinical trial showed an acceptable tolerability profile and evidence of target engagement and iron mobilization and augmented erythropoiesis. At the highest dose, a single 56 mg dose delivered by subcutaneous administration, DISC-0974 increased hemoglobin levels by greater than 1 g/dL relative to the placebo group. Data from the Phase 1 trial were presented at the 2022 European Hematology Association meeting and the 2022 American Society of Hematology annual meeting. in 2022. We initiated a Phase 1b/2 open-label clinical trial in patients with anemia of MF in July 2022 and initiated a separate Phase 1b/2 placebo controlled, single- and multiple-ascending dose clinical trial in patients with non-dialysis dependent CKD and anemia in February 2023. We expect interim Interim data from both of these trials was presented in December 2023. DISC-0974 has undergone testing in healthy volunteers and has just begun clinical testing for anemia of MF and CKD, and therefore there can be no assurance that DISC-0974 will achieve the desired effects in these indications. In addition, we are developing a preclinical anti-HJV monoclonal antibody, DISC-0998, which also is designed to target hepcidin suppression and was in-licensed from AbbVie. DISC-0998 is designed to increase serum iron levels and has an extended serum half-life as compared to DISC-0974. We believe this profile may be desirable in certain subsets of patients with anemia associated with inflammatory diseases.

As part of our portfolio to modulate iron homeostasis, we are also advancing MWTX-003, DISC-3405, a monoclonal antibody against TMPRSS6 that we in-licensed from Mabwell. MWTX-003 DISC-3405 is part of our iron homeostasis portfolio and is designed to induce hepcidin production and reduce serum iron levels. An IND for MWTX-003 DISC-3405 has been cleared by the FDA, and we plan to initiate a Phase 1 clinical trial in healthy volunteers was initiated in the second half of October 2023. We plan to develop MWTX-003 DISC-3405 for the treatment of disease where iron restriction may be beneficial, initially for patients with PV as well as diseases of iron overload. We selected this target based on the genetic confirmation of the effects of decreased TMPRSS6 activity in both animal knockout studies and in patients with iron-refractory iron deficiency anemia who lack fully functional genes encoding TMPRSS6.

Our Pipeline

We are building an innovative pipeline of product candidates that aim to modify fundamental biological pathways associated with the formation and function of red blood cells. We own have obtained exclusive, worldwide rights to each of our current product candidates. licenses for the development and

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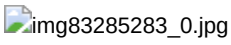
commercialization of bitopertin, DISC-0974, and DISC-0998, and exclusive rights for DISC-3405 and related antibodies in all territories outside of Greater China and Southeast Asia.

Clinical-Stage Product Candidates

The diagram below reflects the status of the clinical-stage product candidates, bitopertin, DISC-0974 and MWTX-003, DISC-3405, and clinical trials that have been completed, are ongoing or are expected to initiate by the end of 2023. 2024. The timelines described reflect our current expectations and beliefs based on our internal plans and certain limited regulatory interactions to date.



We also plan to develop bitopertin, DISC-0974 and MWTX-003 DISC-3405 for other indications. For example, we are exploring the potential of bitopertin as a treatment for macrocytic anemias, such as DBA and certain types of myelodysplastic syndromes, or MDS, in preclinical studies and have entered into a collaborative research and development agreement with the NIH to conduct an NIH-sponsored clinical trial of bitopertin in DBA. The FDA authorized the clinical trial to proceed and we expect the trial to begin by mid-year began in July 2023.

Preclinical Product Candidates

We also have preclinical-stage programs in development. This includes DISC-0998: a separate, preclinical anti-HJV monoclonal antibody, which is also designed to target hepcidin suppression and was in-licensed from AbbVie. DISC-0998 is designed to increase serum iron levels and has an extended serum half-life as compared to DISC-0974. We believe this profile may be desirable in certain subsets of patients with anemia associated with inflammatory diseases.

Our Corporate History and Team

We were founded in 2017 with the mission to design, develop, and commercialize medicines for patients with hematologic diseases. Since inception, we have focused on building our pipeline of product candidates through both internal drug discovery activities and external business development, conducting preclinical studies and clinical trials, and establishing and maintaining our intellectual property portfolio.

We have assembled a management team with extensive experience in successfully developing, manufacturing, and commercializing transformative therapies as well as in business development and alliance management. Collectively, our team led, or was involved in, the development, regulatory approval, and commercialization of therapies for hematologic diseases, such as Idhifa, Reblozyl, Pyrukynd, Adynovate and Tibsovo, as well as numerous late-stage clinical and approved therapies for other therapeutic areas. Our team has significant previous experience at leading biotechnology and pharmaceutical companies, including Acceleron Pharma, Inc., Agios Pharmaceuticals, Inc., Albireo Pharma, Inc., Astellas Pharma, Inc., Bristol-Myers Squibb Company, GlaxoSmithKline, Genzyme Corporation, Johnson & Johnson, Merck & Co., Inc., Pfizer Inc., Replimune Group, Inc., Takeda Pharmaceutical Co., Vertex Pharmaceuticals Incorporated, and The Medicines Company. Our management team's wide-ranging expertise in rare diseases, hematology, medicinal chemistry, protein biochemistry, and clinical development provide a singular vision for building a company focused on fundamental mechanisms to develop treatments for patients with hematologic diseases.

Our Strategy

Our mission is to significantly improve the lives of patients suffering from hematologic diseases by developing differentiated product candidates, including ones designed to target fundamental pathways associated with the formation and function of red blood cells. To achieve our mission, we are focused on the following key elements of our strategy:

- **Advance the clinical development of bitopertin for the treatment of patients with EPP and XLP and expand into other**

diseases characterized by dysregulation of the heme biosynthesis pathway. In multiple clinical trials conducted by Roche in other indications, bitopertin was observed to be a regulator of heme biosynthesis. We are initially developing bitopertin for the treatment of patients with EPP and XLP, which are part of a group of severe diseases, known as porphyrias, caused by defects in the heme biosynthesis pathway that cause an accumulation of toxic metabolites referred to as porphyrins. Based on the clinical data generated by Roche in multiple clinical trials in other indications and the compelling preclinical data we have generated, we believe bitopertin has the potential to be a disease-modifying treatment for these patients. In July 2022, we initiated BEACON, a Phase 2 open-label, parallel-dose clinical trial of bitopertin in EPP and XLP patients that is being conducted at sites in Australia. Interim data is expected was presented in the first half of 2023. Separately, in July 2022, we received IND clearance from the FDA and in October 2022 initiated AURORA. AURORA is a Phase 2, randomized, double-blind, placebo-controlled clinical trial of bitopertin in EPP patients that is being conducted at sites in the United States. Topline data from AURORA is expected by year-end 2023. March or April 2024. We also plan to explore the potential of bitopertin to treat other hematologic diseases, including DBA.

- **Advance the clinical development of DISC-0974 for the treatment of anemia associated with MF, CKD and other inflammatory diseases.** We are initially developing our lead hepcidin-suppressing program, DISC-0974, for the treatment of anemia associated with MF and CKD. We have completed a Phase 1, placebo-controlled, single-ascending dose clinical trial of DISC-0974 in healthy volunteers. Data from the Phase 1 clinical trial showed an acceptable tolerability profile and evidence of target engagement and iron mobilization and augmented erythropoiesis. We initiated a Phase 1b/2 open-label clinical trial in patients with anemia of MF in June 2022 and initiated a separate Phase 1b/2 placebo controlled, single/multiple ascending dose clinical trial in patients with non-dialysis dependent CKD and anemia in February 2023. We expect interim Interim data from these two trials was presented in December 2023. We also plan to further expand the development of DISC-0974 into anemias associated with other inflammatory diseases, such as inflammatory bowel disease.
- **Advance the clinical development of MWTX-003 DISC-3405 for the treatment of PV and expand into other diseases associated with excess iron availability.** The second program in our iron homeostasis portfolio is MWTX-003, DISC-3405, which is designed to induce hepcidin production. We plan to initiate initiated a Phase 1 clinical trial in healthy volunteers in the second half of October 2023, followed by which we plan to follow with a study in patients with PV. The inhibition of TMPRSS6 has been shown in non-clinical studies to increase hepcidin levels and restrict iron availability, and MWTX-003 DISC-3405 demonstrated activity in disease models of PV and beta-thalassemia. In clinical trials conducted by third parties, iron restriction through a hepcidin mechanism resulted in disease control in patients with PV, which is our initial indication of focus for this program.
- **Continue to build our pipeline through internal research or business development.** Though we have yet to generate complete clinical data for our product candidates, other than Phase 1 data for DISC-0974, we believe that all of our current product candidates, if approved, could have pipeline-in-a-product potential, and for each product candidate, we plan to explore its potential across multiple hematologic diseases. In addition, we plan to leverage our expertise in hematology to further grow our pipeline through both internal discovery and development of new therapeutic candidates and in-licensing of external assets. This approach includes developing both next-generation programs to support our existing heme biosynthesis and iron homeostasis portfolios as well as molecules that target other pathways associated with red blood cells that may be of strategic and biological interest. For example, we are developing DISC-0998, a preclinical monoclonal antibody as a next generation product candidate against HJV, the same target as DISC-0974. We believe DISC-0998 has improved pharmacokinetic, or PK, and pharmacodynamic, or PD, properties that may benefit certain subsets of patients with anemia associated with inflammatory diseases.
- **Opportunistically evaluate strategic collaborations to maximize the value of our product candidates and preclinical programs.** We have obtained exclusive, worldwide licenses for the development and commercialization of bitopertin, DISC-0974, and DISC-0998, and exclusive worldwide rights for MWTX-003 DISC-3405 (formerly MWTX-003) and related antibodies in all territories outside of Greater China and Southeast Asia. As we advance the development of our product candidates and preclinical programs across multiple indications and continue to generate additional data, we intend to continuously evaluate our options for maximizing the value of our overall portfolio. For example, in certain geographies, we may opportunistically enter into strategic collaborations to accelerate the development and maximize the commercial potential of any or all of our product candidates or preclinical programs. For each product candidate, preclinical program, indication, and geographic region, our goal is to find the best path forward for the development of our product candidates

and preclinical programs in order to treat patients in need of new therapies, while also maximizing value for our stockholders.

Our Approach

Our goal is to continue to build and advance a portfolio of product candidates that focus on fundamental biological pathways associated with the formation and function of red blood cells. Red blood cells have the essential role of carrying oxygen via hemoglobin to all tissues and organs in the body. The biological processes that are required to maintain normal levels of functional red blood cells are complex, and a variety of congenital and acquired diseases occur due to imbalances or deficiencies

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in red blood cell formation and function. Two key components needed to support the formation and function of red blood cells are heme and iron. Heme is an essential part of red blood cells, and when complexed into the hemoglobin protein, it performs the vital function of transporting oxygen throughout the body. Iron is a key component of heme, and therefore both iron and heme are required for erythropoiesis, the biological process by which precursor cells in the bone marrow mature to become red blood cells. Based on previously conducted animal models and preclinical data, we believe our product candidate portfolio, by targeting fundamental pathways in red blood cell biology, has the potential to address a range of hematologic diseases in which modification of iron and heme plays a critical function.

We are focused on therapeutic approaches that modulate heme and iron to address diseases of heme biosynthesis and red blood cell production. Our current pipeline is focused on the following three approaches:

- Modulating the heme biosynthesis pathway, which is anticipated to be useful in diseases caused by excesses in toxic heme pathway metabolites, e.g. EPs;
- Increasing iron availability to red blood cell precursors, which is anticipated to have direct effects on increasing red blood cell productio to correct anemia in diseases of iron restriction, e.g. anemia associated with inflammatory diseases; and
- Decreasing iron availability, which is anticipated to lower red blood cell production in diseases of excessive red cell production, e.g. PV.

Additionally, we focus on therapeutic mechanisms that have been validated in humans, through evidence from either human genetics or third-party clinical trials. For example, our lead program, bitopertin, which has been evaluated in over 4,000 individuals, has demonstrated suppression of heme biosynthesis in multiple clinical trials conducted by Roche. The targets of our iron homeostasis portfolio, HJV and TMPRSS6, have both been genetically validated in humans and shown to have a role in the regulation of hepcidin and iron homeostasis. For example, individuals with inherited loss of the HJV gene exhibit low levels of hepcidin and individuals with inherited loss of the TMPRSS6 gene exhibit elevated levels of hepcidin.

By focusing on fundamental red blood cell biology that is validated in humans, we believe that our product candidates are more likely to exhibit well-defined biological effects in clinical trials and have the potential for broad applicability across a wide range of hematologic diseases.

Our Heme Biosynthesis Modulation Portfolio

Our first therapeutic approach is focused on the treatment of diseases caused by defects in heme biosynthesis, a multistep enzymatic process that is critical for the formation of new red blood cells. Heme is an essential part of red blood cells, and when complexed into the hemoglobin protein, it performs the vital function of transporting oxygen throughout the body. However, genetic or acquired defects in the

enzymes that mediate heme biosynthesis, as well as deficiencies in the incorporation of heme into hemoglobin, can result in the accumulation of toxic metabolites, leading to a range of hematologic diseases.

Heme Biosynthesis: Fundamental to Erythropoiesis

Erythropoiesis is the biological process by which precursor cells in the bone marrow mature to become red blood cells. The primary function of red blood cells is to transport oxygen throughout the body. Hemoglobin, an iron-containing protein found in all red blood cells, is responsible for binding to oxygen in the lungs, transporting it throughout the body and releasing it in peripheral tissues. The key oxygen binding function of hemoglobin is mediated by its heme component, a molecular complex comprising a porphyrin molecule and iron. Because red blood cells consist largely of heme-containing hemoglobin, newly forming red blood cells must synthesize tremendous amounts of heme. Heme biosynthesis is a complex process that begins with the amino acid glycine and requires multiple subsequent enzymatic reactions, as shown in the figure below. Heme is a highly reactive and potentially toxic complex, as are many of the porphyrin molecules that are generated as metabolic intermediates during heme biosynthesis. As a result, heme biosynthesis is tightly regulated to avoid a build-up of free heme or porphyrins. As new red blood cells are forming in the bone marrow, the heme biosynthesis pathway is tightly coordinated with the expression of the protein subunits of hemoglobin, the globins, and the uptake of iron. The vast majority of newly synthesized heme is incorporated into hemoglobin and does not accumulate in free form to toxic levels. Moreover, the entire process of erythropoiesis

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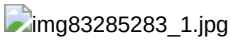
is regulated by the availability of heme. As a result, agents that affect heme biosynthesis have broad potential to treat diseases of the heme and hemoglobin biosynthesis pathways and other hematologic diseases resulting from dysregulated erythropoiesis.

Overview of the Heme Biosynthesis Process - Eight Enzymatic Steps from Glycine to Heme



Heme Biosynthesis as a Therapeutic Target for Diseases

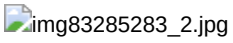
In many hematologic diseases, there is abnormal proliferation and differentiation of the progenitor cells that develop into red blood cells. An alteration in any aspect of red blood cell maturation can result in the build-up of metabolic intermediates from heme and hemoglobin biosynthesis, and these intermediates can cause a variety of disease states. Defects of the heme biosynthesis enzymes in the erythroid lineage can cause the build-up of metabolic intermediates called porphyrins and lead to a set of diseases referred to as EPs. In EPs, porphyrins accumulate to inappropriately high levels and cause damage, particularly in the skin, gallbladder, and liver. Similarly, defects in globin biosynthesis, often caused by mutations in the ribosomes that are necessary for mediating globin biosynthesis, result in the build-up of heme that is not complexed with globin. This free heme can damage newly forming red blood cells, leading to forms of anemia observed in DBA and in certain types of MDS. In diseases characterized by defects in the genes coding for the globins, such as sickle cell disease and beta thalassemia, the reduction of heme biosynthesis has the potential to reduce the production of pathologically altered globins that aggregate or polymerize, causing oxidative damage and hemolysis. In people without globin abnormalities, excessive production of red blood cells with normal hemoglobin can cause PV, in which the higher hematocrit can lead to thrombotic disease, including stroke. Restricting heme formation has the potential to ameliorate symptoms in certain patients with these hemoglobinopathies and disorders of red blood cell excess.

Therefore, we believe that inhibitors of heme biosynthesis have the potential to treat a wide range of hematologic diseases by restricting the production of damaging metabolites, including porphyrins, heme and globins.

Erythropoietic Porphyrias

EPs are a family of rare, debilitating, and potentially life-threatening diseases caused by mutations that affect the heme biosynthesis pathway. These mutations result in the toxic accumulation of metabolic intermediates in the blood called porphyrins, which can absorb light through the skin and mediate the generation of toxic reactive oxygen species that cause damage to the skin and other tissues. Consequently, when patients with porphyria are exposed to sunlight, they experience excruciating pain, blistering, and edema in the skin. This severe phototoxicity often results in a lifelong aversion to and fear of light, which has a negative impact on patients and their families, particularly for young children. These effects include impaired psychosocial development and conditions, such as anxiety, depression, and social isolation that may require significant adjustments to career and other life choices. EPs comprise three subtypes that are each linked to a specific mutation or deficiency in one of the enzymes in the heme biosynthesis pathway: (1) EPP, which is linked to the ferrochelatase, or FECH, enzyme; (2) XLP, which is linked to the delta-aminolevulinic acid synthase-2, or ALAS2, enzyme; and (3) congenital erythropoietic porphyria, or CEP, which is linked to the uroporphyrinogen III cosynthase, or UROS, enzyme. As shown below, mutations in the FECH and ALAS2 enzymes lead to a pathological accumulation of PPIX, and as a result, patients with EPP or XLP typically have high levels of PPIX.

Genetic and Biochemical Basis for EPP and XLP: FECH and ALAS2 Mutations Increase PPIX Levels



EPP is a rare, inherited metabolic disease characterized by a deficiency of the FECH enzyme. FECH is responsible for the last step in heme biosynthesis and catalyzes the insertion of iron into PPIX to create the final heme moiety. In patients with EPP who have abnormally low levels of FECH, excessive amounts of PPIX accumulate in the bone marrow, blood plasma, and red blood cells. This accumulation of PPIX, which becomes highly reactive and toxic when exposed to light, causes the hallmark EPP symptom of photosensitivity, or skin hypersensitivity to sunlight and some types of artificial light, such as fluorescent lights. After exposure to light, the patient's skin may initially become itchy and red, and then affected individuals often experience a severe burning sensation that may persist for days. PPIX also accumulates in the gallbladder and liver and causes complications in these organs for some patients. An estimated 25% of patients may develop gallstones that require surgical removal. Many patients live with subclinical liver damage, which progresses to overt liver failure and requires liver transplant in approximately 2% to 5% of patients. The onset of symptoms affecting the skin usually occurs in early childhood; however, in some cases, onset may not occur until adolescence or adulthood. EPP has been reported worldwide, with prevalence between 1 in 75,000 to 1 in 200,000, but a recent genetic study suggests that the genetic prevalence may be higher at approximately 1 in 17,000. 17,000, and recent analyses we completed of medical claims data using the ICD-10 code for EPP suggests a prevalence ranging from 1 in 100,000 up to 1 in 24,000, depending on the definition used.

XLP is a genetically distinct inherited metabolic disease with a clinical presentation that is similar to EPP. The causative mutation in XLP occurs in the ALAS2 gene, which codes for the first enzyme in the heme biosynthesis pathway that is found on the X chromosome and inherited with an X-linked pattern. The mutation causes increased ALAS2 function, which results in pathologic accumulation of PPIX. XLP affects both males and females, but males usually develop a severe form of the disease. Females with an ALAS2 mutation may also develop

the disease, but severity can range from being asymptomatic to a severe form. Similar to EPP, the major symptom of this disease is skin hypersensitivity to sunlight and some types of artificial light. The exact incidence or prevalence of XLP is unknown, but it is often estimated at one-tenth the incidence of EPP. EPP and XLP, when combined, are the third most common porphyria.

CEP, also known as Günther Disease, is the rarest and most severe form of the EPs and results from the deficient function in UROS, the fourth enzyme in the heme biosynthesis pathway. In CEP, the impaired function of this enzyme leads to the accumulation of excessive amounts of certain porphyrins, particularly in the bone marrow, plasma, red blood cells, urine, teeth, and bones. Similar to EPP and XLP, the major symptom of this disease is skin hypersensitivity to sunlight and some types of artificial light. However, in patients with CEP, the photoactivated porphyrins in the skin cause more profound blistering and scarring. Additionally, the accumulation of porphyrins in the bone impairs bone metabolism and can cause bone loss and deformities. CEP is extremely rare and there have been about 220 affected individuals reported to date.

Current Treatment Options for Erythropoietic Porphyrias

There are currently no disease-modifying therapies available to treat EPs other than bone marrow transplantation, which is associated with high rates of morbidity and mortality. Lifestyle alterations to avoid light exposure are the primary approach to managing phototoxicity in EP patients. Sunscreens, tinted windows, and protective clothing are also commonly used in addition to behavioral modifications. The only class of approved therapies for patients with EP are melanocortin 1 receptor agonists, which

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are designed to promote melanin production, or tanning, and thereby increase patient tolerance to sunlight. Afamelanotide, an a-melanocyte-stimulating hormone analog delivered by a surgically-administered subcutaneous implant, was approved by the FDA in 2019 for the treatment of EPP. Afamelanotide provides reduction in photosensitivity, but is not designed to reduce PPIX

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production and is associated with side effects, such as nausea, hyperpigmentation and a darkening of or increase in melanocytic nevi. In a pivotal trial, afamelanotide increased the median number of pain free hours in daytime (10am to 6pm) over 180 days from 40.5 hours in a placebo group to 64.1 hours in the treatment group. Another melanocortin 1 receptor agonist, dersimelagon, which is orally administered, is currently in Phase 3 development by a third party. Overall, there remains a significant unmet need despite the use of melanocortin 1 receptor agonists, as they provide incomplete resolution of photosensitivity and more importantly, are not designed to reduce the production of protoporphyrins or address hepatobiliary complications, such as gallstones and progressive liver disease.

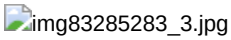
Patients with EP who have progressive liver damage are managed through periodic monitoring, and in cases of liver failure, transplantation is required. While bone marrow transplantation has been used to cure EPs, it is associated with high rates of morbidity and mortality. Therefore, this procedure is usually considered only for younger patients after a liver transplant, for older patients with recurrent disease affecting the liver allograft, or for patients with progressive liver disease.

Our Solution: Bitopertin, an Oral, Selective GlyT1 Inhibitor

Bitopertin is designed to be an oral, selective inhibitor of GlyT1, a key membrane transporter required to supply developing red blood cells with sufficient glycine to support erythropoiesis. By limiting glycine uptake at the first step in heme biosynthesis in newly forming red blood

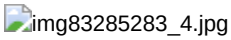
cells, bitopertin is designed to reduce the activity of this pathway, as shown below, and therefore has the potential to treat a range of hematologic disorders associated with the biosynthesis of heme and hemoglobin.

Bitopertin May Treat a Range of Hematologic Disorders



We are initially focused on the ability of bitopertin to suppress the accumulation of PPIX, as shown below, based on preclinical data from cellular and mouse models of disease. Based on its mechanism of action, we believe bitopertin has the potential to be a disease-modifying treatment for EPP and XLP.

Mechanism of Action for Bitopertin



EPP and XLP are diseases marked by severe photosensitivity and damage to the hepatobiliary system caused by the accumulation of PPIX. PPIX has been well-characterized to absorb light and induce inflammation and tissue damage, manifesting clinically as painful phototoxic reactions. Lower levels of PPIX are associated with lower disease severity. Epidemiologic data correlate increasing PPIX concentrations with decreased light tolerance, and interventions that reduce PPIX in patients correlate directly with increased light tolerance. Lower PPIX levels (by roughly 30-50%) increased light tolerance in patients. 25% of patients with lower PPIX levels experienced symptoms versus 75-100% of patients with medium to high PPIX levels under

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controlled light exposure. During pregnancy, women with EPP experience temporary disease remissions that increase sunlight tolerance and coincide with a reduction in PPIX levels. For example, in a study conducted by a third-party, pregnant women were observed to have a median reduction of 53% in PPIX levels during pregnancy, resulting in a significant reduction in their EPP symptoms. Disease symptoms return after delivery when PPIX levels revert to pre-pregnancy levels, leading to the hypothesis that the fetus may utilize plasma PPIX as a substrate for its own escalating heme biosynthesis requirements, thus reducing PPIX levels in the mother's bloodstream. In a third-party study of extracorporeal photoinactivation, a process that reduces circulating PPIX

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levels, symptoms were markedly improved after reduction in blood PPIX concentrations. In this study, blood was removed from the body and illuminated with controlled wavelength light to inactivate PPIX, and the blood in which the PPIX was inactivated was re-infused. This procedure resulted in PPIX reductions of approximately 30% and light tolerance was temporarily increased 14-fold, a level of improvement that is expected to permit near-normal patient lifestyle. However, given the technical complexities associated with this procedure, it has not been widely adopted as a therapeutic option in patients.

Bitopertin has been evaluated in an extensive clinical program focused on neurological disease conducted by Roche in over 4,000 individuals, which demonstrated the activity of bitopertin as a GlyT1 inhibitor and suppressor of heme biosynthesis. We have also conducted preclinical studies in cellular models of EPP and animal models of EPP and XLP, which showed that bitopertin significantly decreased PPIX by 45 and 73%, respectively, which is more than the threshold 30% reduction that has been associated with marked symptom improvement in the

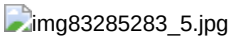
studies described above. In a separate study, we also demonstrated that bitopertin reduced liver fibrosis in an animal model of EPP. Based on the aggregate of these results, we have initiated a clinical program to study bitopertin in EPP and XLP. In July 2022, we initiated BEACON, a Phase 2 open-label, parallel-dose clinical trial of bitopertin in EPP and XLP patients that is being conducted at sites in Australia. Interim data is expected from BEACON was presented in 2023 and showed dose dependent reductions in PPIX of approximately 40% across the first half 20 mg and 60 mg dose groups. This PPIX reduction was associated with increases in light tolerance, as measured by participant diary light exposure data, and improvements in quality of 2023. life, as assessed by patient reported outcomes. Separately, in July 2022, we received IND clearance from the FDA and initiated AURORA in October 2022. AURORA is a Phase 2, randomized, double-blind, placebo-controlled clinical trial of bitopertin in EPP patients that is being conducted at sites in the United States. Topline data from AURORA is expected by year-end 2023. March or April 2024. We also plan to explore the potential of bitopertin to treat other hematologic diseases, and have entered into a collaborative research and development agreement with the NIH to initiate an NIH-sponsored clinical trial of bitopertin in DBA. The FDA authorized the clinical trial to proceed and we expect the trial to begin by mid-year initiated in July 2023.

Clinical Data

In May 2021, we licensed exclusive worldwide rights to develop and commercialize bitopertin from Roche. Roche had previously developed bitopertin as a potential therapy for certain symptoms of schizophrenia and obsessive-compulsive disorder, but chose to discontinue the program due to failure to meet primary endpoints in Phase 3 trials for those indications after completing over 30 clinical trials in more than 4,000 individuals. Roche conducted a pilot study for the treatment of anemia in 12 patients with beta-thalassemia, a population with a normal heme biosynthesis pathway; this trial did not show consistent increases in hemoglobin at the doses tested. Despite the observed lack of efficacy, the clinical program established a well-defined and generally well-tolerated profile for bitopertin. Importantly, these trials confirmed that bitopertin inhibits glycine uptake in red blood cells and demonstrated the role of GlyT1 inhibition in heme biosynthesis during red blood cell production. This was observed in multiple clinical trials by a mild, dose-dependent decrease in heme biosynthesis, which manifested as a decrease in hemoglobin of approximately 0.5 to 2 g/dL that stabilized after approximately 16 weeks, the approximate lifespan of a red blood cell.

For example, a single dose clinical trial in healthy volunteers evaluating bitopertin at doses ranging from 3 mg to 80 mg administered once-daily in 24 individuals demonstrated dose-dependent inhibition of erythrocyte glycine uptake levels, as shown below.

Bitopertin Inhibits Inhibited Erythrocyte Glycine Uptake in Humans in a Dose-Dependent Manner



In multiple Phase 3 clinical trials, Roche demonstrated that in patients with schizophrenia who are otherwise hematologically normal, inhibition of glycine uptake resulted in a reduction in hemoglobin production. Patients were administered placebo or bitopertin at 10 mg/day or 20 mg/day dose levels. The effect on hemoglobin was dose-dependent, with patients receiving 10 mg/day and 20 mg/day of bitopertin experiencing a mean decrease in hemoglobin at 52 weeks of approximately 0.5

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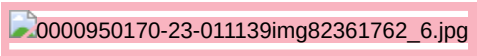
g/dL and approximately 1.0 g/dL, respectively. The effect of bitopertin on hemoglobin reached a plateau at approximately week 26 and effects were generally stable for the remainder of the 52-week trial.

Preclinical Data

PPIX is well-established as the pathologic driver in EPP and XLP, and we believe that the suppression of heme biosynthesis in patients with EPP and XLP will result in reduced levels of PPIX. As described above, there is clinical evidence suggesting that reduction of PPIX by greater than 30% has the potential to significantly reduce photosensitivity in EPP and potentially XLP patients. Based on this clinical evidence, we conducted preclinical research to validate the effects of bitopertin on PPIX levels in disease relevant cell and animal models. In our studies bitopertin reduced PPIX levels in a dose-responsive manner in human cell lines that were genetically modified to recapitulate the EPP disease state and in mice that were genetically modified to recapitulate the EPP and XLP disease states.

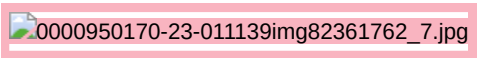
To create a cellular model of EPP, we genetically modified a human erythroleukemia cell line, K562, to introduce the mutations that cause EPP in human patients. Similar to the human disease state, the genetically modified cells exhibited a greater than 50-fold increase in PPIX levels. In the K562 model, bitopertin decreased the formation of 5-aminolevulinic acid, or 5-ALA, which is the first metabolite of the heme biosynthesis pathway, and prevented PPIX accumulation, as demonstrated by an EC50 of 3 nM to 10 nM, without significantly affecting heme levels, as shown below. EC50, or half maximal effective concentration, refers to the concentration of drug that induces a response halfway between baseline and the maximum potential response after a specified exposure time and nM refers to nanomolar, a measure of concentration.

Effects of Bitopertin on PPIX and Heme Levels in a Human Erythroid Cell Line Carrying EPP Mutations



To further assess the potential of bitopertin to reduce PPIX levels *in vivo*, we conducted studies in mice that were genetically modified with mutations similar to those that cause EPP and XLP in humans. Bitopertin was evaluated in female Fechm1Pas EPP and male Alas2Q548X/Y XLP mouse models. In both models, mice developed protoporphyria characterized by elevated red blood cell and liver PPIX levels. Fechm1Pas and Alas2Q548X mice were fed a diet containing 0 or 100 ppm of bitopertin for 8 weeks starting at 6 weeks of age, which is a dose level that is similar to a once-daily 30 mg dose of bitopertin in humans. As shown in the figures below, after 8 weeks of treatment, PPIX levels decreased in Fechm1Pas and Alas2Q548X animals receiving bitopertin with a mean reduction of 45% and 73%, respectively, compared to the control group. Changes in hemoglobin levels were limited, indicating bitopertin can potentially reduce PPIX accumulation without impacting erythropoiesis to a degree that is clinically relevant. In a separate study designed to evaluate liver pathology in a mouse model of EPP, bitopertin treatment was shown to significantly reduce liver fibrosis, demonstrating the potential for bitopertin to be disease modifying.

Effects of Bitopertin on PPIX and Hemoglobin Levels in Mouse Models of EPP and XLP



Clinical Development Plan

We believe that the findings from our preclinical studies and the clinical trials conducted by Roche demonstrate that bitopertin has the potential to act as a durable, and well-tolerated inhibitor of heme biosynthesis in humans. Importantly, we believe these studies support the potential for bitopertin to reduce PPIX to a degree that has, in third-party studies, been associated with marked symptom improvement in patients with EPP and XLP. Accordingly, we have initiated a clinical program to study bitopertin in EPP and XLP. In July 2022, we initiated BEACON, a Phase 2 open-label, parallel-dose clinical trial of bitopertin in EPP and XLP patients that is being conducted at sites in Australia. Interim data is expected was presented in the first half of 2023. 2023 and additional data will be presented in 2024. Separately, in October 2022

we initiated AURORA, a Phase 2, randomized, double-blind, placebo-controlled clinical trial of bitopertin in EPP patients being conducted at sites in the United States. We filed an IND for this study with the FDA in April 2022 and were on clinical hold until the study design was finalized with the FDA. In July 2022, we received IND clearance from the FDA to initiate the study. study and the trial began in October 2022. Topline data from AURORA is expected by year-end 2023. March or April 2024. We also plan to explore the potential of bitopertin to treat other hematologic diseases, and have entered into a collaborative research and development agreement with the NIH to initiate an NIH-sponsored clinical trial of bitopertin in DBA. The FDA authorized the clinical trial to proceed and we expect the trial to begin by mid-year began in July 2023.

Phase 2 Clinical Development Program in Patients with EPP and XLP

As part of our clinical development program, we have initiated a clinical development program that consists of two separate Phase 2 clinical trials of bitopertin in patients with EPP and XLP.

In July 2022, we initiated BEACON, a Phase 2 clinical trial of bitopertin in EPP and XLP patients that is being conducted at sites in Australia. The study is a randomized, open-label, parallel-dose clinical trial designed to evaluate the safety, tolerability, and efficacy of bitopertin. It is was designed to enroll approximately 20 adult patients with EPP or XLP at sites in Australia. Australia, and in 2023, upon completion of enrollment for adults, the study was expanded to include adolescents. The study will primarily assess changes in levels of PPIX as well as the PK profile, safety and tolerability of bitopertin in EPP or XLP patients. It will also include measures of photosensitivity, daylight tolerance, pain and exploratory biomarkers of hepatobiliary disease. Patients will receive orally-administered bitopertin for 24 weeks at doses of either 20 mg once-daily or 60 mg once-daily. These dose levels have a well-understood profile and similar dosage strengths have been shown to provide substantial inhibition of erythroid glycine uptake in the clinical trials conducted by Roche. Upon completion of the 24-week treatment period, patients may continue on bitopertin for enroll in an additional 24 weeks. We expect to report interim data in the first half of 2023. open label extension study. The trial design is summarized in the figure below.

BEACON Trial Design: Open-Label, Phase 2 Clinical Trial of Bitopertin in Patients with EPP or XLP (N ~ 20)

Interim data from BEACON were presented at the European Hematology Association annual meeting in June 2023 and at the American Society of Hematology annual meeting in December 2023. As of the December 2023 presentation (with a data cutoff of September 18, 2023 for PPIX data and October 20, 2023 for all other endpoints), all 22 adults planned for enrollment had completed at least 6 weeks on study, with 14 having completed 24 weeks of dosing. The average age of participants was 44 years, with 64% being female. Bitopertin significantly reduced whole blood metal-free PPIX by >40% in the overall study population, with greater reductions in the 60 mg group than the 20 mg group. Most of the PPIX reduction occurred in the first 6 weeks of treatment. Overall, there was a 92% reduction in the incidence of patient-reported full phototoxic reactions compared to baseline. The proportion of symptom-free days improved from 33% at baseline to 78% while taking bitopertin. Sunlight tolerance improved in a series of sunlight challenges that participants self-administered weekly, according to the protocol. People with EPP experience prodromes, or early warning symptoms, of an impending full phototoxic reaction. These prodromes are reversible when sunlight exposure is discontinued, and the time until a prodrome starts is an indicator of light tolerance. Combining data from

all participants showed a >3-fold improvement in average time to prodrome, as compared to baseline (p<0.001). The proportion of participants who conducted a sunlight challenge that did not elicit a prodrome increased from 7% at baseline to 54% while taking bitopertin. Of the participants that completed the treatment period (n=14), nearly all participants who completed the quality of life responses (n=13) reported improvements in quality of life measures, with 12 of 13 reporting that their EPP was “much better” or “a little better”, 12 of 13 reporting that their EPP was “not at all” or “mild” in severity, and 11 of 13 reporting that EPP impacted their quality of life in the last 7 days “not at all” or “a little bit”. Safety analyses showed no serious adverse events, stable hemoglobin levels, and no anemia adverse events reported. There was one discontinuation due to a Grade 3 headache. Overall, 32% of participants reported dizziness, 23% lightheadedness, 18% headache, and 14% nausea.

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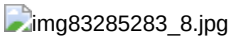
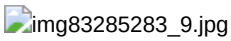


Separately, in October 2022 we initiated AURORA, a Phase 2, randomized, double-blind, placebo-controlled, parallel dosing trial in approximately 75 adult patients with EPP. We expect to enroll enrolled patients into a placebo group, a 20 mg/day dose group and a 60 mg/day dose group, with bitopertin delivered as tablets taken orally once per day for a period of 17 weeks. These dose levels have a well-understood profile and similar dosage strengths have been shown to provide substantial inhibition of erythroid glycine uptake based on the clinical trials conducted by Roche. This trial will include assessments of blood PPIX levels and patient photosensitivity. Additional study measures will include time to prodromal symptom, hepatobiliary markers, quality of life, safety and tolerability, among others. The FDA has previously approved afamelanotide for the treatment of photosensitivity in EPP patients on the basis of a clinical endpoint measuring a change in pain-free time spent in sunlight in treated patients, relative to patients treated with placebo. In July 2022, we received IND clearance from the FDA for the AURORA clinical trial. Topline data is expected by year-end 2023. March or April 2024. The trial design is summarized in the figure below.

AURORA Trial Design: Randomized, Double-Blind, Placebo-Controlled Phase 2 Clinical Trial of Bitopertin in Patients with EPP (N ~ 75)



Additional Safety Data from Selected Clinical Trials Conducted by Roche

Based on the comprehensive data package from Roche’s healthy volunteer trials, we anticipate that bitopertin will have an acceptable tolerability profile. The identified risks established by Roche across the development program are (percentage bitopertin treated vs. percentage placebo treated): headache (9.8% vs. 6.7%), somnolence (5.2% vs. 3.7%), and dizziness (4.2% vs. 3.6%). The results of single dose bitopertin clinical trials in healthy volunteers at doses ranging from 3 mg to 240 mg (n=290) and multiple dose trials at doses ranging from 10 mg to 180 mg daily for 10 to 120 days (n> 360) demonstrated a comprehensive tolerability profile. In one multiple ascending dose trial, reversible blurred vision was observed in 5 subjects (20%) at or above the 80 mg/day dose level. In a four-month pharmacodynamics study, 11.8% of subjects receiving an active dose noted dysphoria/low mood (mostly at 30 mg/day), as compared to 6.3% of placebo, and dermatological adverse events on hands and feet were observed in 15.7% of subjects (mostly at 60 mg/day). In Phase 3 studies, no association with bitopertin was

found for dermatological adverse events or adverse events of blurred vision or low mood. The amount of hemoglobin per red blood cell or per reticulocyte decreased in a dose-dependent manner. No hematologic parameter reached a level at which we would expect clinical signs or symptoms. Roche's Phase 3 program in schizophrenia consisted of six Phase 3 clinical trials (total n=2,438) of 5 mg, 10 mg, and 20 mg doses of bitopertin for up to 52 weeks, followed by extension phases. In these trials, bitopertin treatment was not associated with any significant tolerability issues. Most of the adverse events were considered mild or moderate in severity in all trials.

Additional Preclinical Safety Data from Studies Conducted by Roche

There is also comprehensive nonclinical safety data for bitopertin supporting further development in the EPP and other hematologic diseases. The main targets for bitopertin toxicity in repeat-dose toxicity studies were identified as the CNS and the intended PD effect of altered erythropoiesis. No primary histopathological findings attributable to bitopertin were noted in any organ. The CNS-related effects following repeated treatment with bitopertin were generally mild and reversible upon cessation of treatment. The incidence, severity, and onset of the CNS-related effects were dose-dependent, and histopathology evaluation did not show any morphological lesions. The repeat-dose toxicity studies were performed in rats for up to 26 weeks and in non-human primates, or NHPs, for up to 52 weeks. Two-year carcinogenicity studies showed that bitopertin was not carcinogenic in mice or rats. In juvenile toxicity studies conducted in rats, treatment was generally well-tolerated and no effects specific to the juvenile rat were identified on development or behavior at any dose level tested.

Bitopertin in Additional Indications: Diamond-Blackfan Anemia and Macrocytic Anemias

We believe that bitopertin may be therapeutically beneficial for the treatment of DBA and other anemias that are characterized as macrocytic anemias. DBA is a genetic condition marked by defective erythropoiesis that is usually caused by genetic mutations in genes coding for ribosomal proteins. Clinically, DBA is a lifelong anemia that presents in infancy and has a 25% mortality rate by age 50. Standard therapy includes chronic steroid treatment and/or regular blood transfusions, and hematopoietic stem cell transplantation is the only known cure for DBA. The ribosomal defects in patients with DBA are thought to cause a build-up of free heme in newly forming red blood cells, and this free heme exerts a toxic effect, resulting in poor red blood cell formation and anemia. Inhibitors of heme biosynthesis have shown marked effects in improving red blood cell production in third-party cellular and animal models of DBA. Accordingly, we anticipate that bitopertin may be able to provide relief from anemia and transfusion in patients with DBA by restricting the accumulation of toxic, free heme. Other anemias characterized by ribosomal defects exhibit a similar phenotype and are collectively referred to as macrocytic anemias. An example is the form of MDS characterized by a deletion in the 5q chromosomal locus, or Del(5q) MDS. Heme biosynthesis inhibitors have shown benefits on red blood cell formation in patient-derived cells from patients with Del(5q) MDS, and therefore we expect bitopertin may be therapeutically beneficial in these related conditions. We are continuing to explore the potential of bitopertin in these additional indications in preclinical studies. We have entered into a collaborative research and development agreement with the NIH to conduct an NIH-sponsored clinical trial of bitopertin in DBA. The FDA authorized the clinical trial to proceed and the trial is planned to begin by mid-year began in July 2023.

Our Iron Homeostasis Portfolio

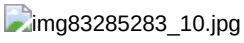
In addition to our heme biosynthesis therapeutic approach, we are developing a portfolio of product candidates focused on the modulation of the hepcidin pathway to normalize iron homeostasis. Iron is an essential element that is required for erythropoiesis as well as other important biological functions. Nearly 70% of iron in the human body resides in red blood cells, where it is a fundamental component of hemoglobin, the protein that enables red blood cells to carry and transport oxygen. Although iron is critical to an array of biological functions,

excessive levels can be toxic. Consequently, the management of iron levels in the body is a critical and carefully controlled process. Hepcidin is a potent hormone produced in the liver that serves as the primary regulator of iron homeostasis and plays a central role in controlling how iron is absorbed, utilized, stored, and recycled systemically. If this process becomes dysregulated, a wide range of serious, debilitating, and potentially fatal conditions can arise.

Hepcidin: The Master Regulator of Iron Homeostasis

Iron typically enters the body when it is absorbed in the intestine from dietary intake. As it enters circulation, iron is bound to carrier proteins. Iron is a highly reactive metal that can cause oxidative stress and tissue damage in an unbound state. Iron is utilized in target tissues, such as the bone marrow, to support erythropoiesis, and the remaining surplus is directed to specific storage tissues, such as the spleen, where it can be sequestered in specialized macrophages and redeployed when needed. This process is governed by hepcidin, which serves as a gatekeeper in tissues that are a source of iron, both blocking absorption of dietary iron from the intestine and preventing the release of stored iron from the spleen, as shown in the figure below. The body exerts control and responds to demands for iron by increasing or reducing the production of hepcidin, which leads to a reduction or increase in iron availability, respectively.

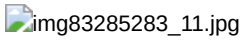
Hepcidin Plays a Central Role in Iron Metabolism and Homeostasis



Hepcidin is a Therapeutic Target for Diseases of Iron Metabolism

Because iron is critical to so many biological functions, particularly in red blood cells, disruptions in its homeostasis, often due to the dysregulated production of hepcidin, can result in a wide range of hematologic diseases, as shown in the figure below. These include diseases that can cause abnormally high production of hepcidin, which deprives developing red blood cells of iron and causes anemia, a frequent complication of cancer, autoimmune conditions, and other inflammatory diseases. Conversely, in certain diseases with abnormally low production of hepcidin, increasing hepcidin and restricting iron availability are expected to provide a therapeutic benefit. For example, in PV, iron restriction through a hepcidin mechanism has been demonstrated to control pathologic production of red blood cells. In other diseases, such as hereditary hemochromatosis, or HH, beta-thalassemia, and MDS, iron levels are pathologically high due to inadequate hepcidin production, and agents that increase hepcidin could be beneficial.

Dysregulated Hepcidin Drives a Wide Range of Hematologic Diseases



We believe that modulating the production of hepcidin to correct pathologic alterations in iron metabolism has the potential to be a powerful therapeutic strategy to address a wide range of diseases. We are leveraging two approaches that are designed to suppress or induce hepcidin production in order to increase or decrease serum iron levels, respectively. Our product candidates target novel pathways whose biological functions have been validated by human genetics and are specific to iron modulation.

Hepcidin Suppression

We are developing a portfolio of product candidates designed to lower hepcidin and restore serum iron levels to address anemia of inflammatory diseases. Our lead product candidate, DISC-0974, is a monoclonal antibody, which we in-licensed from AbbVie, that is designed to inhibit HJV, a critical target for hepcidin production. We selected this target because the effects of inhibiting HJV, namely decreased hepcidin and increased iron availability, have been genetically demonstrated in both animal knockout studies and in patients with juvenile hemochromatosis who lack fully functional genes encoding HJV. We have

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observed the effects of DISC-0974 on hepcidin and serum iron levels in preclinical studies, and have completed a single ascending dose Phase 1 clinical trial to evaluate these effects in healthy volunteers.

Hepcidin Induction

We are also developing a portfolio of product candidates designed to increase hepcidin and decrease serum iron levels, an approach that has the potential to address a range of diseases where restricting iron would be beneficial, such as excessive red blood cell production in PV and diseases of iron overload. Our lead program, MWTX-003 DISC-3405 is a monoclonal antibody designed to inhibit TMPRSS6, a serine protease that normally serves to limit hepcidin production. By inhibiting TMPRSS6, our compounds have the potential to increase production of hepcidin and, in turn, restrict iron availability. We selected this target based on the genetic confirmation of the effects of inhibiting TMPRSS6 in both animal knockout studies and in patients with iron-refractory iron deficiency anemia who lack fully functional genes encoding TMPRSS6. We in-licensed MWTX-003 DISC-3405 from Mabwell and an IND for MWTX-003 DISC-3405 has been accepted by the FDA. We plan to initiate initiated a Phase 1 clinical trial of MWTX-003 DISC-3405 in healthy volunteers in the second half of October 2023.

Our Lead Hepcidin Suppression Program: DISC-0974 For the Treatment of Anemia of Inflammatory Diseases

We are developing DISC-0974, our lead antibody product candidate targeting hepcidin suppression, for the treatment of anemia resulting from iron restriction that typically occurs in the setting of inflammatory diseases. DISC-0974 is designed to be a selective inhibitor of HJV, a bone morphogenetic protein, or BMP, co-receptor. Inflammatory signals, potentiated by BMP signaling, are an underlying cause of elevated levels of hepcidin, leading to low iron bioavailability and subsequent anemia in a broad range of diseases. We believe that abnormally high levels of hepcidin are an important driver of anemia associated with inflammatory diseases and that suppression of hepcidin with DISC-0974 has the potential to provide meaningful benefit in these patients. In July 2021, we initiated a single ascending dose Phase 1 clinical trial of DISC-0974 in healthy volunteers. We have completed our Phase 1 clinical trial. Data from the Phase 1 clinical trial showed an acceptable tolerability profile and evidence of target engagement and iron mobilization and augmented erythropoiesis. We initiated a Phase 1b/2 clinical trial in patients with anemia of MF in June 2022 and initiated a separate Phase 1b/2 placebo controlled, single/multiple ascending dose clinical trial in patients with non-dialysis dependent CKD and anemia in February 2023.

Overview of Anemia Associated with Inflammatory Diseases

Anemia of inflammation is a hallmark of a wide range of autoimmune and chronic diseases, including MF, CKD, rheumatoid arthritis, inflammatory bowel disease, cancer, obesity, chronic obstructive pulmonary disease, and cardiovascular disease. Anemia occurs frequently in these diseases and for example, affects approximately 87% of myelofibrosis, 17-50% of chronic kidney disease, 25-35% of inflammatory

bowel disease, 35-80% of cancer, and 50% of lupus patients. It is a common cause of chronic anemia and has been estimated to affect over one billion individuals worldwide. This type of anemia is caused by the sustained inflammation associated with these diseases, which produces a host of pro-inflammatory cytokines that impair erythropoiesis. Importantly, these cytokines have an impact on iron homeostasis by inducing the production of hepcidin, which in turn deprives developing erythrocytes of iron. There are currently no approved therapies designed to primarily lower hepcidin, and most patients remain anemic or untreated.

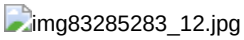
Anemia of Myelofibrosis

MF is a rare, chronic blood cancer that currently affects an estimated 16,000 to 18,500 patients in the United States. It is characterized by progressive fibrosis of the bone marrow brought on by the proliferation of cytokine-producing myeloid cells, which creates a state of chronic inflammation. Severe, progressive, and treatment- resistant anemia is the primary clinical manifestation of MF, and a study in over 200 patients at the Mayo Clinic showed that hepcidin is elevated by approximately 12-fold in these patients, as shown below. Elevated hepcidin levels are correlated with disease severity, anemia, and the need for red blood cell transfusions.

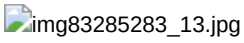
At diagnosis, approximately 87% of patients with MF have anemia, which progressively worsens over time and ultimately renders the majority of patients dependent on chronic red blood cell transfusions. In a study conducted by the Mayo Clinic, within a year of diagnosis, 58% of patients with MF had severe anemia, defined as hemoglobin levels of less than 10 g/dL, and 46% were transfusion-dependent, meaning they required regular transfusion therapy, as shown below. Moreover, existing treatments, such as erythropoiesis-stimulating agents, or ESAs, androgens, corticosteroids, immunomodulators, and splenectomy, are generally viewed as providing minimally effective or inconsistent results, are associated with safety concerns, and do not directly target hepcidin. This is in contrast to the effects observed in a recently published study of a hepcidin-targeted agent conducted in patients with advanced, transfusion-dependent myelofibrosis. In this clinical trial, a partial reduction of hepcidin levels led to approximately 85% of patients having lower transfusion requirements, 41% of patients becoming transfusion independent, increased hemoglobin and improved markers of iron homeostasis.

Currently, patients with MF are treated with JAK inhibitors approved to treat intermediate or high risk MF, including ruxolitinib and fedratinib, which reduce splenomegaly and other symptoms, but typically worsen anemia to the point that patients frequently discontinue treatment.

Elevated Hepcidin Levels in Patients with MF



Anemia of MF is Progressive and Severe



Anemia of Chronic Kidney Disease

CKD is a highly prevalent disease characterized by the progressive loss of kidney function that eventually leads to kidney failure or end-stage renal disease necessitating dialysis or a kidney transplant for survival. It is caused by a constellation of underlying chronic conditions, such as diabetes, hypertension, and heart disease, that damage the kidneys over time and create a chronically inflamed state. CKD is widespread and is estimated to affect nearly 700 million patients worldwide. While it is most common in developed countries, CKD cases are growing rapidly in populous, emerging markets, such as China and India. In the U.S. alone, there are an estimated 39 million patients with CKD, the vast majority of which have not initiated dialysis.

Anemia is a hallmark of CKD and both worsens and becomes increasingly common as kidney function deteriorates. It is associated with increased risk of hospitalization, cardiovascular complications, and death, and frequently causes significant fatigue, cognitive dysfunction, and declining quality of life. The prevalence of anemia in CKD varies depending on the stage of disease and ranges from approximately 17% to 50% in patients with earlier-stage CKD who do not require dialysis to nearly all patients with end-stage renal disease who are dialysis-dependent.

While the underlying cause of anemia of CKD is multifactorial, among the primary molecular drivers are declining production by kidney cells of erythropoietin, or EPO, a growth factor that normally stimulates red blood cell production, and elevated hepcidin levels, which suppress the iron supply needed to support erythropoiesis. Hepcidin levels are correlated with

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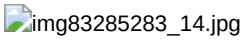
CKD disease stage and severity of anemia and can be nearly 20-fold higher in patients with CKD than in healthy individuals, as shown in the graph below. Hepcidin elevation results from dysregulated overproduction induced by chronic inflammation and accumulation as the body is unable to excrete hepcidin from the kidney. This combination results in a cycle where patients become progressively more anemic and incapable of erythropoiesis as their disease progresses.

Hepcidin Levels Are Elevated in Patients with CKD



Historically, the treatment of anemia of CKD has relied on red blood cell transfusions, but risks associated with iron overload, infection, and the development of antibodies precluding the ability to receive organ transplants have reduced the use of transfusions over time. Beginning in the 1990s, the standard of care shifted to injectable recombinant ESAs, such as EPOGEN (epoetin alfa) and Aranesp (darbepoetin alfa), which are administered to provide supraphysiological levels of erythropoietin to stimulate production of red blood cells. While hemoglobin levels were raised, several large clinical studies conducted by others revealed significant safety risks with the ESAs, including thrombosis, stroke, myocardial infarction, and death, which led to regulatory actions, including a black box warning and other label restrictions. In addition, changes in reimbursement and clinical practice guidelines have all significantly curtailed the use of ESAs for the treatment of anemia of CKD. As a result, a high proportion of patients with anemia of CKD today are either untreated or sub-optimally treated, despite being severely anemic. For example, according to the U.S. Renal Data System, the mean hemoglobin levels of patients who are about to initiate dialysis treatment is 9.3 g/dL, which is significantly below the normal range.

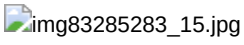
Our Solution: DISC-0974, an Anti-HJV Monoclonal Antibody

DISC-0974 is designed to be an injectable, selective monoclonal antibody targeting HJV, a co-receptor required for hepcidin expression. In multiple preclinical studies, we have demonstrated that DISC-0974 suppressed endogenous production of hepcidin and, as a consequence, increased serum iron levels. Based on this early confirmation of its mechanism, we believe DISC-0974 has the potential to treat a wide range of anemias associated with inflammatory diseases where hepcidin levels are pathologically elevated and serum iron levels for erythropoiesis are restricted. Based on data from our IND-enabling studies, we intend to develop DISC-0974 as a once-monthly, subcutaneous injection.

Hemojuvelin Has a Critical and Specific Role for Hepcidin Regulation and Homeostasis

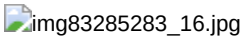
HJV, also called repulsive guidance molecule-c, is a cell surface co-receptor that is primarily expressed in the liver and other tissues with a significant role in iron metabolism, such as skeletal muscle, and is critical for hepcidin production. Signaling through the HJV pathway involves a complex of ligands of the TGF-b superfamily (BMP2/4/6) and other receptors (ALK2/3/6) that induce SMAD phosphorylation and hepcidin (HAMP gene) expression, as shown below. Many components of the BMP signaling pathway are expressed in tissues throughout the body and participate in a range of biological processes, including bone formation and immune cell production. As a result, therapeutic efforts to control hepcidin by targeting the ALK receptors or BMP ligands may affect other tissues and result in off-target side effects. However, based on the phenotype caused by the genetic loss of function of HJV in rodents and humans, we believe that the role of HJV is restricted to iron homeostasis and hepcidin expression, and therefore, we believe that targeting HJV has the potential to result in an improved risk-benefit profile as compared to targeting other members of the BMP pathway.

Hemojuvelin is a Critical and Specific Target for Hepcidin Expression



The importance of HJV in hepcidin expression and iron homeostasis was established through genetic studies in both animals and humans. Specifically, mutations that result in a partial or complete lack of HJV result in significantly reduced hepcidin production and are phenotypically indistinguishable from loss-of-function mutations in hepcidin itself. For example, in a study in mice conducted by a third-party, a knockout of the HJV gene resulted in significantly reduced hepcidin levels in untreated animals as well as in animals challenged with LPS, an inflammatory stimulus, as compared to mice with a functional HJV gene, as shown below.

HJV Gene Knockout in Mice Resulted in Significantly Reduced Hepcidin Levels



In addition, mutations in the HJV gene in humans markedly reduce hepcidin expression in the liver and result in juvenile hemochromatosis, the most severe form of diseases of iron overload. This genetic evidence suggests that the function of HJV is specific to hepcidin and iron regulation. We believe this specificity is an important attribute in selecting HJV as a target and may result in an improved therapeutic outcome by avoiding unwanted side effects that can result from systemic changes in TGF-b superfamily signaling, such as changes in bone mineral density and immune function. By targeting HJV to reduce hepcidin production, we believe that DISC-0974 has the potential to normalize serum iron levels and restore the production of red blood cells, thereby addressing a key underlying driver of anemia of inflammatory diseases.

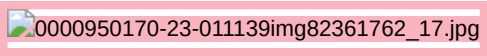
Preclinical Data

In multiple preclinical studies conducted by us and AbbVie, DISC-0974 was observed to be a selective inhibitor of HJV and administration of DISC-0974 resulted in significantly decreased hepcidin production and increased serum iron levels, providing preclinical proof-of-mechanism.

DISC-0974 Decreased Hepcidin Expression and Increased Iron in Preclinical Studies

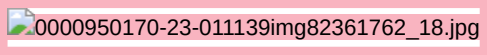
In multiple preclinical studies, we have established the pharmacology of DISC-0974. These studies demonstrated that inhibition of HJV resulted in suppression of hepcidin and increased serum iron levels and other measures of iron. The figure below is representative of the PK / PD effects of DISC-0974. In this experiment, a single, 5 mg/kg dose of DISC-0974 (serum concentration represented in blue) resulted in a rapid decrease of hepcidin levels (in gray) and an increase in serum iron levels (in red). As serum levels of DISC-0974 decreased over time, these effects were reversed and hepcidin levels increased and serum levels decreased.

A Single Dose of DISC-0974 in an NHP Reduced Hepcidin Levels and Increased Serum Iron Levels



These effects were observed to be robust, dose-dependent, and consistent across several studies in both normal animals and models of inflammation. The three panels below show data from a multiple dose study conducted in NHPs. Animals were given vehicle (0 mg/kg; purple dashes) or 0.6 mg/kg (blue lines), 3 mg/kg (red lines) or 60 mg/kg (black lines) of DISC-0974 in three subcutaneous injections, administered once every 14 days. DISC-0974 treatment resulted in dose-dependent decreases in hepcidin (middle panel) and dose-dependent increases in transferrin saturation (TSAT percentage) (right panel). Notably, transferrin saturation levels reached a maximum theoretical level (100%) at dose levels of 3 mg/kg and greater, demonstrating that DISC-0974 is an agent for controlling iron homeostasis.

Repeat Doses of DISC-0974 in NHPs Reduced Hepcidin Levels and Increased Serum Iron Levels

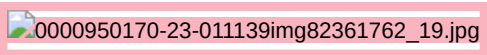


We have also evaluated the pharmacology of DISC-0974 in various animal models of anemia and inflammation, where hepcidin levels are significantly elevated. These studies included models utilizing different stimuli of inflammation, such as

cytokines, peptidoglycan-polysaccharides, or heat-killed bacteria, as well as a genetic model of hepcidin elevation. Across these different settings, we observed that inhibition of HJV with DISC-0974 provided suppression of hepcidin and normalization of iron levels.

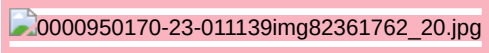
In a mouse model of inflammation, animals were injected with either saline (S) or the heat-killed bacteria *Brucella abortus* (HKBA) to provoke an inflammatory response and induce hepcidin expression. Animals were treated with either an active control antibody (hIgG) or an anti-HJV antibody (an earlier version of DISC-0974 called 5F9-AM8). As shown below, a rapid induction of hepcidin expression was observed in response to the inflammatory stimulus in animals receiving HKBA, as measured by liver Hamp mRNA levels. Administration of 5F9-AM8 inhibited the inflammatory induction of hepcidin, and these animals expressed hepcidin at near normal levels.

Anti-HJV Antibody Suppressed Hepcidin in a Mouse Model of Inflammation



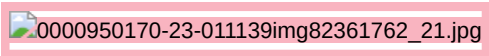
To assess the effect of HJV inhibition in a primate setting, we established a model of inflammation-induced iron restriction by administering interleukin-6, or IL-6, to NHPs. IL-6 is a key driver of anemia across multiple inflammatory diseases, including CKD, MF, inflammatory bowed disease, and rheumatoid arthritis, among others. We observed that administration of IL-6 on day 1 and day 10 resulted in rapid induction of hepcidin and a corresponding suppression of iron, as shown below in gray. However, when the animals were treated with a single dose of DISC-0974 on day 4 in between the IL-6 administrations, this effect was reversed, as shown in blue and red below. We studied both low (0.6 mg/kg) and high (6 mg/kg) doses of DISC-0974 and observed that the effects on hepcidin suppression and increasing serum iron levels were dose-dependent.

DISC-0974 Reduced Hepcidin and Increased Serum Iron Levels in NHPs



We also assessed the potential for DISC-0974 to treat anemia in an established rodent model of CKD. In this study, rats were fed either a 0.75% adenine diet, which induced kidney damage and mimicked human CKD or a control diet, and received treatment with either DISC-0974 or vehicle. We observed that treatment with DISC-0974 significantly suppressed hepcidin, increased serum iron, and increased hemoglobin levels by +1.7 g/dL compared to vehicle.

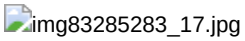
DISC-0974 Reduced Hepcidin, Increased Serum Iron and Increased Hemoglobin Levels in a Rodent Model of CKD Anemia



Phase 1 Clinical Trial

In July 2021, we initiated a first-in-human, Phase 1, single ascending dose, randomized, double-blind, placebo-controlled clinical trial of DISC-0974 in healthy volunteers to evaluate safety, tolerability, PK, and PD markers such as hepcidin, serum iron levels, TSAT and measures of erythropoiesis. In the initial cohort of the Phase 1 trial, DISC-0974 was administered intravenously. Subsequent cohorts were dosed with DISC-0974 by subcutaneous administration, which has been shown to be comparable and well-tolerated as compared to intravenous administration in preclinical studies. The trial design is summarized in the figure below.

DISC-0974 Phase 1 Clinical Trial Design



We have completed this Phase 1 clinical trial. Data from the Phase 1 clinical trial showed an acceptable tolerability profile and evidence of target engagement and iron mobilization and augmented erythropoiesis. Additional data are discussed below.

Specifically, in this Phase 1 study, a single dose of DISC-0974 resulted in rapid, dose-dependent and sustained decrease in serum hepcidin and a corresponding, robust increase in measures of circulating iron. This included more than a doubling of transferrin saturation from baseline at the highest dose level (56 mg SC). Changes in serum iron also corresponded with markers of iron mobilization and erythropoiesis,

including decreased ferritin levels, increased reticulocyte hemoglobin, and increased mean corpuscular hemoglobin. These findings are consistent with the mechanism of action of DISC-0974.

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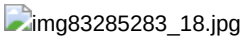
DISC-0974 Phase 1 SAD Study in Healthy Volunteers: Effects on Hepcidin and Transferrin Saturation



Notably, at the 56 mg SC dose level, a single administration of DISC-0974 resulted in a statistically significant improvement in hemoglobin compared to placebo (+1.1 g/dL, p=0.009) at Day 42 and a marked increase in red blood cell count.

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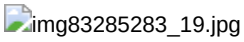
DISC-0974 Phase 1 SAD Study in Healthy Volunteers: Single 56 mg SC Dose Increases Hemoglobin



DISC-0974 was well-tolerated at all dose levels with no serious or severe adverse events, no adverse events leading to study withdrawal, and no adverse event greater than Grade 1. Plasma exposure was dose-related in the 14 to 56 mg SC range and effects were observed through 28 days post-dose, indicating a sustained and potentially clinically meaningful duration of action. These findings were presented at the 2022 European Hematology Association meeting in June 2022 and the 2022 American Society of Hematology annual meeting.

Planned Phase 1b / 2 Clinical Development Program in Anemia of Inflammation

Based on these findings, we plan to initiate initiated multiple Phase 1b/2 clinical trials of DISC-0974 in patients with anemia of different inflammatory diseases. This includes a Phase 1b/2 clinical trial of DISC-0974 in patients with anemia of MF, which was initiated in June 2022, and a separate Phase 1b/2 clinical trial of DISC-0974 in patients with non-dialysis dependent CKD, and anemia which was initiated in February 2023. We expect to report reported interim data from both of these studies in December 2023.

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Phase 1b/2 Clinical Trial in Myelofibrosis Patients

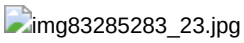
In June 2022, we initiated an open-label, multi-center, Phase 1b/2 trial to evaluate the safety, tolerability, and efficacy of DISC-0974 in patients with anemia of MF. The study endpoints include hepcidin levels, serum iron and markers of iron mobilization and measures of anemia benefit such as hemoglobin, reductions in transfusion burden and transfusion independence (TI) rate. The study allows enrollment of patients receiving stable background therapy, including Janus Kinase (JAK) inhibitors. The study will be conducted in two parts:

- Phase 1b (Dose-Escalation): Ascending, monthly doses of DISC-0974 administered for six months to patients with anemia of MF, (Hb levels < 10 g/dL,), where a dose level will be selected based on optimal increases in hemoglobin and serum iron;

- Phase 2 (Expansion Stage): Multiple, doses of DISC-0974 administered once-a-month at the dose level selected from the Phase 1b portion of the study to patients with anemia of MF who are transfusion dependent (TD) or non-transfusion dependent (NTD), generally defined according to International Working Group-Myeloproliferative Neoplasms Research and Treatment, or IWG-MRT, criteria, define as receiving >6 units of RBC the baseline transfusion burden in a 12-week period.

Phase 1b/2 Open-Label, Clinical Trial of DISC-0974 in Myelofibrosis Patients with Anemia

Interim data from this trial was presented at the American Society of Hematology annual meeting in December 2023. Data from 11 evaluable participants in the first 3 dose cohorts (14 mg, 28, 50 mg) were presented as of an October 20, 2023 data cutoff date. Four of 11 participants were taking concomitant JAK inhibitors, and two were transfusion dependent. Hepcidin data from the 14 mg (n=1) and 28 mg (n=7) groups showed a dose-dependent decrease in hepcidin, exceeding 75% reduction in the 28 mg group. The anticipated reciprocal increase in iron was observed in a dose-dependent manner as well, with sustained 75% increases in serum iron observed in the 28 mg group. Hemoglobin response data in a combined 28 mg (n=7) and 50 mg (n=2 [1 participant at 50 mg had follow up <4 weeks and was not included]) showed a 1.5 g/dL increase in four of seven participants, regardless of concomitant JAK inhibitor use. One of two transfusion dependent participants achieved transfusion independence, defined as no blood transfusion in 12 weeks. Safety analyses showed that DISC-0974 was generally well tolerated. There was one serious adverse event of hip pain, assessed as unrelated to DISC-0974. Grade 3 adverse events included anemia (n=3) and headache (n=1). One DISC-0974-related adverse event of diarrhea (Grade 2) was reported.



Phase 1b/2 Clinical Trial in Patients with Non-Dialysis Dependent Chronic Kidney Disease (NDD-CKD)

In February 2023, we initiated a Phase 1b/2 clinical trial to evaluate the safety, tolerability and efficacy of DISC-0974 in patients with CKD who are not receiving dialysis and are anemic. The study consists of two parts, including: a Phase 1b,

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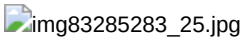
randomized, placebo-controlled, single-ascending dose stage, where a dose level will be selected based on optimal increases in serum iron; followed by a Phase 2, open-label, expansion stage where patients will receive multiple doses of DISC-0974 at the selected dose level. The study endpoints include hepcidin levels, serum iron and markers of iron mobilization and measures of anemia benefit such as hemoglobin.

Phase 1b/2 Clinical Trial of DISC-0974 in NDD-CKD Patients with Anemia

Interim data from the initial 28 mg single dose cohort showed consistent suppression of hepcidin that led to iron increases that were comparable to iron increases observed in the 28 mg single dose cohort of the healthy volunteer DISC-0974 study. In the CKD population, DISC-0974 was generally well tolerated as of the October 20, 2023 data cutoff date; two subjects treated with DISC-0974 28 mg had a treatment emergent adverse event (33%) compared to two on placebo (100%); two treated subjects had serious adverse events deemed not related to DISC-0974 (atrial fibrillation and worsening of end stage renal disease).



Our Second Hepcidin Suppression Program: DISC-0998

We are also developing a preclinical product candidate targeting hepcidin suppression, DISC-0998, an anti-HJV monoclonal antibody in-licensed from AbbVie. DISC-0998 is designed to be a highly selective anti-HJV mAb with an adapted Fc region to increase PK half-life. In preclinical studies DISC-0998 demonstrated biological activity, low immunogenicity potential, and desirable PK and PD properties.

A dose response PK/PD study of DISC-0998 in NHPs demonstrated that it had a lower clearance (~30 - 40%), higher volume of distribution (~30 - 70%), and longer half-life (~2 times), which translated to a longer duration of PD effects compared to DISC-0974. As shown below, a single dose of DISC-0998 resulted in sustained elevation of serum iron levels. If these data are

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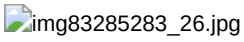
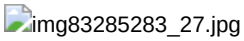
confirmed in humans, it would suggest the potential for an infrequent dosing regimen (such as potentially once every 2 or 3 months). We expect that such a dosing regimen would be perceived as convenient by patients and promote compliance.

DISC-0998 Dose Response PK / PD Study (NHP)



Our Hepcidin Induction Program

We are also focused on developing product candidates designed to increase hepcidin levels and decrease serum iron levels to address a range of diseases where restricting iron would be beneficial, such as erythrocytosis of PV and diseases of iron overload, including HH, beta-thalassemia, and MDS. Our lead hepcidin induction program, MWTX-003, DISC-3405, is a Phase 1 ready monoclonal antibody that is designed to target TMPRSS6. TMPRSS6 proteolytically degrades HJV in liver cells, as shown below. Inhibitors of TMPRSS6 are expected to increase HJV levels and thereby increase the expression of hepcidin. By inhibiting TMPRSS6, our compounds are designed to increase hepcidin production and, in turn, restrict iron availability. We selected TMPRSS6 as our target because the effects of reducing TMPRSS6 levels have been genetically confirmed in both animal knockout studies and in patients with iron-refractory iron deficiency anemia who lack fully functional genes encoding TMPRSS6. An IND for MWTX-003 DISC-3405 has been accepted by the FDA, and we plan to initiate initiated a Phase 1 clinical trial in healthy volunteers in the second half of October 2023.



Polycythemia Vera

PV is a chronic and rare myeloproliferative neoplasm characterized by the overproduction of red blood cells and increased red cell mass. It is frequently caused by acquired mutations of the JAK2 gene that drive abnormal proliferation of red blood cells. The increased number of red blood cells alters the viscosity of blood, causing it to thicken and placing patients at an increased risk of cardiovascular and thromboembolic events, such as heart attack and stroke. The prevalence of PV is estimated to be 44 to 57 cases per 100,000 persons, with approximately 150,000 patients with PV in the United States and with prevalence estimates in Europe ranging from 10 to 50 cases per 100,000 persons. PV tends to primarily affect individuals over 60 years old.

Current management of PV centers around depleting the number of red blood cells to maintain a patient's hematocrit (a measure of red blood cell mass) below 45%, the target threshold recommended by the National Comprehensive Cancer Network to reduce the risk of cardiovascular or thromboembolic events. Most patients receive low-dose aspirin and chronic therapeutic phlebotomy to physically remove blood and iron to limit erythropoiesis. However, most patients fail to achieve their target hematocrit levels and remain at risk for thrombosis and other complications. Moreover, phlebotomy causes discomfort and inconvenience for patients as well as side effects such as headaches, ringing in the ears, dizziness, and, over time, iron deficiency. Cytoreductive chemotherapy is recommended for patients at higher risk of thrombosis, including those who fail to meet their hematocrit threshold, or conversion to leukemia. These include hydroxyurea, interferons, or ruxolitinib, marketed as Jakafi, each of which are associated with side effects and can affect multiple cell types. There is currently no oral, non-cytoreductive option for the treatment of PV, which we believe would be beneficial for both low and high-risk patients.

Hereditary Hemochromatosis

HH is an inherited iron overload disorder caused by genetic mutations that lead to a deficiency in hepcidin production. This results in lifelong, abnormal iron homeostasis, specifically excessive absorption of iron from a patient's diet and dysregulated distribution of iron stores in the body. Over time, this leads to the accumulation of iron at toxic levels in multiple organs, including the liver, heart, joints, skin, and others, which, if left untreated, can lead to severe organ damage and potentially organ failure. HH is one of the most common genetic disorders among Whites, affecting millions worldwide, including over 1 million individuals in the United States alone.

There are currently no approved pharmacologic therapies for the treatment of HH and the standard of care is regular and lifelong therapeutic phlebotomy to deplete iron. However, similar to PV, phlebotomy can be a significant burden to patients due to discomfort, frequency of treatments required, and patient inconvenience. Additionally, despite not being approved for HH, iron chelators may be used off-label in certain cases but are often associated with toxicities, particularly with chronic use.

Other Iron Overload Disorders: Beta-Thalassemia and Myelodysplastic Syndromes

Iron overload is a serious and potentially fatal complication of blood disorders associated with ineffective erythropoiesis, such as beta-thalassemia or MDS. Patients with these conditions become severely anemic due to mutations that affect the production of functional red blood cells. This results in persistent and pathologic suppression of hepcidin, leading to unchecked

increases in iron and, ultimately, accumulation of toxic iron levels in organs such as the heart, liver, and kidneys, as well as in the bone marrow, which exacerbates anemia.

Both beta-thalassemia and MDS arise from mutations that cause ineffective erythropoiesis. In the case of beta-thalassemia, the genetic defects are inherited and result in impaired synthesis of beta-globin chains, a critical subunit of hemoglobin. This deficiency results in the premature death of developing erythrocytes in the marrow or peripheral circulation, resulting in severe anemia. Globally, beta-thalassemia has an incidence of approximately 1 in 100,000 individuals, but can range significantly depending on the region. In Europe, where it is more common, beta-thalassemia has an incidence of 1 in 10,000 individuals, while it is rare in the United States, and exact numbers are not known. In contrast, MDS is a form of cancer where mutations prevent precursor cells in the marrow from maturing into functional erythrocytes, which results in severe anemia and other cytopenias. MDS tends to affect older patients and has an overall estimated annual incidence of 20-50 cases per 100,000 individuals over 60 years old. There are an estimated 60,000 to 170,000 patients with MDS in the United States and a similar number in Europe.

Currently, chronic red blood cell transfusions are a mainstay of treatment for anemia caused by beta-thalassemia and MDS. However, the benefit is transient and transfusions are burdensome and carry the risk of further iron overload. While iron chelation therapy may be used in conjunction, it requires careful dose titration and is often associated with toxicities. Recently, luspatercept (marketed as Reblozyl), a red blood cell maturation agent, was approved by the FDA and EMA to treat certain forms of beta-thalassemia and MDS, with a response rate of 21.4% and 37.9% for a primary endpoint of transfusion independence in the respective pivotal trials. Based on these response rates, many patients do not respond and would benefit from an alternative treatment. Lentiglobin, marketed as Zynteglo, is a gene therapy that was approved by the FDA and EMA for the treatment of a subset of patients with beta-thalassemia requiring RBC transfusions, but uptake has been limited. Patients with more advanced forms of MDS may receive additional therapies such as lenalidomide, demethylating agents such as 5-azacitidine and decitabine, and chemotherapy.

Our Solution: MWTX-003, DISC-3405 (MWTX-003), an anti-TMPRSS6 monoclonal antibody

In January 2023, we in-licensed MWTX-003 and other related molecules from Mabwell. In the Disc compound catalog, MWTX-003 is named DISC-3405. DISC-3405 is a monoclonal antibody designed to inhibit TMPRSS6, a serine protease that degrades HJV, a receptor required for hepcidin expression. TMPRSS6 plays a critical and specific function in iron metabolism by limiting the production of hepcidin. By inhibiting TMPRSS6, MWTX-003 DISC-3405 has been shown in preclinical studies to increase endogenous production of hepcidin and reduce serum iron levels. This mechanism has been validated by human genetics, where patients with mutations in TMPRSS6 develop elevated hepcidin levels and an iron restrictive phenotype. In addition, iron restriction has been recently validated as a potential approach to treat PV. In a Phase 2 clinical trial conducted by a third-party, a peptide hepcidin mimetic administered weekly by subcutaneous injection lowered iron availability and reduced hematocrit in patients with PV, resulting in a substantial reduction in requirements for phlebotomy and improvements in disease symptoms. We are initially focused on developing our anti-TMPRSS6 programs as a potential treatment for PV with plans to expand development to encompass diseases of iron overload and other conditions where restriction of iron would have therapeutic benefit.

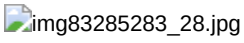
Preclinical Data

Preclinical studies of MWTX-003 have demonstrated that TMPRSS6 inhibition with a monoclonal antibody can induce hepcidin expression and consequently restrict iron availability. Specifically, preclinical studies have demonstrated:

- Dose-dependent induction of endogenous hepcidin production in rodent and NHP studies;
- Increases in hepcidin, reductions in serum and liver iron, and increases in red blood cells in a murine model of beta-thalassemia; and
- Reductions in iron and hematocrit in a murine model of PV.

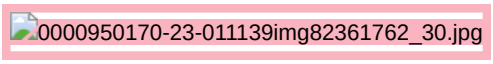
Across several preclinical studies in both rodents and non-human primates, treatment with MWTX-003 was shown to increase hepcidin production and reduce serum iron levels. For example, in the below experiment in NHPs, treatment with a single, intravenously administered 30 mg/kg or 150 mg/kg dose of MWTX-003 resulted in deep and sustained suppression of serum iron levels for at least 3 weeks.

Treatment with MWTX-003 resulted in deep and sustained suppression of serum iron levels in normal non-human primates



The potential efficacy of MWTX-003 was also assessed in HbbTh3/+ mice, an established, genetic rodent model of beta-thalassemia. In this study, mice with mutations in the Hbb gene leading to underproduction of beta-globin genes were treated with 10 mg/kg MWTX-003 once every 3 days for 4 weeks which resulted in recapitulated features of beta-thalassemia such as ineffective erythropoiesis, iron overload and enlarged spleens. Treated mice showed decreased serum iron levels and liver non-heme iron, reduced splenomegaly and improved ineffective erythropoiesis compared to control. Additionally, a study was conducted assessing the efficacy of MWTX-003 in PV using a Jak2

Treatment V617F bone marrow transplantation mouse model. In these mice, treatment with MWTX-003 Induced Hepcidin at 2-10 mg/kg every 4 days for 3 weeks led to significantly increased serum hepcidin with reduced hematocrit levels, red blood cell counts, and Decreased Serum Iron Levels in a Mouse Model hemoglobin concentration that were comparable to that of Beta Thalassemia**wildtype control mice.**



Next Steps

We believe our preclinical studies have demonstrated that MWTX-003 DISC-3405 has the potential to increase hepcidin levels sufficiently to reduce iron availability in a variety of animal models. MWTX-003 is Phase 1-ready and DISC-3405 received clearance of an IND from the FDA in November 2022. We plan to initiate initiated a Phase 1 clinical trial of MWTX-003 DISC-3405 in healthy volunteers in the second half of October 2023.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We rely on, and expect to continue to rely on for the foreseeable future, third-party contract development and manufacturing organizations, or CDMOs, to produce our product

candidates and preclinical materials, including bitopertin, DISC-0974, DISC-0998, MWTX-003 DISC-3405 and any candidates arising from our research programs, for preclinical and clinical use. We plan to continue to rely on third-party CDMOs for any future trials as well as for the commercial manufacture of our product candidates and preclinical materials, if approved. In addition, we contract with additional CDMOs to package, label, and distribute drug product for preclinical and clinical use.

Manufacturing biologics is complex, especially in large quantities. Biologic products must be made consistently and in compliance with a clearly defined manufacturing process. We require that our CDMOs produce bulk drug substances and finished drug products in accordance with current Good Manufacturing Practices, or cGMPs, and all other applicable laws and regulations.

We have assembled a team of experienced employees and external consultants to provide the required technical, quality, and regulatory oversight of our CDMOs and have implemented a comprehensive plan for regular audits of our CDMOs. We maintain agreements with our manufacturers that include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

We obtain supplies of our product candidates from single-source CDMOs on a purchase order basis and do not currently have any long-term supply arrangements in place. While any reduction or halt in supply of our product candidates from these CDMOs could limit our ability to develop our product candidates until we find a qualified replacement CDMO, we have procured or are in the process of procuring sufficient supply to support our planned Phase 2 trials for bitopertin and DISC-0974. In addition, we believe that we can identify and establish additional CDMOs to provide API and finished drug product without significant disruption to our business or clinical development timelines. As our pipeline programs expand and we build new process efficiencies, we expect to continually evaluate this strategy with the objective of satisfying demand for registration trials and, if approved, the manufacture, sale, and distribution of commercial products.

A commercial-scale production process has been designed for bitopertin, including a four-step chemical synthesis and an optimized oral formulation. The API has been shown to be highly stable for at least 5 years, and we have access to substantial drug substance supplies of bitopertin manufactured and stored by Roche under cGMP conditions. To support our Phase 2 clinical trials, we have requalified, including establishing a shelf-life that would enable its use in clinical trials, Roche-manufactured drug substance and formulating it as film-coated tablets. To support pivotal clinical trials and commercial launch, if approved, we are establishing the manufacturing process at a CDMO.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on intellectual property. While we believe that our product candidates, preclinical programs, scientific capabilities, know-how, and experience provide us with competitive advantages, we compete in a highly competitive industry and face significant competition from many sources, including pharmaceutical and biotechnology companies, as well as academic institutions, governmental agencies, and private and public research institutions worldwide. Many of our competitors, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites, and recruiting patients in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license, or commercialize products before or more successfully than we do.

We face competition more specifically from companies that discover, develop, and market therapies for the treatment of hematologic diseases, including a group of diseases called porphyrias and anemia associated with inflammatory diseases. There are many other companies, including large biotechnology and pharmaceutical companies, that have commercialized or are developing therapies for the same

diseases that we are targeting with our product candidates. These companies include, but are not limited to, Agios Pharmaceuticals, Inc., Akebia Therapeutics, Inc., Amgen, Inc., Astellas Pharma, Inc., Bristol-Myers Squibb Company, FibroGen,

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Inc., GlaxoSmithKline, plc, Incyte Corporation, Ionis Pharmaceuticals, Inc., Keros Therapeutics, Inc., Merck & Co., Inc., Otsuka Pharmaceutical Co., Ltd. and Vifor Pharma AG, among others.

We are developing bitopertin, our lead product candidate in our heme biosynthesis modulation portfolio, for the treatment of EPs. If approved, bitopertin will face competition from melanocortin-1 receptor agonists, including afamelanotide, a subcutaneously implanted therapy that is approved in the U.S. and other territories and marketed as Scenesse by Clinuvel, and dersimelagon, an oral therapy in Phase 3 development by Mitsubishi Tanabe Pharma Corporation. In addition, there are other potential treatments currently in the discovery stages of development that may become competitors in the future. These therapies include, but are not limited to, gene therapies, heme biosynthesis modulators that target GlyT1 or other enzymes in the heme biosynthesis pathway, and molecules that target porphyrin export.

Bitopertin is a selective inhibitor of GlyT1 that we are developing to treat porphyrias and hematologic diseases. GlyT1 inhibition has been pursued in the past as an approach to treat schizophrenia. We are aware that Boehringer Ingelheim is conducting a Phase 3 clinical study of BI 425809 (iclepertin), a GlyT1 inhibitor, for the improvement of cognition in patients with schizophrenia. Other companies have also had research programs designed to inhibit GlyT1 as a treatment for schizophrenia, but to our knowledge, all of these have been discontinued at various stages of development. These include PF-03463275 (Pfizer Inc.), LY2365109 (Eli Lilly and Company), ORG25935 (Organon & Co.), ALX5407 (NPS Pharmaceuticals, Inc., now Shire plc), ASP2535 (Astellas Pharma Inc.) and others. We believe bitopertin has an optimal profile for development as a potential treatment for EP. However, we recognize that other companies may choose to develop a novel GlyT1 inhibitor or repurpose an existing one; if successfully developed as a treatment for EP, such a program would be a potential competitor to bitopertin. Additionally, BridgeBio Pharma, Inc. is developing an ABCG2 inhibitor for EPP.

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We are also developing DISC-0974, our lead program in our hepcidin suppression portfolio, for the treatment of anemia caused by inflammatory diseases, including MF and CKD. For the treatment of anemia of MF, there are no approved therapies, but several classes of drugs are used off-label, including ESAs, such as Procrit (Janssen Pharmaceuticals, Inc.), Epogen and Aranesp (Amgen, Inc.), and Mircera (Roche), corticosteroids, and androgenic hormones, such as danazol. There are also multiple classes of drugs in development for the treatment of anemia. For example, multiple erythroid maturation agents are in development, such as luspatercept, which is in a myelofibrosis Phase 3 trial by Bristol-Myers Squibb, and KER-050, which is in a Phase 2 trial by Keros, Inc. In addition, multiple ALK2 inhibitors, which work by a hepcidin-lowering mechanism similar to, but less specific than that of DISC-0974, are in Phase 1/2 development, including KER-047 by Keros, Inc. and INCB00928 (zilurgisertib) by Incyte Corporation. Sierra Oncology, Inc. (recently acquired by GlaxoSmithKline) is developing a JAK2 kinase inhibitor, momelotinib, which has completed a Phase 3 trial and has a New Drug Application, or NDA, under review was approved by the FDA.FDA to treat myelofibrosis with anemia.

For the treatment of non-dialysis dependent CKD and anemia, there are several therapies approved or in clinical development, including, but not limited to, ESAs, oral hypoxia inducible factor-prolyl hydroxylase inhibitors, or HIF-PHIs, which are approved in ex-U.S. territories but not in the U.S., and various forms of intravenous iron. We are not aware of any therapies in clinical development for the treatment of anemia of CKD that work by decreasing hepcidin levels. There are several therapies in development for the treatment of MF and CKD that do not directly target anemia, but their approvals may potentially change the treatment landscape and affect our ability to compete.

We are developing MWTX-003, DISC-3405, an anti-TMPRSS6 monoclonal antibody designed to induce hepcidin production and restrict serum iron levels. There are several therapies in development that are also designed to increase hepcidin production or mimic hepcidin activity, such as hepcidin mimetics, TMPRSS6 inhibitors, and ferroportin inhibitors. These are in various stages of development by companies, including Regeneron, Silence Therapeutics plc, Ionis Pharmaceuticals, Inc., Rallybio, Protagonist Therapeutics, Inc., and CSL Vifor, among others. We may also face competition from therapies that are currently marketed or in development that affect pathways unrelated to hepcidin, including growth and differentiation factor-based therapies, cytoreductive therapies, and chemotherapeutic agents, among others.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive, or receive a more favorable label than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

Collaborations and License Agreement

2019 Exclusive License Agreement with AbbVie Deutschland GmbH & Co. KG

In September 2019, we entered into an exclusive license agreement with AbbVie. Under the license agreement with AbbVie, or the AbbVie Agreement, we obtained an exclusive, worldwide license, with the right to sublicense to commercial pharmaceutical and biopharmaceutical companies (subject to AbbVie's prior consent or pre-authorization, except with respect to

our affiliates), under certain patents and technical information of AbbVie, to make, have made, use, have used, sell, have sold, lease, have leased, import, have imported or otherwise transfer licensed products for all therapeutic, diagnostic and prophylactic uses in humans and animals, excluding uses in neuroscience and neurology. The anti-hemojuvelin antibodies, DISC-0974 and DISC-0998, are licensed products under the AbbVie Agreement. We are required to use commercially reasonable efforts to develop and commercialize at least one licensed product in certain major markets and to maximize net sales of licensed products in certain major markets.

Under the terms of the AbbVie Agreement, we made an initial license payment to AbbVie of $0.6 million. Additionally, we are required to pay certain development milestone payments for each licensed product, which milestone payments are up to $18.0 million in the aggregate, certain commercial milestone payments for each licensed product, which milestone payments are up to $45.0 million in the aggregate, and certain milestone payments based on the level of net sales of all licensed products worldwide, which milestone payments are up to $87.5 million in aggregate. The first potential milestone is a $3.0 million payment payable upon the initiation of the first Phase 2 clinical trial with a licensed product. We are also obligated to pay a royalty on net sales of licensed products at a low-single digit rate. The royalty rates are subject to up to a high first decile percentage reduction for lack of a valid claim on a country-by-country basis. See "Business-Intellectual Property-Iron Homeostasis Portfolio" for additional information concerning the intellectual property related to the AbbVie Agreement.

The obligation to pay royalties under the AbbVie Agreement expires on a licensed product-by-licensed product and country-by-country basis upon the later of expiry of (a) (i) the last valid claim of the licensed patents that cover such licensed product or the exploitation thereof in such country or (ii) the last-to-expire improvement patent in such country, whichever is later, (b) the expiration of regulatory exclusivity in such country, and (c) ten years from the first commercial sale of such product in such country.

The AbbVie Agreement expires upon expiry of the last remaining royalty obligation for the last licensed product. Under the AbbVie Agreement, either party may terminate the agreement upon the other party's uncured material breach or insolvency, and AbbVie may also terminate the agreement upon our failure to conduct any relevant material development or commercialization activity in a 12-month period, or, to the extent AbbVie is permitted pursuant to applicable law, a challenge by us of the licensed patents. We may terminate the agreement for any reason upon specified prior written notice to AbbVie.

In connection with the AbbVie Agreement, we also entered into a stock purchase agreement with AbbVie in September 2019, pursuant to which we agreed to issue 4,336,841 shares of our common stock to AbbVie, with 2,295,174 shares vesting immediately and 2,041,667 shares subject to a performance condition tied to the second and third subsequent closings of our Series A Preferred Stock financing. During the year ended December 31, 2020, the performance conditions were met and the remaining 2,041,667 shares vested. At the closing of the merger, shares of our common stock held before the merger were exchanged for shares of common stock in the combined publicly-traded company based on an exchange ratio of 0.1096.

2021 Exclusive License Agreement with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc.

In May 2021, we entered into a license agreement, or the Roche Agreement, with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc., or together, Roche, pursuant to which Roche granted us an exclusive and sublicensable (subject to Roche's consent, not to be unreasonably withheld, except with respect to affiliates) worldwide license under certain of Roche's patent rights and know-how to develop and commercialize bitopertin, including certain backup compounds and derivatives, in all indications and for all therapeutic and prophylactic uses, except diagnostic use. Roche retained the rights with respect to diagnostic uses and its own internal non-clinical research purposes.

Under the Roche Agreement, Roche has an exclusive right to negotiate a license or purchase of all licensed compounds and products in certain specified circumstances. If we, for a specified period of time following entry into the Roche Agreement or before completion of a Phase 3 clinical trial of a licensed product (whichever is later), intend to enter into a sublicense or assignment of the Roche Agreement granting rights in the U.S., China or one or more major EU countries, then Roche will have a specified amount of time to perform diligence and negotiate the applicable license, purchase, or acquisition. If the parties are not able to come to terms during the applicable negotiation period, we are free to enter into the applicable transaction, provided that we may not enter into such a transaction on terms less favorable to us than the terms offered by Roche during a specified period after the conclusion of the negotiation period.

We are required to use commercially reasonable efforts to develop, seek regulatory approval and, on a country-by-country basis where such regulatory approval has been obtained, commercialize at least one licensed product in each such country.

Under the Roche Agreement, we paid Roche an initial license payment of $4.5 million and we will pay Roche up to an aggregate of $50.0 million in development and regulatory milestone payments for development and approval in a first indication, up to an aggregate of $35.0 million in development and regulatory milestone payments for development and approval in a second indication. The first potential milestone is a $10.0 million payment upon the initiation of the first Phase 3 clinical trial with a licensed product in a first indication. We will also pay Roche up to an aggregate of $120.0 million based on achievement of certain thresholds for annual net sales of licensed products. We are also obligated to pay a royalty on net sales of licensed

products at a tiered rate ranging from the high-single digits to the high teens. The royalty rates are subject to a reduction (i) by 25% for lack of a valid claim covering the licensed product generating such sales, and (ii) by 50% for prevalence of generic products (or 25% if there are generic products on the market but there is still a valid claim), in each case on a country-by-country basis. Additionally, royalties are apportioned where licensed compounds are commercialized in combination products.

The obligation to pay royalties under the Roche Agreement expires on a licensed product-by-licensed product and country-by-country basis upon the later of (a) expiry of the last valid claim of the licensed and improvement patents that cover such licensed product in such country, (b) the expiration of regulatory exclusivity in such country, and (c) twelve years from the first commercial sale of such product in such country. The expiry of the last valid claim of the licensed and improvement patents subject to the Roche agreement is currently scheduled to occur in April 2035.

In connection with the Roche Agreement and pursuant to an addendum to the Roche Agreement between the parties executed in December 2021, we agreed to issue to Roche or its affiliates, immediately following the closing of the merger and for no additional consideration, shares of common stock estimated to be approximately 2.85% of the combined company's issued and outstanding capitalization immediately following the closing of our merger with Gemini Therapeutics, Inc., or Gemini, and our pre-closing financing. Upon completion of the merger, we issued 482,313 shares of common stock to Roche.

The Roche Agreement expires upon expiry of the last remaining royalty obligation for the last licensed product. Under the Roche Agreement, either party may terminate the agreement upon the other party's uncured material breach or insolvency. We may terminate the agreement for any reason upon specified prior written notice to Roche. In the event the Roche Agreement is terminated for certain causes, if Roche elects to continue development or commercialization of licensed products, certain single-digit royalties may be owed to us in connection with such continued development or commercialization.

2023 Exclusive License Agreement with Mabwell Therapeutics, Inc.

On January 19, 2023, we entered into an exclusive license agreement with Mabwell (a wholly-owned subsidiary of Mabwell (Shanghai) Bioscience Co., Ltd), or the Mabwell Agreement, pursuant to which Mabwell granted us 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). We also granted Mabwell an exclusive, sublicensable, royalty-free license under our patents and know-how arising under the Mabwell Agreement to develop and commercialize licensed antibody products in Greater China and Southeast Asia.

The Mabwell Agreement requires us to pay Mabwell an upfront payment of $10.0 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. In October 2023, the first patient was dosed in the Phase 1 clinical trial of polycythemia vera for DISC-3405, resulting in a milestone payment of $5.0 million due to Mabwell. We are further obligated to pay a tiered percentage of revenue that we receive from our 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, we are 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 Agreement 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.

Our 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 Mabwell 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. We may also terminate the Mabwell Agreement for convenience on 60 days' written notice to Mabwell. In the event the Mabwell Agreement is terminated other than by us for cause, we have agreed to grant Mabwell an exclusive, sublicensable, worldwide license under our patent rights and know-how arising under the Mabwell Agreement to develop and commercialize products

containing the licensed antibodies. In such circumstances, we and Mabwell will negotiate a royalty to be paid by Mabwell on the net sales of such products in the licensed territory.

Intellectual Property

Overview

We strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patent protection in the United States and internationally for our current and future product candidates. We also rely on trademarks, copyrights, trade secrets, confidentiality procedures, employee disclosure, invention assignment agreements, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We seek to obtain domestic and international patent protection, and endeavor to promptly file patent applications for new commercially valuable inventions. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

We plan to continue to expand our intellectual property estate by filing patent applications directed to pharmaceutical compositions, methods of treatment, methods of manufacture or identified from our ongoing development of our product candidates, which include both small molecule and biologic products, such as antibodies. Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce any patents that we may obtain, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties.

The patent positions of companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent may be challenged in courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot guarantee that our pending patent applications, or any patent applications that we may in the future file or license from third parties, will result in the issuance of patents. We cannot predict whether the patent applications

we are currently pursuing will issue as patents in any particular jurisdiction or at all, whether the claims of any patent applications, should they issue, will cover our product candidates, or whether the claims of any issued patents will provide sufficient protection from competitors or otherwise provide any competitive advantage. We cannot predict the scope of claims that may be allowed or enforced in our patents. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries and patent application filings, we cannot be certain of the priority of inventions covered by pending patent applications. Accordingly, we may not have been the first to invent the subject matter disclosed in some of our patent applications or the first to file patent applications covering such subject matter, and we may have to participate in interference proceedings or derivation proceedings declared by the United States Patent and Trademark Office, or USPTO, to determine priority of invention. For more information regarding the risks related to our intellectual property, see “Risk Factors-Risks Related to Our Intellectual Property.”

Patent Portfolio

Our patent portfolio includes patents and patent applications in the United States and selected jurisdictions outside of the United States. As of March 14, 2023 February 29, 2024, our patent portfolio in total consisted of 11 15 issued U.S. patents and 200 211 issued patents in foreign jurisdictions (e.g., Australia, China, United Kingdom, Germany, Mexico, Japan, and others), six five PCT applications, 57 107 pending non-provisional applications (U.S., EP and other jurisdictions), and five eight pending U.S. provisional applications, which include claims directed to compositions and methods of use.

The patent portfolio includes patents and applications with claims related to the following programs:

Heme Biosynthesis Modulation Portfolio - GlyT1 Inhibition - Bitopertin

With regard to our bitopertin heme biosynthesis modulation program, we own five eleven pending PCT applications patent families directed to GlyT1 inhibitors (e.g., bitopertin) and various methods of treatment and use claims related, but not limited to EPP, XLP, CEP, DBA, PV, and PV. In addition, we own one pending U.S. provisional application directed to various methods of treatment and use claims related to hepatic porphyrias. Patents and pending applications directed to bitopertin GlyT1 inhibitors (e.g., bitopertin) and methods of making and using them are expected to expire between 2041 and 2043, 2044, without accounting for any potential terminal disclaimers, available patent term adjustments or extensions. In particular, our first and second families are directed to methods of treating EPP, XLP, and CEP with bitopertin and related compounds, and solid forms of bitopertin, and these families, upon grant, will have a twenty-year statutory expiration date of 2041 and 2042, respectively. The first family has entered the national phase in the U.S. Australia,

Canada, China, Europe, Hong Kong, Japan, and Korea. One U.S patent has granted from the first patent family and is directed to methods of treating EPP or XLP with bitopertin. This patent is expected to expire in 2041, without accounting for any potential terminal disclaimers, available patent term adjustments or extensions. The second family has entered the national phase in the U.S., Australia, Canada, China, Europe, and Japan. Our third family is directed to methods of treating polycythemias, including PV, with bitopertin and related compounds, and this family, upon grant, will have a twenty-year statutory expiration date of 2042. 2042, without accounting for any potential terminal

disclaimers, available patent term adjustments or extensions. The third patent family has entered the national phase in the U.S. Australia, Brazil, Canada, China, Europe, Israel, Japan, Korea, and Mexico. Our fourth family is directed to methods of treating anemia associated with a ribosomal disorder (e.g., DBA) with bitopertin and related compounds, and this family, upon grant, will have a twenty-year statutory expiration date of 2042. 2042, without accounting for any potential terminal disclaimers, available patent term adjustments or extensions. The fourth patent family has entered the national phase in the U.S. Australia, Brazil, Canada, China, Europe, Israel, Japan, Korea, and Mexico. Our fifth family is directed to methods of treating hepatic porphyria porphyrias with bitopertin and related compounds, and this family, upon grant, will have a twenty-year statutory expiration date of 2043. 2043, without accounting for any potential terminal disclaimers, available patent term adjustments or extensions. The fifth family is a pending PCT application. Our sixth family is directed to methods of treating EPP, XLP, and CEP with additional GlyT1 inhibitors, and this family, upon grant, will have a twenty-year statutory expiration date of 2042. 2042, without accounting for any potential terminal disclaimers, available patent term adjustments or extensions. The sixth patent family has entered the national phase in the U.S. Australia, Canada, China, Europe, Japan. Our remaining five patent families are all U.S. provisional applications directed to GlyT1 inhibitors (e.g., bitopertin) and methods of treating various disorders and conditions. These provisional patent families, upon grant, will have a twenty-year statutory expiration date of 2044. We have also in-licensed multiple patent families from F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. comprising eight issued U.S. patents and additional granted patents in the following jurisdictions: Algeria, Australia, Austria, Belarus, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, Egypt, Estonia, Eurasian Patent Convention, European Patent Convention, Finland, France, Germany, Great Britain, Greece, Gulf Cooperation Council, Hong Kong, Hungary, India, Indonesia, Ireland, Israel, Italy, Japan, Kazakhstan, Kosovo, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mexico, Monaco, Montenegro, Morocco, Netherlands, New Zealand, Norway, Philippines, Poland, Portugal, Republic of Korea, Republic of Serbia, Romania, Russian Federation, Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, Ukraine, and Vietnam. Patents and pending applications directed to bitopertin, synthetic intermediates, synthetic methods, synthetic processes of making bitopertin, treatment of hematologic disorders characterized by elevated cellular hemoglobin, and crystalline forms of bitopertin are expected to expire between 2024 and 2035, without accounting for any potential terminal disclaimers, available patent term adjustments or extensions. In particular, the first family is directed to composition of matter of bitopertin and processes of preparation, and this family has a twenty-year statutory expiration date of 2024. This family has issued patents in the U.S. and the following jurisdictions: Algeria, Australia, Austria, Belarus, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, Egypt, Estonia, Eurasian Patent Convention, European Patent Convention, Finland, France, Germany, Great Britain, Greece, Gulf Cooperation Council, Hong Kong, Hungary, India, Indonesia, Ireland, Israel, Italy, Japan, Kazakhstan, Kosovo, Latvia, Lithuania, Luxembourg, Malaysia, Mexico, Monaco, Montenegro, Morocco, Netherlands, New Zealand, Norway, Philippines, Poland, Portugal, Republic of Korea, Republic of Serbia, Romania, Russian Federation, Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, Ukraine, and Vietnam. The second family is directed to processes of preparation of bitopertin, and this family has a twenty-year statutory expiration date of 2028. This family has issued patents in the U.S. and the following jurisdictions: Australia, Austria, Belgium, Brazil, Canada, China, European Patent Convention, Finland, France, Germany, Great

Britain, Hungary, Ireland, Israel, Italy, Japan, Mexico, Netherlands, Republic of Korea, Spain, Sweden, and Switzerland. The third and fourth families are directed to synthetic processes for synthetic intermediates, and these families have twenty-year statutory expiration dates of 2026 and 2027, respectively. These families each have issued patents in the U.S. and the following jurisdictions: China, European Patent Convention, France, Germany, Great Britain, Japan, and Switzerland. The fifth family is directed to methods of treating hematological disorders characterized by elevated cellular hemoglobin levels with bitopertin, and this family has a twenty-year statutory expiration date of 2035. This family has issued patents in the U.S. and the following jurisdictions: Algeria, China, Croatia, Cyprus, European Patent Convention, France, Germany, Great Britain, Greece, Hong Kong, Indonesia, Italy, Japan, Malaysia, Morocco, Philippines, Portugal, Republic of Korea, Republic of Serbia, Slovenia, South Africa, Spain, Switzerland, and Turkey. The sixth family is directed composition of matter of additional GlyT1 inhibitors, and this family has a twenty-year statutory expiration date of 2026. This family has issued patents in the U.S. and the following jurisdictions: China, European Patent Convention, France, Germany, Great Britain, Hong Kong, Japan, and Switzerland. The seventh

family is directed to crystalline forms of bitopertin, and this family has a twenty-year statutory expiration date of 2027. This family has issued patents in the following jurisdictions: Australia, Austria, Belgium, Brazil, Bulgaria, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, European Patent Convention, Finland, France, Germany, Great Britain, Greece, Gulf Cooperation Council, Hungary, Indonesia, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mexico, Monaco, Morocco, Netherlands, New Zealand, Norway, Philippines, Poland, Portugal, Republic of Korea, Republic of Serbia, Romania, Russian Federation, Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan, Turkey, Ukraine, and Vietnam.

Several of the indications that we expect to pursue with bitopertin, including EPP, XLP and DBA, are rare diseases. We have received orphan drug designation from the FDA for bitopertin for the treatment of EPP and the European Committee for

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Orphan Medical Products adopted a positive opinion on Orphan Designation for bitopertin for treatment of EPP. We expect to file for an orphan drug designation for other indications in the United States and other relevant jurisdictions. If successful, orphan drug designation may provide a form of exclusivity for a period of years, described in greater detail below. See “Our Business-Governmental Regulation-Orphan Drug Designation and Exclusivity.”

Iron Homeostasis Portfolio – Hepcidin Suppression – DISC-0974 and DISC-0998

With regard to our iron homeostasis portfolio, including our DISC-0974 and DISC-0998 programs, we own five seven patent families, including one PCT patent application that has entered the national phase in Australia, Canada, China, Europe, Hong Kong, Israel, Japan, Korea, and United States, one PCT patent application that has entered the national phase in Europe, and United States, one PCT patent application that has entered the national phase in Australia, Canada, China, Europe, Hong Kong, Israel, Japan, Korea, and United States, one PCT patent application that has entered the national phase in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Korea, Mexico, New Zealand, Singapore, and United States, two pending PCT patent applications, and two one pending U.S. provisional applications application containing composition of matter, method of treatment and use claims related to our initial indication, indications, anemia of myelofibrosis and our expansion indications, e.g., chronic kidney disease anemia, as well as other indications, e.g., anemia of inflammatory bowel disease and other anemias of chronic disease involving iron restriction from elevated hepcidin. Patents issuing from these PCT applications are expected to expire in between, 2040 and 2041, not including 2044 without accounting for any potential terminal disclaimers, available patent term adjustments and any patent term or extensions. Further, several of the above owned patent applications within our iron homeostasis portfolio are Joint Patents according to the AbbVie Agreement, whereby we own the patent applications and any patents granted thereon jointly with AbbVie, and we hold an exclusive license to AbbVie’s interest in the patent applications and any patents granted thereon pursuant to the AbbVie Agreement.

We also in-licenses in-license a patent family from AbbVie comprised of two issued U.S. patents that are expected to expire in 2032 and 2035, and issued patents in Australia, Canada, Brazil, China, the United Kingdom, Germany, Mexico, and Japan that are each expected to expire in 2032. These in-licensed patents include composition of matter claims, as well as method of treatment and use claims related to diseases of iron metabolism, such as anemia of chronic disease, iron-refractory iron-deficiency anemia, and anemia of chronic kidney disease. This in-licensed patent family also includes eight pending non-provisional applications in the United States, Australia, Brazil, Canada, China, Europe, Japan, and Mexico. Any patents that issue on these pending non-provisional applications are likewise expected to expire in 2032, not including without accounting for any potential terminal disclaimers, available patent term adjustments and any patent term or extensions.

Iron Homeostasis Portfolio – Hepcidin Induction – MWTX-001, MWTX-002, and MWTX-003 DISC-3405 (formerly MWTX-003)

With regard to our TMPRSS6 inhibitor program, we in-license a patent family from Mabwell comprised of ten eight pending non-provisional applications in Australia, Canada, China, Europe, India, Japan, Korea, Taiwan, and United States. States, one pending PCT application, and one pending U.S. provisional application. These in-licensed patent applications include composition of matter claims to antibodies designed to inhibit TMPRSS6, including MWTX-001, MWTX-002, and MWTX-003, DISC-3405, as well as method of treatment and use claims related to diseases of iron metabolism. Any patents that issue on these pending non-provisional applications are metabolism (e.g., PV). One U.S patent has granted from the in-licensed patent family and is directed to the DISC-3405 TMPRSS antibody. This patent is expected to expire in 2041, not including without accounting for any potential terminal disclaimers, available patent term adjustments and or extensions. We also own one provisional patent application directed to methods of treatment claims related to diseases of iron metabolism. This application, upon grant, will have a twenty-year statutory expiration date of 2044, without accounting for any potential terminal disclaimers, available patent term adjustments or extensions.

We also own a patent family comprising seven pending non-provisional applications in U.S., Europe, Japan, Australia, Canada, China, and India and a second patent family comprising one pending PCT international application and one non-provisional application in the U.S. directed to compounds that inhibit TMPRSS6 and methods of using the same. Any patents that issue in on the non-provisional applications in the first family are expected to expire in 2039, not including without accounting for any potential terminal disclaimers, available patent term adjustments and any or extensions. Any patent term extensions. Any that issue on applications claiming priority to the PCT application or patents that issue as a patent from the non-provisional application in the second family are expected to expire in 2041, not including without accounting for any potential terminal disclaimers, available patent term adjustments and any patent term or extensions.

Patent Term

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the U.S., the base term is 20 years from the filing date of the earliest-filed non-provisional patent application from which the patent claims priority. The term of a U.S. patent can be lengthened by patent term adjustment, which compensates the owner of the patent for administrative delays at the USPTO. In some cases, the term of a U.S. patent is shortened by terminal disclaimer that reduces its term to that of an earlier-expiring patent. The term of a U.S. patent may be eligible for patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act, to account for at least some of the time the drug is under development and regulatory review after the

patent is granted. With regard to a drug for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent that includes at least one claim covering the composition of matter of such an FDA-approved drug, an FDA-approved method of treatment using the drug and/or a method of manufacturing the FDA-approved drug. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or fourteen years from the date of the FDA approval of the drug, and a patent cannot be extended more than once or for more than a single product. During the period of extension, if granted, the scope of exclusivity is limited to the approved product for approved uses. Some foreign jurisdictions, including Europe and Japan, have analogous patent term extension provisions, which allow for extension of the term of a patent that covers a drug approved by the applicable foreign regulatory agency.

In the future, if and when our product candidates receive FDA approval, we expect to apply, if appropriate, for patent term extension on patents directed to those product candidates, their methods of use and/or methods of manufacture. However, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions. For more information regarding the risks related to our intellectual property, see “Risk Factors-Risks Related to Our Intellectual Property.”

Trade Secrets

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements provide that all confidential information developed or made known during the course of an individual or entities’ relationship with us must be kept confidential during and after the relationship. These agreements also provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. For more information regarding the risks related to our intellectual property, see “Risk Factors-Risks Related to Our Intellectual Property.”

Governmental Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs and biologics. We, along with our vendors, contract research organizations, or CROs, clinical investigators and contract manufacturing organizations, or CMOs, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of drugs and biologics and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and biologics under the FD&C Act and the Public Health Service Act, or PHSA, as amended, and their implementing regulations. Both drugs and biologics are also subject to other federal, state and local statutes and regulations. We believe that bitopertin, which is a small molecule, will be regulated by the FDA as a drug product, and DISC-0974, DISC-0998 and MWTX-003, DISC-3405, which are monoclonal antibodies, will be regulated by FDA as biologic products. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other regulatory requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA’s refusal to approve pending

applications, issuance of clinical holds for ongoing studies, suspension or revocation of approved applications, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

Our product candidates must be approved for therapeutic indications by the FDA before they may be marketed in the United States. For drug product candidates regulated under the FD&C Act, FDA must approve an NDA. For biologic product candidates

regulated under the FD&C Act and PHSA, FDA must approve a Biologics License Application, or BLA. The process is similar for both drugs and biologics and generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance wit good laboratory practice, or GLP, requirements;
- completion of the manufacture, under current Good Manufacturing Practices, or cGMP, conditions, of the drug substance and drug product that the sponsor intends to use in human clinical trials along with required analytical and stability testing;
- submission to the FDA of an IND which must become effective before clinical trials may begin and must be updated annually and w certain changes are made;
- approval by an institutional review board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, good clinical practice, or G requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- preparation and submission to the FDA of an NDA or BLA;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of one or more FDA pre-approval or pre-license inspections of the manufacturing facility or facilities where th drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequat preserve the drug or biological product's identity, strength, quality and purity;
- satisfactory completion of FDA audit of the clinical trial sites that generated the data in support of the NDA or BLA;
- payment of user fees for FDA review of the NDA or BLA, unless a waiver is applicable; and
- FDA review and approval of the NDA or BLA, including, where applicable, consideration of the views of any FDA advisory committe prior to any commercial marketing or sale of the drug in the United States.

Preclinical Studies and Clinical Trials for Drugs and Biologics

Before testing any drug or biologic in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of product chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulation and requirements, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND.

An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes the results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions

about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a full or partial clinical hold. FDA must notify the sponsor of the grounds for the hold and any identified deficiencies must be resolved before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND. A clinical hold can also be imposed once a trial has already begun, thereby halting the trial until the deficiencies articulated by FDA are corrected.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, who generally are physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be

used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable compared to the anticipated benefits. The IRB also approves the informed consent form that must

be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about clinical trials, including results for clinical trials other than Phase 1 investigations, must be submitted within specific timeframes for publication on www.ClinicalTrials.gov, a clinical trials database maintained by the National Institutes of Health.

Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a clinical trial may move forward at designated check points based on access that only the group maintains to available data from the trial and may recommend halting the clinical trial if it determines that the participants or patients are being exposed to an unacceptable health risk or other grounds, such as no demonstration of efficacy. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, FDA will nevertheless accept the results of the study in support of an NDA or BLA if the study was well-designed and well-conducted in accordance with GCP requirements, including that the clinical trial was performed by a qualified investigator(s); the data are applicable to the U.S. population and U.S. medical practice; and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support NDAs and BLAs for marketing approval are typically conducted in three sequential phases, which may overlap.

- *Phase 1* - Phase 1 clinical trials involve initial introduction of the investigational product in a limited population of healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage

tolerance, absorption, metabolism and distribution of the investigational product in humans, excretion the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- *Phase 2* - Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the drug's potential efficacy, to determine the optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- *Phase 3* - Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and physician labeling. Generally, two adequate and well-controlled Phase 3 trials are required by the FDA for approval of an NDA or BLA.

Post-approval trials, sometimes referred to as Phase 4 clinical trials or post-marketing studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of NDA or BLA approval.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information. During the development of a new drug or biological product, sponsors have the opportunity to meet with the FDA at certain points, including prior to submission of an IND, at the end of Phase 2 and before submission of an NDA or BLA. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity of the final drug product. For biological products in particular, the PHSA

emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined in order to help ensure safety, purity and potency. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Marketing Approval for Drugs and Biologics

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. An NDA is a request for approval to market a new drug for one or more specified indications and must contain proof of the drug's safety and efficacy for the requested indications. A BLA is a request for approval to market a new biologic for one or more specified indications and must contain proof of the biologic's safety, purity and potency for the requested indications. The marketing application is required to include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug, or the safety, purity and potency of the investigational biologic, to the satisfaction of the FDA. FDA must approve an NDA or BLA before a drug or biologic may be marketed in the United States. The FDA reviews all submitted NDAs and BLAs to ensure they are sufficiently complete to permit substantive review before it accepts them for filing and may request additional information rather than accepting the NDA or BLA for filing. The FDA must make a decision on accepting an NDA or BLA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA or BLA. The FDA reviews an NDA or BLA to determine, among other things, whether the product is safe and effective for the indications sought and whether the facility in which it is manufactured, processed, packaged or held meets standards, including cGMP requirements, designed to assure and preserve the product's continued identity, strength, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial review of a new molecular entity NDA or BLA and respond to the applicant, and six months from the filing date of a new molecular entity NDA or BLA for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs or BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each NDA or BLA must be accompanied by a substantial user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy, or REMS, if it believes that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh its risks. A REMS can include use of risk evaluation and mitigation strategies like medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, special monitoring or other risk-minimization tools.

The FDA may refer an application for a novel drug or biologic to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

After evaluating the NDA or BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter generally contains a statement of specific conditions that must be met in order to secure final approval

of the NDA or BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may require additional clinical or preclinical testing or recommend other actions, such as requests for additional information or clarification, that the applicant might take in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an

approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition with either a patient population of fewer than 200,000 individuals in the United States, or a patient population of 200,000 or more individuals in the United States when there is no reasonable expectation that the cost of developing and making the product available in the United States for the disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and waiver of application fees.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity during which the FDA may not approve any other applications to market the same therapeutic agent for the same indication, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. Competitors, however, may receive approval of different therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same therapeutic agent for a different indication than that for which the orphan product has exclusivity. Orphan product exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same therapeutic agent for the same indication before we do, unless we are able to demonstrate that our product is clinically superior. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity.

Further, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

The FDA may further reevaluate its regulations and policies under the Orphan Drug Act. It is unclear as to how, if at all, the FDA may change the orphan drug regulations and policies in the future.

Rare Pediatric Disease Designation and Priority Review Vouchers

Under the FD&C Act, the FDA incentivizes the development of products that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects 200,000 or more in the United States and for which there is no reasonable expectation that the cost of developing and making in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug application after the date of approval of the rare pediatric disease drug product, referred to as a priority review voucher, or PRV. A sponsor may request rare pediatric disease designation from the FDA prior to the submission of its NDA or BLA. A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its NDA or BLA. Moreover, a sponsor who chooses not to submit a rare pediatric disease designation request may nonetheless receive a PRV upon approval of its marketing application if it requests such a voucher in its original marketing application and meets all of the eligibility criteria. If a PRV is received, it may be sold or transferred an unlimited number of times. Congress has extended the PRV program through September 30, 2024, with the potential for PRVs to be granted through September 30, 2026.

Expedited Development and Review Programs for Drugs and Biologics

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs and biologics to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include fast track designation, breakthrough therapy designation, priority review and accelerated approval, and the purpose of

these programs is to either expedite the development or review of important new drugs and biologics to get them to patients more quickly than standard FDA review timelines typically permit.

A new drug or biologic is eligible for fast track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. Fast track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed. Rolling review means that the FDA may review portions of the marketing application before the sponsor submits the complete application. Additionally, the FDA may rescind a fast track designation if it believes that the designation is no longer supported by data emerging in the clinical trial process.

In addition, a new drug or biologic may be eligible for breakthrough therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic, alone or in combination with one or more

other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation provides all the features of fast track designation in addition to intensive guidance on an efficient product development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with fast track or breakthrough therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including priority review designation and accelerated approval. A product is eligible for priority review, once an NDA or BLA is submitted, if the product that is the subject of the marketing application has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA's goal date to take action on the marketing application is six months compared to ten months for a standard review.

Products are eligible for accelerated approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Accelerated approval is usually contingent on a sponsor's agreement to conduct, in a diligent manner, adequate and well-controlled additional post-approval confirmatory trials to verify and describe the product's clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date accelerated approval is granted. Additionally, under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a product or an indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. After the 120-day period has passed, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, breakthrough therapy designation, priority review and accelerated approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval, though they may expedite the development or review process.

Pediatric Information and Pediatric Exclusivity

Under the Pediatric Research Equity Act, or PREA, as amended, certain NDAs and BLAs and certain NDA and BLA supplements must contain data that can be used to assess the safety and efficacy of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The FD&C Act requires that a sponsor who is planning to submit a marketing application for a product candidate that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to

the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other

clinical development programs. Unless otherwise required by regulation, PREA does not apply to a drug or biologic for an indication for which orphan designation has been granted.

A product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for biologics and drugs and patent terms. terms for drugs. This six-month exclusivity, which runs from the end of other exclusivity protection for biologics and drugs or patent term for drugs, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued “Written Request” for such a study.

U.S. Post-Approval Requirements for Drugs and Biologics

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as “off-label use”) and limitations on industry-sponsored scientific and educational activities.

Although physicians may prescribe approved products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, including not only by company employees but also by agents of the company or those speaking on the company’s behalf, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Promotional materials for approved drugs and biologics must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or BLA or NDA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA or BLA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization. In addition, manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs and biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements on sponsors and their CMOs. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that a sponsor may use. Additionally, manufacturers and other parties involved in the drug supply chain for prescription drug and biological products must also comply with product tracking and tracing requirements and for notifying FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. Failure to comply with statutory and regulatory requirements may subject a manufacturer to

possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual program user fee for any marketed product.

The FDA may withdraw approval of a product if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or othe safety information about the product;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approva

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- product seizure or detention, or refusal to permit the import or export of products;

- injunctions or the imposition of civil or criminal penalties;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; and
- mandated modification of promotional materials and labeling and issuance of corrective information

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our future product candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA plus the time between the submission date of an NDA or BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for our currently owned or licensed patents to add patent life beyond a patent's current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA.

Marketing exclusivity provisions under the FDCA also can delay the submission or the approval of certain drug product applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same

active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an Abbreviated New Drug Application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

U.S. Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars in the United States. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed.

During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

Other Regulatory Matters

Manufacturing, labeling, packaging, distribution, sales, promotion and other activities of product candidates following product approval, where applicable, or commercialization are also potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to which we may be subject. Additionally, the activities associated with the commercialization of product candidates

is subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive recordkeeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements may subject firms to legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a firm to enter into supply contracts, including government contracts. Any claim or action against us for violation of these laws, even if we successfully defends against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on marketing, sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in statutes, regulations, or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling or packaging; (iii) the recall or discontinuation of our products; or (iv) additional recordkeeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business that may constrain the financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing authorization. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, and transparency laws and regulations related to drug pricing and payments and other transfers of value made to physicians and other healthcare providers. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and responsible individuals may be subject to imprisonment.

Affordable Care Act and Legislative Reform Measures

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as gene therapy and therapies addressing rare diseases such as those we are developing. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during

their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On June 17, 2021, for example, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, In addition, President Biden has issued an Executive Order multiple executive orders that have sought to initiate reduce prescription drug costs. Although a special enrollment period from February 15, 2021 number of these and other proposed measures may require authorization through August 15, 2021 foradditional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will

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purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies

continue to review and reconsider their existing policies and rules that limit access seek new legislative measures to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. control drug costs. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, on March 11, 2021, President Biden signed the U.S. American Rescue Plan Act of 2021 into law, which eliminates eliminated the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning effective January 1, 2024. Further, in August 2011, the Budget Control Act of 2011, and subsequence legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. Further, the U.S. Budget Control Act of 2011, included aggregate reductions of Medicare payments to providers of 2% per fiscal year that will remain in effect through 2031. The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Further, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, (2018) provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

In August 2022, the The Inflation Reduction Act of 2022, or the IRA, was signed into law. The IRA, includes several provisions that will impact our business to varying degrees, including provisions depending on how various aspects of the IRA are implemented. Provisions that

create may impact our business include a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, starting in 2025, impose the imposition of new manufacturer financial liability on all most drugs in Medicare Part D, allow permitting the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay until January 1, 2032 the implementation of the HHS rebate rule that would require pass through of have limited the fees that pharmacy benefit manager rebates to beneficiaries. managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The effect of IRA on our business and the healthcare industry in general is not yet known.

Other U.S. Environmental, Health and Safety Laws and Regulations

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintains workers' compensation insurance to cover costs and expenses we may incur due to injuries to our employees as well as insurance for environmental liability, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Employees and Human Capital Resources

As of February 28, 2023 February 29, 2024, we had 46 74 full-time employees, including 19 31 who hold Ph.D. or M.D. degrees, and no part-time employees. Of the full-time employees, 33 54 employees are engaged in research and development and 13 20 employees are engaged in management or general and administrative activities. None of our employees are subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relationship with our employees to be good.

Our human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Facilities

Our principal office is located at 321 Arsenal Street, Suite 101, Watertown, MA 02472, where we lease and sublease a total of approximately 7,566 16,847 square feet of office space. The lease term began in November 2021 and sublease terms will end in November 2026. We believe that these facilities will be adequate for our near-term needs. If required, we believe that suitable additional or substitute space will be available in the future on commercially reasonable terms to accommodate any such expansion of our operations.

Legal Proceedings

From time to time, we may be involved in various other claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any material legal proceedings.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements, and other information, including amendments and exhibits to such reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, are available free of charge on our website located at www.discmedicine.com, as soon as reasonably practicable after they are filed with or furnished to the SEC. These reports are also available at the SEC's Internet website at www.sec.gov.

ITEM 1A. RISK FACTORS

Set forth below are the risks that we believe are material to our investors and they should be carefully considered. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and other factors not presently known to us or that we currently believe are immaterial may affect our business, prospects, financial condition and results of operations if they occur. This section contains forward-looking statements. You should refer to the explanation of the qualifications and limitations on forward-looking statements beginning on page ii of this Annual Report on Form 10-K.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced operations in 2017 and are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Since our inception in October 2017, we have devoted substantially all of our efforts to organizing and staffing our company, business planning, capital raising, establishing and maintaining our intellectual property portfolio, building our pipeline of product candidates, conducting drug discovery activities, undertaking preclinical studies, conducting early-stage clinical trials, and providing general and administrative support for these operations. We have not yet demonstrated our ability to successfully develop any product candidate, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

In addition, as our business grows, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of

supporting commercial activities. We may not be successful in such a transition.

We have incurred significant net losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

Our net losses were $36.0 million $76.4 million and $46.8 million for the years twelve months ended December 31, 2021 December 31, 2023 and 2022, respectively. We had an accumulated deficit of $112.2 million $188.6 million as of December 31, 2022 December 31, 2023. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect our research and development expenses to increase significantly in connection with the commencement and continuation of clinical trials of our product candidates. In addition, if we obtain regulatory approval for our product candidates, we will incur significant sales, marketing and manufacturing expenses. We also will continue to incur additional costs associated with operating as a public company and expect to continue to incur significant and increasing operating losses over the next several years and for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our ability to successfully open clinical trial sites and recruit and retain subjects for clinical trials and any delays caused by difficulties such efforts;
- our ability to obtain regulatory approval for our product candidates, and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which n change from time to time;
- the cost of manufacturing our product candidates and products, should they receive regulatory approval, which may vary depending the quantity of production and the terms of our agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;

- the level of demand for our products should they receive regulatory approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and poten future therapeutics that compete with our product candidates;
- the changing and volatile U.S. and global economic environments, including as a result of the ongoing COVID-19 pandemic; public hea crises; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in us failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating

results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even if we have met any previously publicly stated guidance we may provide.

We have no products approved for commercial sale and have not generated any revenue from product sales.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated collaborative revenue from our product candidates and have not generated revenue from product sales, and do not expect to generate any revenue from the sale of products in the near future. We do not expect to generate significant revenue unless and until we obtain regulatory approval of, and begins begin to sell, one or more of our product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete our ongoing and planned preclinical studies for our current and future product candidates;
- timely file and receive acceptance of our Investigational New Drug applications, or INDs, in order to commence our planned clinical tr or future clinical trials;
- successfully enroll subjects in and complete, our ongoing and planned clinical trials;
- initiate and successfully complete all safety and efficacy studies necessary to obtain U.S. and foreign regulatory approval for our prod candidates;
- successfully address the prevalence, duration and severity of potential side effects or other safety issues experienced with our prod candidates, if any;
- timely file New Drug Applications, or NDAs, and Biologic License Applications, or BLAs, and receive regulatory approvals for our prod candidates from the U.S. Food and Drug Administration, or the FDA, and comparable foreign regulatory authorities;
- establish and maintain clinical and commercial manufacturing capabilities or make arrangements with third-party manufacturers for clin supply and commercial manufacturing;
- obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- position our product candidates to effectively compete with other therapies;
- obtain and maintain healthcare coverage and adequate reimbursement;
- enforce and defend intellectual property rights and claims;
- implement measures to help minimize the risk of COVID-19 to our employees as well as patients and subjects enrolled in our clinical trials; and
- maintain a continued acceptable safety profile of our products following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

We will need to raise substantial additional funding. If we are unable to raise capital when needed or on terms acceptable to us, we would may be forced to delay, reduce or eliminate some of our product development programs or commercialization efforts.

The development of pharmaceutical products is capital-intensive. We are currently advancing our hematologic disease programs through preclinical and clinical development. We expect our expenses to significantly increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate and complete clinical trials of, and seek regulatory approval for, our product candidates. In addition, depending on the status of regulatory approval or, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our current or future product candidates or otherwise expand more rapidly than presently anticipated. Furthermore, we expect to incur additional costs associated with operating as a newly-public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would may be forced to delay, reduce or eliminate certain of our research and development programs or future commercialization efforts.

We believe that we have cash and cash equivalents that will enable us to fund operating expenses and capital expenditure requirements well into 2025. 2026. However, we have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than expected. Our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to raise additional funds necessary to complete clinical development of and commercialize our product candidates;
- our ability to establish new and maintain existing licensing or collaboration arrangements and the progress of the development efforts third parties with whom we may enter into such arrangements;
- our ability to maintain our current research and development programs and to establish new programs;
- the successful initiation, enrollment and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities for any product candidates;
- the availability of raw materials for use in production of our product candidates;
- establishing agreements with third-party manufacturers for supply of product candidate components for our clinical trials;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally
- our ability to protect our other rights in our intellectual property portfolio;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement for any approved products; and
- the potential additional expenses attributable to adjusting our development plans (including any supply related matters) to the ongo COVID-19 pandemic. any public health crises.

Identifying potential product candidates and conducting preclinical development testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for many several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Disruptions in the financial markets in general and more recently due to the ongoing

COVID-19 pandemic may make equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product that has received

regulatory approval or be unable to expand our operations or otherwise capitalize on our business opportunities as desired, which could materially affect our business, financial condition and results of operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, we can generate substantial product revenue, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. The terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted, and the terms of those securities may include liquidation or other preferences that may materially adversely affect your rights as a common stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, acquiring, selling or licensing intellectual property rights, and making capital expenditures, declaring dividends or other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to meet certain milestones in connection with debt financing and the failure to achieve such milestones by certain dates may force us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us which could have a material adverse effect on our business, operating results and prospects.

We also could be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable. If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, grant licenses on terms that may not be favorable to us or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourself, any of which may have a material adverse effect on our business, operating results and prospects.

Stockholders who hold contingent value rights, or CVRs, potentially may not receive any payment on the CVRs and the CVRs may otherwise expire valueless.

On December 29, 2022, prior to the effective time of our merger with Gemini, we entered into a Contingent Value Rights Agreement, or the CVR Agreement, with a rights agent pursuant to which Gemini's pre-merger common stockholders received one CVR for each outstanding share of Gemini common stock held by such stockholders on December 29, 2022. Each CVR represents the contractual right to receive payments, in the form of shares of our stock, upon the actual receipt by us or our affiliates of certain proceeds derived from consideration paid to us as a result of the disposition of Gemini's pre-merger legacy assets, net of certain expenses and other deductions. Any payments under

the CVR Agreement will be in the form of shares of our stock, determined on the basis of a volume weighted average for the five (5) trading days prior to the date of issuance.

We may not be able to achieve successful results from the disposition of such assets as described above. If this is not achieved for any reason within the time periods specified in the CVR Agreement, no payments will be made under the CVRs, and the CVRs will expire valueless. There can be no assurance that any payment of any of our shares will be made or that any holders of CVRs will receive any amounts with respect thereto.

Risks Related to the Discovery and Development of Our Product Candidates

The ongoing COVID-19 pandemic, or a similar pandemic, epidemic, or outbreak of an infectious or highly contagious disease, may materially and adversely affect our business and financial results and could cause a disruption to the development of our product candidates.

Public health crises such as pandemics, including the ongoing COVID-19 pandemic, or similar outbreaks could adversely impact our business. The extent to which COVID-19, or the future outbreak of other highly infectious or contagious diseases impacts our operations or those of our third-party partners, including our preclinical studies or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of the outbreak, actions taken to contain the outbreak or mitigate its impact, and the direct and indirect economic effects of the outbreak and containment measures, among others.

In addition, the patient populations that our product candidates target may be particularly susceptible to COVID-19 or other highly infectious or contagious diseases, which may make it more difficult for us to identify patients able to enroll in our current and future clinical trials and may impact the ability of enrolled patients to complete any such trials.

We have only successfully completed one Phase 1 clinical trial and may be unable to successfully complete any additional clinical trials for any product candidates we develop. Certain of our programs are still in preclinical development and may never advance to clinical development.

We have completed one Phase 1 clinical trial and have not yet demonstrated our continued ability to successfully complete clinical trials, including large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful commercialization. Our programs are still in preclinical and early clinical development. Our clinical programs may not advance to the next stage of clinical development, and our preclinical programs may never advance to clinical development or through clinical development, as applicable. We currently only have two three product candidates in clinical development. In July 2022, we initiated BEACON, a Phase 2 open-label, parallel-dose clinical trial of bitopertin in EPP and XLP patients that is being conducted at sites in Australia. Separately, in October 2022, we initiated AURORA, a Phase 2, randomized, double-blind, placebo-controlled clinical trial of bitopertin in EPP patients that is being conducted at sites in the United States. We completed our Phase 1 clinical trial of DISC-0974 in healthy volunteers. We initiated a Phase 1b/2 clinical trial of DISC-0974 in June 2022 in patients with anemia of MF, and initiated a separate Phase 1b/2 clinical trial in February 2023 in patients with non-dialysis dependent CKD and anemia. We plan to initiate initiated a Phase 1 clinical trial of MWTX-003 DISC-3405 in healthy volunteers in the first half of October 2023. We may not initiate any clinical trial of our product candidates until we have submitted an IND to the FDA or comparable submissions with equivalent regulatory authorities and received regulatory clearance. We may not be able to submit INDs or other regulatory filings for bitopertin or any of our other product candidates on the timelines we expect, if at all. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of regulatory filings with the FDA or other regulatory authorities will result in such regulatory authorities allowing clinical trials to begin on a timely basis or at all, or that, once begun, such trials will be completed on schedule, if at all, or that issues will not arise that require us to revise, postpone, suspend or terminate our clinical trials. For example, we filed an IND in April 2022 with the FDA to initiate the AURORA Phase 2 trial of bitopertin in EPP patients, but the FDA initially placed the initiation of

this trial on clinical hold; we received clearance to initiate the study in July 2022 after the study design was finalized with the FDA, and we initiated the study in October 2022. Commencing each any of these our clinical trials is subject to finalizing the trial design based on discussions with the FDA and other regulatory authorities. Any guidance we receive from the FDA or other regulatory authorities is subject to change. These regulatory authorities could change their position, including on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or result in the composition of stricter approval conditions than currently expected. For a further example, we relied on the data package generated by F. Hoffmann-La Roche Ltd. and

Hoffmann-La Roche Inc., or collectively, Roche, to support our IND submission for bitopertin to initiate our AURORA Phase 2 clinical trial in patients with EPP, as well as our submission of an application with the Australian Therapeutic Goods Administration, or TGA, for our BEACON Phase 2 clinical trial in patients with EPP or XLP, and it is possible that the FDA or TGA, as applicable, may require us to conduct additional preclinical studies to support a future marketing application of bitopertin. Successful completion of our clinical trials is a prerequisite to submitting an NDA or a BLA to the FDA, a Marketing Authorisation Application, or MAA, to the European Medicines Agency, or EMA, or other marketing applications to regulatory authorities in other jurisdictions, for each product candidate and, consequently, the regulatory approval of each product candidate.

A single well-controlled clinical trial may not be sufficient for approval. In general, the FDA requires two well-controlled clinical trials to support registration of a new drug or biologic. Exceptions may be made in cases of a severe disease with few treatment options, and in principle this exception may appear applicable to many of the diseases that we seek to treat, such as EPP, XLP, anemia of MF, DBA and others. Nonetheless, the FDA and other regulators may always require additional clinical trials to support regulatory approval.

If we are required to conduct additional preclinical studies or clinical trials or other testing of our product candidates beyond those that are currently contemplated, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining regulatory approval for our product candidates;
- not obtain regulatory approval at all;
- obtain regulatory approval for indications or patient populations that are not as broad as intended or desired;
- continue to be subject to post-marketing testing requirements; or
- experience having the product removed from the market after obtaining regulatory approval.

Our programs are focused on the development of therapeutics for patients with hematologic diseases, which is a rapidly evolving area of science, and the approach we are taking to discover and develop product candidates is novel and may never lead to approved or marketable products.

The discovery and development of therapeutics for patients with hematologic diseases is an emerging field, and the scientific discoveries that form the basis for our efforts to discover and develop product candidates are relatively new. The scientific evidence to support the feasibility of developing product candidates based on these discoveries is both preliminary and

limited. Although we believe, based on our preclinical work that our programs have the potential to provide disease-modifying therapies, clinical results in patients may not confirm this hypothesis or may only confirm it for certain alterations or certain indications. The patient populations for our product candidates are limited to those with specific hematologic diseases. We cannot be certain that the patient populations for each specific disease will be large enough to allow us to successfully obtain approval and commercialize our product candidates and achieve profitability.

Clinical product development involves a lengthy and expensive process, with an uncertain outcome.

Our preclinical studies and future and ongoing clinical trials may not be successful. Currently, all of our programs are in preclinical and early clinical development. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining regulatory approval from regulatory authorities for the sale of any product candidate, we must complete preclinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates or the safety, purity and potency of our biological product candidates in humans. There is no guarantee that our product candidates will advance in accordance with the timelines we anticipate, if at all. Clinical testing is expensive, difficult to design and implement, can take many years to complete and outcomes are uncertain. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim, top-line, initial or preliminary results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their product candidates. Our preclinical studies and future and ongoing clinical trials may not be successful.

Additionally, some of the clinical trials we conduct may be open-label in study design and may be conducted at a limited number of clinical sites on a limited number of patients. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as

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patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label clinical trial may not be predictive of future clinical trial results when studied in a controlled environment with a placebo or active control.

In May 2021, we entered into a license agreement with Roche, or the Roche Agreement,, pursuant to which, among other things, Roche granted us an exclusive and sublicensable (subject to Roche’s consent, except with respect to affiliates) worldwide license under certain of Roche’s patent rights and know-how to develop and commercialize bitopertin. Although bitopertin was originally evaluated by Roche in over 4,000 individuals, Roche did not evaluate bitopertin in EPP or XLP, so the safety data generated from Roche’s clinical trials of bitopertin may not be predictive or indicative of the results of our clinical trials. Regulatory authorities may also raise questions regarding the transition in the

future from Roche-manufactured drug substance to drug substance manufactured by us or another party, and we may be required to conduct comparability assessments, which could result in delays in development and additional costs. We may face similar challenges with respect to MWTX-003, our other product candidates, for which pre-clinical preclinical results may not be indicative or predictive of future clinical trial results.

Because we are developing some of our product candidates for the treatment of diseases in which there is little clinical experience and, in some cases, using new endpoints or methodologies, the FDA or other regulatory authorities may not consider the endpoints of our clinical trials to predict or provide clinically meaningful results.

Many of our product candidates are designed to treat diseases for which there are few available therapeutic options. For example, in the United States there are currently no therapies approved to treat anemia of MF and there is only one approved therapy to treat EPP. As a result, the design and conduct of clinical trials of product candidates for the treatment of these diseases may take longer, be more costly or be less effective as part of the novelty of development in these diseases. In some cases, we may use new or novel endpoints or methodologies. The FDA or other regulatory authorities may not consider the endpoints of our clinical trials to be validated or clinically meaningful and we may need to conduct proof-of-concept studies or additional work to refine our endpoints and inform the design of future studies before initiating pivotal studies of our product candidates. Even if applicable regulatory authorities do not object to our proposed endpoints in an earlier stage clinical trial, such regulatory authorities may require evaluation of additional or different clinical endpoints in later-stage clinical trials.

Even if the FDA does find our clinical trial success criteria to be sufficiently supported and clinically meaningful at the time, we may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we may conduct for our product candidates. Further, even if we do achieve the pre-specified criteria, our trials may produce results that are unpredictable or inconsistent with the results of the more traditional efficacy endpoints in the trial. The FDA also could

change its view or give overriding weight to other efficacy endpoints over a primary endpoint, even if we achieve statistically significant results on that primary endpoint, if for example we do not do so on our secondary efficacy endpoints. The FDA also weighs the benefits of a product candidate against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of approval. Other regulatory authorities in Europe and other countries may make similar findings with respect to these endpoints.

Interim, top-line, initial and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to confirmation, audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, top-line, initial or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. For example, we announced top-line results from the Phase 1 DISC-0974 clinical trial in June 2022. 2022 and initial data from our Phase 2 BEACON clinical trial of bitopertin in June 2023. We also announced updated data from our Phase 2 BEACON clinical trial of bitopertin and initial data from our Phase 1b/2 DISC-0974 trials in patients with anemia of MF and patients with anemia and NDD-CKD in December 2023. We also may make assumptions, estimations, calculations and conclusions as part of our analyses of data, and may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, top-line, initial or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, top-line, initial and preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim, top-line, initial and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim, top-line, initial or preliminary data we previously published. As a result, interim, top-line, initial and preliminary data should be viewed with caution until the final data are available. Adverse differences between

interim, top-line, initial or preliminary data and final data could significantly harm our business prospects and may cause the price of our common stock to fluctuate or decline.

Further, regulatory agencies and others, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could adversely impact the potential of the particular program, the likelihood of obtaining regulatory approval of the particular product candidate, commercialization of any approved product and the business prospects of the company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line, initial or preliminary data that we report differs from actual results, or if regulatory authorities or others, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be significantly impaired, which could materially harm our business, operating results, prospects or financial condition.

We may incur additional costs or experience delays in initiating or completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may experience delays in initiating or completing our preclinical studies or clinical trials, including as a result of delays in obtaining, or failure to obtain, the FDA's authorization to initiate clinical trials under future INDs. Additionally, we cannot be certain that preclinical studies or clinical trials for our product candidates will not require redesign, will enroll an adequate number of subjects on time, or will be completed on schedule, if at all. We may experience numerous unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive regulatory authorizations, regulatory approval or commercialize our product candidates, including:

- We we may receive feedback from regulatory authorities that requires us to modify the design or implementation of our preclinical stud or clinical trials or to delay or terminate a clinical trial;
- regulators or institutional review boards, or IRBs, or ethics committees may delay or may not authorize us or our investigators commence a clinical trial or conduct a clinical trial at a prospective trial site;
- We we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospec clinical research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly amo different CROs and trial sites;
- preclinical studies or clinical trials of our product candidates may fail to show safety or efficacy or otherwise produce negative inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or we n decide to abandon product research or development programs;
- preclinical studies or clinical trials of our product candidates may not produce differentiated or clinically significant results acr indications;

- the number of patients required for clinical trials of our product candidates may be larger than anticipated, enrollment in these clinical tr may be slower than anticipated or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a hig rate than anticipated;

- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, be unable to prov us with sufficient product supply to conduct or complete preclinical studies or clinical trials, fail to meet their contractual obligations to u a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clin trial sites or investigators;
- We we may elect to, or regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clin research for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our clinical tr are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than anticipated;
- clinical trials of our product candidates may be delayed due to complications associated with the ongoing COVID-19 pandemic;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may insufficient or inadequate, and any transfer of manufacturing activities may require unforeseen manufacturing or formulation changes;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us, regulators or IRBs or eth committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other hematologic disea therapies that raise safety or efficacy concerns about our product candidates;

- any future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us; and
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as anticipated.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions at which such trials are being conducted or by the FDA or other regulatory authorities, or if the Data Safety Monitoring Board, or DSMB, for such trial recommends suspension or termination of the trial. Such authorities may impose or recommend such a suspension or termination or clinical hold due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, adverse findings upon an inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. For example, we filed an IND in April 2022 with the FDA to initiate the AURORA Phase 2 trial of bitopertin in EPP patients, but the FDA initially placed the initiation of this trial on clinical hold; we received clearance to initiate the study in July 2022 after the study design was finalized with the FDA and initiated the study in October 2022. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA may disagree with our clinical trial design or our interpretation of data from clinical trials or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

Moreover, principal investigators for our current and future clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected the interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site, and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

Our product development costs will also increase if we experience delays in testing or regulatory approvals. We do not know whether any of our future clinical trials will begin as planned, or whether any of our current or future clinical trials will need to be restructured or will be completed on schedule, if at all. Significant preclinical study or clinical trial delays including those caused by the ongoing COVID-19 pandemic, also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may significantly harm our business, operating results, financial condition and prospects.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities, or as needed to provide appropriate statistical power for a given trial. In particular, because we are focused on patients with specific rare hematologic diseases for the development of our product candidates, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

We may experience difficulties with identifying specific patient populations for any defined trial cohorts. The patient eligibility criteria defined in our trial protocols may limit the patient populations eligible for our clinical trials. We will also rely on the willingness and ability of clinicians to screen their patients, such as for specific genetic hematologic conditions, to indicate which patients may be eligible for enrollment in our clinical trials.

In addition, some of our competitors have ongoing clinical trials for product candidates that are intended to treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may choose instead to enroll in clinical trials of our competitors' product candidates. Furthermore, our ability to enroll patients may be significantly delayed by the ongoing COVID-19 pandemic, and we cannot accurately predict the extent and scope of such delays at this point.

Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit or enroll a sufficient number of patients to complete our clinical trials because of the small patient populations with rare hematologic diseases, the perceived risks and benefits of the product candidates under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed.

Patient enrollment may be affected by other factors, including:

- the severity of the disease under investigation;
- the efforts to obtain and maintain patient consents and facilitate timely enrollment in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;

- reporting of the preliminary results of any of our clinical trials; and
- factors we may not be able to control, including the impacts of the COVID-19 pandemic, any public health crises, that may limit patie principal investigators or staff or clinical site availability.

Results from early preclinical studies and clinical trials of our programs and product candidates are not necessarily predictive of the results of later preclinical studies and clinical trials of our programs and product candidates. If we cannot replicate the results from earlier preclinical studies and clinical trials of our programs and product candidates in our later preclinical studies and clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates.

Any results from early preclinical studies and clinical trials of bitopertin, DISC-0974, DISC-0998, MWTX-003 DISC-3405 or our other product candidates or programs may not necessarily be predictive of the results from later preclinical studies and clinical trials. For example, DISC-0974 has undergone testing in healthy volunteers, a Phase 1b/2 clinical trial in patients with anemia of MF was initiated in June 2022 and a separate Phase 1b/2 clinical trial in patients with non-dialysis dependent CKD and anemia was initiated in February 2023. However, there can be no assurance that DISC-0974 will achieve the desired effects in these indications. Additionally, MWTX-003 has only been evaluated we initiated a Phase 1 clinical trial of DISC-3405 in pre-clinical models, healthy adult volunteers in October 2023, which may not be indicative or predictive of future clinical trial results. Similarly, even if we are able to complete our planned preclinical studies and clinical trials of our product candidates according to our current development timeline, the results from such preclinical studies and clinical trials of our product candidates may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain regulatory approval.

Our clinical trials or those of our future collaborators may reveal significant adverse events not seen in prior preclinical studies or clinical trials and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates regulated as drugs are safe and effective and our product candidates regulated as biologics are safe, pure and potent for use in each target indication. Clinical testing is expensive and can take many years to complete, and outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process. Because our programs and product candidates are in an early stage of development, there is a high risk of failure, and we may never succeed in developing marketable products. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials also may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. For example, Roche had previously developed bitopertin as a potential therapy for certain symptoms of schizophrenia and obsessive-compulsive disorder, but discontinued the program for lack of efficacy in those indications after completing over 30 clinical trials in over 4,000 individuals. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to the safety and efficacy of our programs and product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented from, or delayed in, obtaining regulatory approval for such product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures

set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or

comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims.

Further, our product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed, or if our product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In addition, our product candidates could cause undesirable side effects that have not yet been observed. For example, bitopertin may demonstrate toxicities in patients with hematologic diseases not previously observed by Roche when it was studied in different indications. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound. Most product candidates that commence clinical trials are never approved as products, and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development or regulatory approval of any of our product candidates.

As is the case with many treatments for hematologic and rare diseases, it is likely that there may be side effects associated with the use of our product candidates. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities, or an IRB may suspend or terminate clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Even if the side effects do not preclude the product from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, operating results, financial condition and prospects.

Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, which may result in greater research and development expenses, regulatory issues that could delay or prevent approval or discovery of unknown or unanticipated adverse effects on safety or efficacy.

Some of our product candidates modulate pathways for which there are currently no approved or effective therapies, which may result in uncertainty. We select programs for targets based on compelling biological rationale, including evidence of expected biological effects in humans. We explore new programs based on extensive preclinical data analysis which sometimes cannot predict efficacy or safety in humans. Regulatory approval of novel product candidates such as ours can be more expensive, riskier and take longer than for other, more well-known or extensively studied pharmaceutical or biopharmaceutical product candidates due to our and regulatory agencies' lack of experience with them. The novelty of the mechanism of action of any of our product candidates may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. The novel mechanism of action also means that fewer people are trained in or experienced with product candidates of this type, which may make it more

difficult to find, hire and retain personnel for research, development and manufacturing positions. If our product candidates utilize a novel mechanism

of action that has not been the subject of extensive study compared to more well-known product candidates, there is also an increased risk that we may discover previously unknown or unanticipated adverse effects during our preclinical studies and clinical trials. Our product candidates may achieve lower efficacy in patients than expected. Any such events could adversely impact our business prospects, operating results and financial condition.

We are currently conducting a Phase 2 clinical trial for bitopertin in Australia and may in the future conduct additional clinical trials of our product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

In July 2022, we initiated BEACON, a Phase 2 open-label, parallel-dose clinical trial of bitopertin in EPP and XLP patients that is being conducted at sites in Australia. We may in the future choose to conduct additional clinical trials of our product candidates outside the United States, including in Europe, Australia, or other foreign jurisdictions. The acceptance of trial data from clinical trials conducted outside the United States by the FDA may be subject to certain conditions. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practices, (ii) the trials were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials will be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any

comparable foreign regulatory authority, including the TGA, will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving regulatory approval or clearance for commercialization in the applicable jurisdiction.

Although we intend to explore other therapeutic opportunities in addition to the programs and product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional product candidates, our business could be materially harmed.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;

- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate tl are unlikely to be effective products; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our prod candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to devel diversify and expand our product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities. Before we can commercialize any of our product candidates, we must obtain regulatory approval. Currently, all of our product candidates are in discovery, preclinical or clinical development, and we have not received

approval to market any of our product candidates from regulatory authorities in any jurisdiction. It is possible that our product candidates, including any product candidates we may seek to develop in the future, will never obtain regulatory approval. We have limited experience in filing and supporting the applications necessary to gain regulatory approvals and relies rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use. In addition, regulatory authorities may find fault with our manufacturing process or facilities or that of third-party contract manufacturers. We may also face greater than expected difficulty in manufacturing our product candidates.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and often takes many years. If the FDA or a comparable foreign regulatory authority requires that we perform additional preclinical studies or clinical trials, approval may be delayed, if obtained at all. The length of such a delay varies substantially based upon a variety of factors, including the type, complexity and

novelty of the product candidate involved. Changes in regulatory approval policies during the development period, changes in or enactment of additional statutes or regulations, or changes in regulatory review policies for each submitted NDA, BLA, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- We may not be able to enroll a sufficient number of patients in our clinical trials;
- We may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidat safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulat authorities for approval;
- We may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trial
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, BLA or ot submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facili of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change such that our clin data are insufficient for approval.

Even if we were to obtain regulatory approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, thereby narrowing the commercial potential of the product candidate. In addition, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we experience delays in obtaining, or if we fail to obtain, approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

A public health crisis, pandemic, epidemic, or outbreak of an infectious or highly contagious disease, may materially and adversely affect our business and financial results and could cause a disruption to the development of our product candidates.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. The extent to which an outbreak of highly infectious or contagious diseases impacts our operations or those of our third-party partners, including our preclinical studies or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of the outbreak, actions taken to contain the outbreak or mitigate its impact, and the direct and indirect economic effects of the outbreak and containment measures, among others.

In addition, the patient populations that our product candidates target may be particularly susceptible to highly infectious or contagious diseases, which may make it more difficult for us to identify patients able to enroll in our current and future clinical trials and may impact the ability of enrolled patients to complete any such trials.

Risks Related to Commercialization

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new products in the biopharmaceutical and related industries is highly competitive. We compete in the segments of the pharmaceutical, biotechnology, and other related markets that develop therapies in the field of hematologic diseases. There are other companies focusing on developing therapies in the field of hematologic

diseases. We also compete more broadly across the market for cost-effective and reimbursable treatments. Some of these competitive products

and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future from segments of the pharmaceutical, biotechnology and other related markets. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. We believe principal competitive factors to our business include, among other things, our ability to successfully transition research programs into clinical development, ability to raise capital and the scalability of the platform, pipeline and business.

Many of the companies that we compete against or which we may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. If these or other barriers to entry do not remain in place, other companies may be able to more directly or effectively compete with us.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their products sooner than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, level of generic competition and availability of reimbursement from government and other third-party payors.

If the market opportunities for our programs and product candidates are smaller than we estimate or if any regulatory approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability could be

materially adversely affected.

The incidence and prevalence for the target patient populations of our programs and product candidates have not been established with precision. Our lead heme biosynthesis modulation product candidate, bitopertin, is an oral, selective inhibitor of GlyT1. We are initially focused on developing bitopertin for the treatment of EPP and XLP, which are both diseases marked by severe photosensitivity and damage to the hepatobiliary system caused by the accumulation of PPIX. In July 2022, we initiated BEACON, a Phase 2 open-label, parallel-dose clinical trial of bitopertin in EPP and XLP patients that is being conducted at sites in Australia. Separately, in October 2022, we initiated AURORA, a Phase 2, randomized, double-blind, placebo-controlled clinical trial of bitopertin in EPP patients that is being conducted at sites in the United States. We initiated a Phase 1b/2 clinical trial of DISC-0974 in June 2022 in the United States in patients with anemia of MF, and initiated a separate Phase 1b/2 clinical trial in the February 2023 in patients with non-dialysis dependent CKD and anemia. anemia, and initiated a Phase 1 clinical trial of DISC-3405 in healthy adult volunteers in October 2023. We are initially focused on developing MWTX-003 DISC-3405 for the treatment of PV. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our programs and product candidates, are based on our estimates.

The total addressable market opportunity will ultimately depend upon, among other things, the diagnosis criteria included in the final label, the indications for which our product candidates are approved for sale, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients with erythropoietic porphyria and anemias of inflammation for which our product candidates may be approved as treatment may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, which may prove to be the wrong choice and may adversely affect our business.

If our current product candidates or any future product candidates do not achieve broad market acceptance, the revenue that we generate from our sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if our current product candidates and any future product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we may obtain regulatory approval do not gain an adequate level of market acceptance, we may not generate significant revenue and may not become profitable or may be significantly delayed in achieving profitability. Market acceptance of our current product candidates and any future product candidates by the medical community, patients and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients, and patients may be reluctant to switch, from existing therapies even when new and potentially more effective or safer treatments enter the market. If public perception is influenced by claims that the use of heme biosynthesis modulation therapies or hepcidin-targeted agents is unsafe, whether related to our or our competitors' products, our products may not be accepted by the general public or the medical community. Future adverse events in the hematologic diseases or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our product candidates.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

Efforts to educate the medical community and third-party payors on the benefits of our current product candidates and any future product candidates may require significant resources and may not be successful. If our current product candidates or any future product candidates are approved but do not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any of our current product candidates and any future product candidates will depend on a number of factors, including:

- the efficacy of our current product candidates and any future product candidates;
- the prevalence and severity of adverse events associated with our current product candidates and any future product candidates;
- the clinical indications for which our product candidates are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling or those of comparable foreign regulatory authorities, includ potential limitations or warnings for our current product candidates and any future product candidates that may be more restrictive th other competitive products;
- changes in the standard of care for the targeted indications for our current product candidates and any future product candidates, wh could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable fore regulatory authorities, if obtained;
- the relative convenience and ease of administration of our current product candidates and any future product candidates;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third-party payors, including government healthcare programs such Medicare and Medicaid and other healthcare payors;
- the price concessions required by third-party payors to obtain coverage;
- the willingness of patients to pay out-of-pocket in the absence of adequate coverage and reimbursement;
- the extent and strength of our marketing and distribution of our current product candidates and any future product candidates;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later approved;

- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our current prod candidates and any future product candidates or to which we agree as part of a Risk Evaluation and Mitigation Strategy, or REMS, voluntary risk management plan;
- the timing of market introduction of our current product candidates and any future product candidates, as well as competitive products;
- our ability to offer our current product candidates and any future product candidates for sale at competitive prices;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- the approval of other new products;
- adverse publicity about our current product candidates and any future product candidates or favorable publicity about competi products; and
- potential product liability claims.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Further, due to the COVID-19 pandemic, millions of individuals have lost or will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products. It is unclear what effect, if any, the American Rescue Plan will have on the number of covered individuals.

We may not be successful in addressing these or other factors that might affect the market acceptance of our product candidates. Failure to achieve widespread market acceptance of our product candidates would materially harm our business, financial condition and results of operations.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions and even recall or market withdrawal if unanticipated safety issues are discovered following approval. In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, monitoring and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. For certain commercial prescription drug and biological products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. Additionally, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, sponsors of approved drugs and biologics must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory prod recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediatio

- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other saf information, including boxed warnings;
- imposition of a REMS which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- clinical trial holds;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocatior approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our Phase 2 clinical trials of bitopertin, Phase 1b/2 clinical trials of Disc-0974 DISC-0974 and planned Phase 1 clinical trial of MWTX-003 DISC-3405 and expect to rely on third parties to conduct other clinical trials for our product candidates, as well as potential investigator-sponsored clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely and expect to continue to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidates, including our Phase 2 clinical trials of bitopertin, Phase 1b/2 clinical trials of DISC-0974 in patients with anemia of MF or non-dialysis dependent CKD and anemia, our planned Phase 1 trial of MWTX-003, DISC-3405, as well as any other product candidates that we develop. We may also rely on academic and private non-academic institutions to conduct and sponsor clinical trials relating to our product candidates, such as the planned ongoing clinical trial of bitopertin in DBA, which will be is being conducted by NIH under a collaborative research and development agreement. We will not control the design or conduct of any investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if

investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future clinical trials ourself may be adversely affected.

We rely and expect to continue to rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of our activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs or other third parties will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We, our principal investigators and our CROs are required to comply with regulations, including GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic

Area, or the EEA, and comparable foreign regulatory authorities for any products in clinical development. The FDA

enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we, our principal investigators or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced under current Good Manufacturing Practice, or cGMP, regulations. Our failure or the failure of our principal investigators or CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, significantly increase our expenditures and could also subject us to enforcement action. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we designed our ongoing Phase 1b/2 clinical trials of DISC-0974, and ongoing Phase 2 clinical trials of bitopertin, and ongoing Phase 1 clinical trial of DISC-3405, and intend to design the future clinical trials for our product candidates, these trials are or will be conducted by CROs and we expect CROs will conduct all of our future clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future clinical trials also results in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or

- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the principal investigators or CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our principal investigators or CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party principal investigators or CROs terminate, we may not be able to enter into arrangements with alternative CROs. If principal investigators or CROs do not successfully carry out their contractual obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such principal investigators or CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We might not realize the anticipated benefits of our current collaborations with Mabwell or NIH, or any other collaborations we enter into in the future.

Research, development, commercialization and/or strategic collaborations, including those that we have with Mabwell and NIH, are subject to numerous risks, which include the following:

- collaborators may have significant control or discretion in determining the efforts and resources that they will apply to a collaboration, a might not commit sufficient efforts and resources or might misapply those efforts and resources;
- we may have limited influence or control over the approaches to research, development and/or commercialization of product candida in the territories in which our collaboration partners lead research, development and/or commercialization;
- collaborators might not pursue research, development and/or commercialization of collaboration product candidates or might elect no continue or renew research, development and/or commercialization programs based on preclinical studies

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and/or clinical trial results, changes in their strategic focus, availability of funding or other factors, such as a business combination t diverts resources or creates competing priorities;

- collaborators might delay, provide insufficient resources to, or modify or stop research or clinical development for collaboration prod candidates or require a new formulation of a product candidate for clinical testing;
- collaborators with sales, marketing and distribution rights to one or more product candidates might not commit sufficient resources sales, marketing and distribution or might otherwise fail to successfully commercialize those product candidates;
- collaborators might not properly maintain or defend our intellectual property rights or might use our intellectual property improperly or i way that jeopardizes our intellectual property or exposes us to potential liability;
- collaboration activities might result in the collaborator having intellectual property covering our activities or product candidates, wh

could limit our rights or ability to research, develop and/or commercialize our product candidates;

- collaborators might not be in compliance with laws applicable to their activities under the collaboration, which could impact collaboration and us;
- disputes might arise between a collaborator and us that could cause a delay or termination of the collaboration or result in costly litigat that diverts management attention and resources; and
- collaborations might be terminated, which could result in a need for additional capital to pursue further research, development and commercialization of our product candidates.

In addition, funding provided by a collaborator might not be sufficient to advance product candidates under the collaboration. If a collaborator terminates a collaboration or a program under a collaboration, including by failing to exercise a license or other option under the collaboration, whether because we fail to meet a milestone or otherwise, any potential revenue from the collaboration would be significantly reduced or eliminated. In addition, we will likely need to either secure other funding to advance research, development and/or commercialization of the relevant product candidate or abandon that program, the development of the relevant product candidate could be significantly delayed, and our cash expenditures could increase significantly if we are to continue research, development and/or commercialization of the relevant product candidates.

Any one or more of these risks, if realized, could reduce or eliminate future revenue from product candidates under our collaborations, and could have a material adverse effect on our business, financial condition, results of operations and/or growth prospects.

We have established collaborations with Mabwell and NIH and may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies, such as our collaborations with Mabwell and NIH, for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's own evaluation of a potential collaboration. Such factors a potential collaborator will use to evaluate a collaboration may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We are also restricted by Roche's right of first negotiation under our current license agreement with them and may in the future be restricted under other license or collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities

at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

In addition, any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

We contract with third parties for the manufacture of our product candidates for preclinical development and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities. Although we believe we have obtained sufficient material to produce bitopertin tablets to complete our ongoing Phase 2 clinical trials, DISC-0974 vials to complete our ongoing Phase 1b/2 clinical trials, and vials to complete our planned Phase 1 trial of MWTX-003, DISC-3405, we cannot be sure we have correctly estimated our drug product and API requirements or that such drug product or API will not expire before we want to use it. While we have identified a contract development and manufacturing organization, or CDMO, to produce our own GMP material, we are in the early stages of manufacturing such material. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical development and clinical testing, including Mabwell for the supply of vials to complete our planned Phase 1 trial of MWTX-003. DISC-3405. We also expect to rely on third parties for the commercial manufacture of our products if any of our product candidates receive regulatory approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by our CDMOs to manufacture our product candidates must be inspected by the FDA pursuant to pre-approval inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our CDMOs for compliance with cGMPs in connection with the manufacture of our product candidates. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to pass regulatory inspections and/or maintain regulatory compliance for our manufacturing facilities. In addition, we have no control over the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it finds deficiencies or withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

If any CDMO with whom we contract fails to perform its obligations, we may be forced to enter into an agreement with a different CDMO, which we may not be able to do on reasonable terms, if at all. In such a scenario, our clinical trials supply could be delayed significantly as we established alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CDMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Further, our failure, or the failure of our CDMOs, to comply with applicable regulations could result in sanctions being imposed on it, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license

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revocation, seizures or recalls of product candidates or products, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

We may be unable to establish any additional agreements with CDMOs or do so on acceptable terms. Reliance on CDMOs entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our product candidates and any products that we may develop may compete with other product candidates and approved products for access to manufacturing facilities. There are a limited number of CDMOs that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval. If our current CDMOs cannot perform as agreed, we may be required to replace such CDMOs. In addition, there has been increased governmental focus in the U.S. on contracting with Chinese companies for the development or manufacturing of pharmaceutical products. Efforts to discourage such contracting have included U.S. legislative proposals and a recent call from certain U.S. legislators to add WuXi AppTec Co., Ltd., WuXi's parent company, and the affiliated WuXi Biologics to the Department of Defense's Chinese Military Companies List (1260H list), the Department of Commerce's Bureau of Industry and Security Entity List, and the Department of Treasury's Non-SDN Chinese Military-Industrial Complex Companies List. While the Biden administration has yet to take action on this letter, adding either or both previously

mentioned WuXi entities on any or all of the aforementioned lists or other geopolitical tensions with China could lead to material supply chain disruptions or delays for our biologic drug candidates manufactured by WuXi Biologics. We may incur added costs and delays in identifying and qualifying any such replacement.replacement CDMOs.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

The third parties upon whom we rely for the supply of the active pharmaceutical ingredients used in our product candidates are our sole sources of supply, and the loss of any of these suppliers could significantly harm our business.

The active pharmaceutical ingredients, or API, used in certain of our product candidates are supplied to us from single-source suppliers. Our ability to successfully develop our product candidates, and to ultimately supply our commercial products in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API for these products in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. We do not currently have arrangements in place for a redundant or second-source supply of any such API in the event any of our current suppliers of such API cease their operations for any reason. We are also unable to predict how changing global economic conditions or potential global health concerns such as the COVID-19 pandemic or crises will affect our third-party suppliers and manufacturers. Any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

For all of our product candidates, we intend to identify and qualify additional manufacturers to provide such API prior to submission of an NDA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess our ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API used in our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory inspection or approval, which could result in further delay. While we seek to maintain adequate inventory of the API used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

The manufacture of biologics is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide supply of product candidates for clinical trials or products for patients, if approved, could be delayed or prevented.

DISC-0974, DISC-0998, and MWTX-003 DISC-3405 are monoclonal antibodies. Manufacturing biologics, like monoclonal antibodies, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities

specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain regulatory approval for any of our current product candidates or any future product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired, and we may not be able to compete effectively in our market.

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection in the U.S. and other countries for our current or future product candidates, including our current lead product candidates, bitopertin, DISC-0974 and MWTX-003, DISC-3405, and our other current or future programs, including DISC-0998, as well as for their respective compositions, formulations, methods used to manufacture them and methods of treatment, in addition to successfully defending these patents against third-party challenges. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the U.S. and abroad related to our proprietary technology, inventions, and improvements that are important to the development and implementation of our business. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

We have in-licensed, and may in the future in-license, a portion of our intellectual property, and, if we fail to comply with our obligations under these license arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property. In particular, we have exclusively licensed intellectual property rights from Roche to develop and commercialize bitopertin, including certain back-up compounds and derivatives, for all prophylactic and therapeutic uses. The Roche license covers know-how, and certain specified Roche patent rights, including a composition of matter patent for bitopertin that expires in 2025. We also have exclusively licensed intellectual property rights from AbbVie Deutschland GmbH & Co. KG, or AbbVie, to develop and commercialize DISC-0974 and DISC-0998. The AbbVie license covers know-how, and certain specified AbbVie patent rights, including composition of matter and methods of use patents and patent applications for DISC-0974 and DISC-0998. We also have exclusively licensed intellectual property rights from Mabwell Therapeutics, Inc., or Mabwell, to develop and commercialize antibody products containing Mabwell's MWTX-001, MWTX-002, and MWTX-003 antibodies. The Mabwell license covers know-how and certain specified Mabwell patent rights, including composition of matter and methods of use patents and patent applications for MWTX-001, MWTX-002 and MWTX-003.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The degree of patent protection we require to successfully commercialize our current or future product candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect bitopertin, DISC-0974, MWTX-003 DISC-3405 or our other current or future product candidates. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in-license is threatened, we could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. For example, in jurisdictions outside the U.S., a license may not be enforceable unless all the owners of the intellectual property agree or consent

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to the license. Accordingly, any actual or purported co-owner of our patent rights could seek monetary or equitable relief requiring us to pay it compensation for, or refrain from, exploiting these patents due to such co-ownership. Furthermore, patents have a limited lifespan. In the U.S., and most other jurisdictions in which we have undertaken patent filings, the natural expiration of a patent is generally twenty years after it is filed, assuming all maintenance fees are paid. Various extensions may be available, on a jurisdiction-by-jurisdiction basis; however, the life of a patent, and thus the protection it affords, is limited. Additionally, our product candidates may or may not be eligible for such extensions or we may not be able to obtain such protections due to procedural or other reasons. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, patents we may own or in-license may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our current or future product candidates, including generic versions of such drugs.

Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same compounds, methods, formulations or other subject matter, in either case that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until at least 18 months after the earliest priority date of the patent filing, or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in patents we may own or in-license patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to certain pending patent applications covering our current or future product candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the relevant patent office(s) may be significantly narrowed by the time they issue, if they ever do. It is also possible that we will fail to identify patentable aspects of our research and development output before

it is too late to obtain patent protection. Prosecution could require that claim scope narrow such that a clinical or product candidate or program is not adequately protected by the patent. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to establish and/or maintain a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. We may become involved in post-grant proceedings such as opposition, derivation, reexamination, *inter partes* review, post-grant review, invalidation, or interference proceedings challenging our patent rights or the patent rights of others from whom we may in the future obtain licenses to such rights, in the U.S. Patent and Trademark Office, or USPTO, the European Patent Office, or EPO, or in other countries. In addition, we may be subject to a third-party submission to the USPTO, the EPO, or elsewhere, that may reduce the scope or preclude the granting of claims from our pending patent applications. Competitors may allege that they invented the inventions claimed in our issued patents or patent applications prior to us, or may file patent applications before we do. Competitors may also claim that we are infringing their patents and that we therefore cannot practice our technology as claimed under our patents or patent applications. Competitors may also contest our patents by claiming to an administrative patent authority or judge that the invention was not patent-eligible, was not original, was not novel, was obvious, and/or lacked inventive step, and/or that the patent application filing failed to meet relevant requirements relating to description, basis, enablement, clarity, and/or support; in litigation, a competitor could claim that our patents, if issued, are not valid or are unenforceable for a number of reasons. If a court or administrative patent authority agrees, we would lose our protection of those challenged patents.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, without payment to it, or could limit the duration of the patent protection covering our technology and current or future product candidates. Such challenges may also result in our inability to manufacture or commercialize our current or future product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent patents we may own or in-license by developing similar or alternative technologies or products in a non-infringing manner. For example, a third-party may develop a competitive product that provides benefits similar to one or more of our current or future product candidates but that has a different composition that falls

outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our current or future product candidates could be negatively affected, which would harm our business.

Furthermore, even if we are able to issue patents with claims of valuable scope in one or more jurisdictions, we may not be able to secure such claims in all relevant jurisdictions, or in a sufficient number to meaningfully reduce competition. Our competitors may be able to develop and commercialize their products, including products identical to ours, in any jurisdiction in which we are unable to obtain, maintain or enforce such patent claims. Furthermore, generic manufacturers may develop, seek approval for and launch generic versions of our products, and may challenge the scope, validity or enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings.

We also intend to rely on regulatory exclusivity for protection of our product candidates, if approved for commercial sale. Implementation and enforcement of regulatory exclusivity, which may consist of regulatory data protection and market protection, varies widely from country to country. Failure to qualify for regulatory exclusivity or failure to obtain or to maintain the extent or duration of such protections that we expect for our product candidates, if approved, could affect our decision on whether to market the products in a particular country or countries or could otherwise have an adverse impact on our revenue or results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, deadlines, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. We may miss a filing deadline for patent protection on these inventions.

The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after issuance of any patent. In addition, periodic maintenance fees, renewal fees, annuity fees and/or various other government fees are required to be paid periodically. While an inadvertent lapse can, in some cases, be cured by payment of a late fee, or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

If our trademarks and trade names for our products or company name are not adequately protected in one or more countries where we intend to market our products, we may delay the launch of product brand names, use different trademarks or tradenames in different countries, or face other potentially adverse consequences to building our product brand recognition.

Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO or from comparable agencies in foreign jurisdictions objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. If we are unable to obtain a registered trademark or establish name

recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents we may own or in-license, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that may not be patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information or technology that may not be covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our

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collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S.

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and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us.

Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or

research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be ineffective or breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may initiate, become a defendant in or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming, and unsuccessful.

Competitors may infringe any patents we may own or in-license. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license is not valid or is unenforceable or that the other party's use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop the other party from using the technology at issue on the grounds that any patents we may own or in-license do not cover the technology in question or that such third-party's activities do not infringe our patent applications or any patents we may own or in-license. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in-license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of its greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Post-grant proceedings provoked by third parties or brought by or before the USPTO or other patent granting authority may be necessary to determine the validity or priority of inventions with respect to our patent applications or any patents we may own or in-license. These proceedings are expensive and an unfavorable outcome could result in a loss of our current patent rights and

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could require us to cease using the related technology or to attempt to license rights to us from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. In addition to potential USPTO post-grant proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices or courts where our patents may be challenged. The costs of these proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result in a post-grant challenge proceeding may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post-grant proceedings within patent offices may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and

distract our management and other employees. We may not be able to prevent, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may not be able to detect infringement against any patents we may own or in-license. Even if we detect infringement by a third party of any patents we may own or in-license, we may choose not to pursue litigation against or settlement with the third party. If we later sue such third-party for patent infringement, the third-party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third party.

Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. As noted above, some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our current or future product candidates, if approved. Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

We may be subject to damages or settlement costs resulting from claims that we or our employees have violated the intellectual property rights of third parties, or are in breach of our agreements. We may be accused of, allege or otherwise become party to lawsuits or disputes alleging wrongful disclosure of third-party confidential information by us or by another party, including current or former employees, contractors or consultants. In addition to diverting attention and resources to such disputes, such disputes could adversely impact our business reputation and/or protection of our proprietary technology.

The intellectual property landscape relevant to our product candidates and programs is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including derivation, interference, reexamination, *inter partes* review and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our current or future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate

or otherwise violate their intellectual property rights. We cannot assure you that our current or future product candidates and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other valid intellectual property rights owned by third parties. For example, many of our employees were

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previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants and advisors, even those related to one or more of our current or future product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims.

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While certain activities related to development and clinical testing of our current or future product candidates may be subject to safe harbor of patent infringement, such as under 35 U.S.C. §271(e)(1), upon receiving regulatory approval for such candidates we or any of our current or future licensors or strategic partners may immediately become party to, exposed to or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that such product candidates infringe, misappropriate or otherwise violate their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our current or future product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our current or future product candidates, technologies or methods.

If a third party claims that we infringe, misappropriate or otherwise violate its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement, misappropriation and other intellectual property claims which, regardless of merit, may be expensive and time-consuming litigate and may divert our management's attention from our core business and may impact our reputation;
- substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the prod candidate or technology at issue infringes, misappropriates or violates the third party's rights, and, if the court finds that the infringem was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our current product candidates, including bitopertin, DIS 0974 and MWTX-003, DISC-3405, or future product candidates, or from using our proprietary technologies, unless the third-party licens its product rights to us, which we are not required to do, on commercially reasonable terms or at all;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cro licenses to intellectual property rights for our products, or the license to us may be non-exclusive, which would permit third parties to u the same intellectual property to compete with us;
- redesigning our current or future product candidates or processes so they do not infringe, misappropriate or violate third-party intellect property rights, which may not be possible or may require substantial monetary expenditures and time; and

- there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securi analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospectsprospects.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our current or future product candidates or proprietary technologies.

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted in U.S. courts only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our current or future product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after their earliest priority filing date, and publications in the scientific literature often lag behind actual discoveries, We we cannot be certain that others have not filed patent applications covering our current or future

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product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over our patent applications or patents we may own or in-license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending third-party patent applications which may later result in issued patents that our current or future product candidates may infringe. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our current or future product candidates or other technologies, could be found to be infringed by our current or future product candidates or other technologies. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our current or future product candidates, molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including patient selection methods, the holders of any such patent

may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our current or future product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our current or future product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our current or future product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our current or future product candidates, which could harm our business significantly.

We may be unable to obtain patent or other intellectual property protection for our current or future product candidates or our future products, if any, in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

We may not be able to pursue patent coverage of our current or future product candidates in all countries. Filing, prosecuting and defending patents on current or future product candidates in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the U.S. These products may compete with our current or future product candidates and in jurisdictions where we do not have any issued patents, our patent applications or other intellectual property rights may not be effective or sufficient to prevent them from competing. Much of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products and/or methods of using biopharmaceutical products, which could make it difficult for us to stop the infringement of any patents we may

own or in-license or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce any rights we may have in our patent applications or any patents we may own or in-license in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we may own or in-license at risk of being invalidated or

interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around

the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents we may own or license that are relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

We may not obtain or grant licenses or sublicenses to intellectual property rights in all markets on equally or sufficiently favorable terms with third parties.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected current or future product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in any agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are party to license agreements with Roche, AbbVie and Mabwell and we may from time to time in the future be party to other license and collaboration agreements with third parties to advance our research or allow commercialization of current or future product candidates. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. See “Business-Collaborations and License Agreement” for more information regarding our license agreements with Roche, AbbVie and Mabwell. In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our current or future product candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and

commercialization of certain of our current or future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;

- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of current or future product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licens and us and our partners.

In addition, the agreements under which we may license intellectual property or technology from third parties are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected current or future product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Any granted patents we may own or in-license covering our current or future product candidates or other valuable technology could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the U.S. or abroad, including the USPTO and the EPO. A patent asserted in a judicial court could be found invalid or unenforceable during the enforcement proceeding. Administrative or judicial proceedings challenging the validity of our patents or individual patent claims could take months or years to resolve.

If we or our licensors or strategic partners initiate legal proceedings against a third party to enforce a patent covering one of our current or future product candidates, the defendant could counterclaim that the patent covering our product candidate, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of patentable subject matter, lack of written description, lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO that was material to patentability, or made a misleading statement, in the process of obtaining the patent during patent prosecution. Third parties may also raise similar claims before administrative bodies in the

U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post grant review and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patent applications or any patents we may own or in-license in such a way that they no longer cover our current or future product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, any rights we may have from our patent applications or any patents we may own or in-license, allow third parties to commercialize our current or future product candidates or other technologies and compete directly with us, without payment to us or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our or our current or future licensors' priority of invention or other features of patentability with respect to our patent applications and any patents we may own or in-license. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our current or future product candidates and other technologies. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our current or future licensing partners and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our current or future product candidates. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and current or future product candidates.

Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the current or future product candidates we may develop. The loss of exclusivity or the narrowing of our patent application claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our current or future product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the U.S. and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first inventor to file" system. The first-inventor-to-file provisions, however, only

became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the U.S. and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might subject us to infringement claims or adversely affect our ability to develop and market our current or future product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the U.S. and abroad that is relevant to or necessary for the commercialization of our current or future product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. As mentioned above, patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our current or future product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our current or future product candidates or the use of our current or future product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope and/or validity of a patent or a pending application may be incorrect, which may negatively impact our ability to market our current or future product candidates. We may incorrectly determine that our current or future product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our current or future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our current or future product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our current or future product candidates that are held to be infringing. We might, if possible, also be forced to redesign current or future product candidates so that we no longer infringes the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not guarantee commercial success of current or future product candidates or other business activities. Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- patent applications that we own or may in-license may not lead to issued patents;
- patents, should they issue, that we may own or in-license, may not provide us with any competitive advantages, may be narrowed scope, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology, including compounds that are similar to the chemical compositions of current or future product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims any patents we may own or in-license, should any patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by a patent applicat that we own or may in-license;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering a particu invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating intellectual property rights;
- our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from pat infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and n then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us fr exercising exclusive rights, or any rights at all, over that intellectual property;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third-party may subsequently file a pat covering such trade secrets or know-how;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants regulatory approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the

product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In short, the foreign regulatory approval process involves all of the risks associated with FDA approval. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we may intend to charge for our products will also be subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable regulatory approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

We may seek priority review designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

We may seek orphan drug designation for certain of our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

We have received orphan drug designation from the FDA for bitopertin for the treatment of EPP. EPP and for DISC-3405 for the treatment of PV. As part of our business strategy, we may seek orphan drug designation for certain of our product candidates and indications, as appropriate. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug or biologic as an orphan drug if it is a product intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population of 200,000 or more in the United States where there is no reasonable expectation that the cost of developing the product will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Union, the European Commission, upon the recommendation of the EMA's Committee for Orphan Medicinal Products, grants orphan drug designation to promote the development in respect of drugs products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not no more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). European Union. Additionally, designation is may be granted for drugs products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug product in Europe the European Union would be generate sufficient return to justify the necessary investment in developing the drug. product. In Europe, each case, there must be no satisfactory method of diagnosis, prevention, or treatment of the applicable condition which is authorized for marketing in the European Union (or, if such a method exists, the applicable product would be of significant benefit to those affected by the condition). In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers. The European Committee for Orphan Medical Products adopted a positive opinion on Orphan Designation for bitopertin for treatment of EPP.

Generally, if a product with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same product and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. the European Union. The European Union market exclusivity period can be reduced to six years if, at the end of the fifth year, it is determined that a product no longer meets the criteria for orphan drug designation, or including if the product is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for one of our product candidates, that exclusivity may not effectively protect our product candidate from competition because different products can be approved for the same condition. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition or if another product with the same active moiety is determined to be safer, more effective, or represents a major contribution to patient care. Orphan drug designation neither shortens

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the development time or regulatory review time of a product nor gives the product any advantage in the regulatory review or approval process. While we may seek orphan drug designation for our product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

The FDA may further reevaluate its regulations and policies under the Orphan Drug Act. We do not know if, when or how the FDA may change its orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

We may seek rare pediatric disease designation for bitopertin. However, a marketing application for bitopertin, if approved, may not meet the eligibility criteria for a rare pediatric disease priority review voucher.

We may seek rare pediatric disease designation for bitopertin in patients with EPP and XLP. The FDA defines “rare pediatric disease” as a (i) serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect ages from birth to 18 years, including age groups often called neonates, infants, children and adolescents; and (ii) a rare disease or condition within the meaning of the Orphan Drug Act. Designation of a product candidate as a product for a rare pediatric disease does not guarantee that a marketing application for such product candidate will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Under the Federal Food, Drug, and Cosmetic Act, we will need to request a rare pediatric disease priority review voucher in our original marketing application for our product candidates for which we have received rare pediatric disease designation. The FDA may determine that a marketing application for bitopertin, if approved, does not meet the eligibility criteria for a priority review voucher.

Under the current statutory sunset provisions, after September 30, 2024, the FDA may only award a priority review voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for the drug or biologic that is the subject of such application, and that designation was granted by September 30, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. However, it is possible the authority for FDA to award rare pediatric disease priority review vouchers will be further extended by Congress. As such, if we do not obtain approval of a marketing application for bitopertin in patients with EPP and XLP on or before September 30, 2026, and if the priority review voucher program is not extended by Congressional action, we may not receive a priority review voucher.

A breakthrough therapy designation and fast track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process, and each designation does not increase the likelihood that any of our product candidates will receive regulatory approval in the United States.

We may seek a breakthrough therapy designation for certain of our product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates are designated as breakthrough therapies, the FDA may later withdraw the designation if it determines that such product candidates no longer meet the conditions for such designation.

We were granted fast track designation by the FDA for DISC-3405 for the treatment of PV in September 2023 and for DISC-0974 for the treatment of anemia in non-dialysis dependent chronic kidney disease in February 2024, and we may seek fast track designation for certain of our product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, the FDA may disagree and instead decide not to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation no longer meets the conditions for such designation. Fast track designation alone does not guarantee qualification for the FDA’s priority review procedures.

Accelerated approval by the FDA, even if granted for our current or any other future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive regulatory approval.

We may seek accelerated approval of our current or future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that

is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. It is possible that at the time of submission of a marketing application, the FDA may determine that our product candidate is not eligible for accelerated approval or that accelerated approval is not warranted. Moreover, FDA may revise how it implements accelerated approval, which could negatively affect the development of our current or future product candidates.

As a condition of approval, the FDA generally requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. Under FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory trial or trials be underway prior to approval or within a specified time period after the date accelerated approval is granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such trials, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct confirmatory studies in a timely manner, send the necessary updates to the FDA, or if such post-approval trials fail to verify the product's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory trial or submit timely reports to the agency on their progress. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products being considered for accelerated approval, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

If our drug product candidates or any of our future drug product candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such products, which may result in a material decline in sales of our competing products.

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, or the FDCA, a company may file an abbreviated new drug application, or ANDA, seeking approval of a generic version of an approved innovator product. Under the Hatch-Waxman Amendments, a company may also submit an NDA under section 505(b)(2) of the FDCA that references the FDA's prior approval of the innovator product or preclinical studies and/or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Amendments also provide for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication "Approved Drug Products with Therapeutic Equivalence

Evaluations," known as the Orange Book. If there are patents listed in the Orange Book for the applicable, approved innovator product, a generic or 505(b)(2) applicant that seeks to market our product before expiration of the patents must include in their applications what is known as a "Paragraph IV" certification, challenging the validity or enforceability, or claiming non-infringement, of the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

Accordingly, if any of our product candidates that are regulated as drugs are approved, competitors could file ANDAs for generic versions of these products or 505(b)(2) NDAs that reference our products. If there are patents listed for such drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or licenses, despite expending a significant amount of resources that could have been focused on other areas of our business. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and our sales would likely decline rapidly and materially.

If approved, our investigational products regulated as biologics may face competition from biosimilars or interchangeable products approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product. Under the BPCIA, an application for a biosimilar or interchangeable product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar or interchangeable product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar or interchangeable product, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain regulatory approval for

biosimilars or interchangeable products referencing our products, our products may become subject to competition from such biosimilars or interchangeable products, with the attendant competitive pressure and consequences.

The FDA, the EMA and other regulatory authorities may implement additional regulations or restrictions on the development and commercialization of our product candidates, and such changes can be difficult to predict.

The FDA, the EMA and regulatory authorities in other countries have each expressed interest in further regulating biotechnology products. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to the COVID-19 pandemic, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the U.S. and global healthcare systems that could prevent or delay regulatory approval of our current or future product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain regulatory approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. In the U.S., there have been and continue to be, on-going legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, or the ACA, was passed, as amended by the Health Care and Education Reconciliation Act of 2010, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as

a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, and provided incentives to programs that increase the federal government's comparative effectiveness research. Since then, the ACA risk adjustment program payment parameters have been updated annually.

Since the ACA's ACA's enactment, there have been numerous judicial, administrative, executive and legislative challenges to certain aspects of the ACA and we expect that there will be additional challenges and amendments to the ACA in the future. On June 17, 2021, for example, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without

specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, In addition, President Biden has issued an Executive Order multiple executive orders that have sought to initiate reduce prescription drug costs. Although a special enrollment period from February 15, 2021 number of these and other proposed measures may require authorization through August 15, 2021 for purposes of obtaining health insurance coverage through additional legislation to become effective, and the ACA marketplace. The Executive Order also instructed certain governmental agencies Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to review and reconsider their existing policies and rules that limit access seek new legislative measures to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. control drug costs. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- On August 2, 2011, the The U.S. Budget Control Act of 2011, among other things, for example, included aggregate reductions of Medicare payments to providers of 2% per fiscal year which that will remain in effect through 2031. Due to the Statutory Pay-As-You-G Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation.
- On January 2, 2013, the The U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recove overpayments to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual an small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the The Right to Try Act was signed into law. The law, among other things, (2018) provides a federal framewo certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are underg investigation for FDA approval.

Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

- On May 23, 2019, CMS published a final rule to allow that allows Medicare Advantage Plans the option of using step therapy for Part drugs, beginning effective January 1, 2020.

- On December 20, 2019, former President Trump signed into law The U.S. American Rescue Plan Act of 2021, which eliminates the Further Consolidated Appropriations statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price for single source and innovator multiple source drugs, effective January 1, 2024. Due to the Statutory Pay-As-You-Go Act (H.R. 1865) which repealed of 2010, estimated budget deficit increases resulting from the Cadillac tax, the health insurance provider tax, American Rescue Plan Act of 2021, and the medical device excise tax. It is impossible subsequent legislation, Medicare payments to determine whether similar taxes could providers will be instated further reduced starting in the future. 2025 absent further legislation.

There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, In addition, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to: (i) support legislative reforms has issued multiple executive orders that would lower the prices of have sought to reduce prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations, as well as to continue to clarify and improve the approval framework for generic drugs and biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede generic drug and biosimilar competition. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021, CMS rescinded the Most Favored

Nations rule. Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. This deadline was pushed back further to January 1, 2027 by the Bipartisan Safer Communities Act and could potentially be pushed back to January 1, 2032 by the Inflation Reduction Act. Further, on December 31, 2020, CMS published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co-pay assistance is passed on to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug, or the Accumulator Rule. On May 17, 2022, the U.S. District Court for the District of Columbia granted the Pharmaceutical Research and Manufacturers of America's (PhRMA) motion for summary judgement invalidating the Accumulator Rule. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize

manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. costs. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

On August 7, 2022 the U.S. Senate passed the Inflation Reduction Act of 2022, which, among other things, The IRA includes several provisions that reduce may impact our business, depending on how various aspects of the IRA are implemented. Provisions that may impact our business include a $2,000 out-of-pocket spending cap for Medicare Part D beneficiaries, from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; imposes imposition of new manufacturer financial liability on certain most drugs under in Medicare Part D, allows permitting the U.S. government to negotiate Medicare Part B and Part D price caps pricing for certain high-cost drugs and biologics without generic or biosimilar competition; requires competition, requiring companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; inflation, and delays delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of which is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, or the frequency with which any such product candidate is prescribed or used, which could result in reduced demand for our current or future product candidates or additional pricing pressures. In particular any policy changes through CMS as well as local state Medicaid programs could have a significant impact on our business.

Our revenue prospects could be affected by changes in healthcare spending and policy in the U.S. and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;

- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Our relationships with customers, healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished future profits and earnings.

Although we do not currently have any products on the market, once we begin commercializing our product candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain regulatory approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offeri receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthc programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific inten violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up three times the remuneration involved, imprisonment of up to ten years, and exclusion from government healthcare programs. In additi the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Stat constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties. The Anti-Kickba Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribe purchasers and formulary managers, on the other. The HHS, Office of Inspector General, or OIG, heavily scrutinizes relationsh between pharmaceutical companies and persons in a position to generate referrals for or the purchase of their products, such physicians, other healthcare providers, and pharmacy benefit managers, among others. However, there are a number of statut exceptions and regulatory safe harbors protecting some common activities from prosecution;
- the federal civil and criminal false claims and civil monetary penalties laws, including the federal False Claims Act, or FCA, which impos criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenti or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statemen avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA ev when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent clai In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickba Statute constitutes a false of fraudulent claim for purposes of the False Claims Act. The federal False Claims Act also permits a priv individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the federal False Clai Act and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executin scheme to defraud any healthcare benefit program (e.g. public or private), or knowingly and willfully falsifying, concealing or covering u

material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or spec intent to violate it in order to have committed a violation;

- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the ACA, which requ manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Hea Insurance Program to report to HHS information related to transfers of value made to physicians, nurse practitioners, certified nu anesthetists, physician assistants, clinical nurse specialists, and certified nurse midwives as well as teaching hospitals. Manufacturers also required to disclose ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially ha consumers; and
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, wh such reported prices may be used in the calculation of reimbursement and/or discounts on approved products.

We are also subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state and require the registration of pharmaceutical sales representatives. State and foreign laws, including for example the European Union General Data Protection Regulation, also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

In the U.S., to help patients afford our approved product, we may utilize programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In addition, in November 2013, the CMS issued guidance to the issuers of qualified health plans sold through the ACA's ACA's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the OIG of the HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons. It is possible

that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. The OIG has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's donor’s product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses and reduce the availability of foundation support for our patients who need assistance.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have

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recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the exclusion from participation in federal and state government funded healthcare programs, such as Medicare and Medicaid, reputational harm, and the curtailment or restructuring of our operations. It may also subject us to additional reporting obligations and oversight, if we become subject to a corporate integrity agreement, deferred prosecution agreement, or other agreement to resolve allegations of non-compliance with these laws. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to similar criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Compliance with U.S. and global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. We possess and process sensitive customer information, including patient health information. Other In the U.S., there are numerous federal and state laws that restrict the use and protect the privacy and data security laws and regulations governing the collection, use, disclosure and protection of personally identifiable personal information, including health information privacy laws, security breach notification laws and consumer protection laws. These federal and state laws, in many cases, are not preempted by HIPAA and may be subject to varying interpretations by the courts and government agencies. These varying interpretations can create complex compliance issues for us and our partners and potentially expose us to additional expense, adverse publicity and liability, any of which could adversely affect our business. There is ongoing concern from privacy advocates, regulators and others regarding data privacy and security issues, and the number of jurisdictions with data privacy and security laws has been increasing. Also, there are ongoing public policy discussions regarding whether the standards for de-identification, anonymization or pseudonymization of health information are sufficient, and the risk of re-identification sufficiently small, to adequately protect patient privacy. We expect that there will continue to be new proposed and amended laws, regulations and industry standards concerning privacy, data protection and information security in the United States, such as States. For example, California enacted the California Consumer Privacy Act, or CCPA, as amended which took effect on January 1, 2020, and became enforceable by the California Attorney General on July 1, 2020. This law broadly defines personal information, gives California residents expanded rights to access and delete their personal information, and places stringent privacy and security obligations on businesses covered by the law, including obligations to provide detailed disclosures to California consumers about their data collection, use and sharing practices, and to provide such consumers with ways to opt out of certain sales or transfers of personal information. It also provides for civil penalties for violations, and allows for a private right of action for data breaches that is expected to increase data breach litigation. In addition, the California Privacy Rights Act, or CPRA, which amendments went into effect became effective on January 1, 2023, The significantly

modified the CCPA creates specific obligations by expanding consumer rights with respect to processing and storing personal certain sensitive information, and the CPRA amendments created creating a new state agency that is vested with authority to implement and enforce the CCPA. Additionally, a

Comprehensive laws similar law went into effect to the CCPA have been passed in Virginia on January 1, 2023, and further U.S.-state comprehensive privacy laws are set to go into effect throughout 2023, including laws in Colorado, Connecticut, and Utah. numerous other states outside of California. These laws are substantially similar in scope and contain many of the same requirements and exceptions as the CCPA, including a general exemption for clinical trial data and limited obligations for entities regulated by HIPAA. However, we cannot yet determine the full impact these laws or other such future laws, regulations and standards may have on our current or future business. Any of these laws may broaden their scope in the future, and similar laws have been proposed on both a federal level and in more than half of the states in the U.S. A In addition, a number of other states have proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. Furthermore, in addition to comprehensive privacy laws, certain states have enacted laws to focus on particular more limited privacy laws. For example, the state of Washington has passed a law to protect medical and health information not subject to HIPAA. This law has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric information. The existence of comprehensive

privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted.

The collection, use, storage, disclosure, transfer or other processing of personal data regarding individuals in the EEA and UK, including personal health data, is subject to the EU General Data Protection Regulation 2016/679, or EU GDPR, which became effective on May 25, 2018. with respect to individuals in the EEA and the UK General Data Protection Regulation (following the incorporation of the EU GDPR into UK law), or UK GDPR, with respect to individuals in the UK, and together with the EU GDPR, GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to having a legal basis for processing health and other personal data, stricter requirements relating to processing sensitive data (such as health data), where required by GDPR obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, requiring data protection impact assessments for high risk processing and taking certain measures when engaging third-party processors. The GDPR permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million (17.5 million for the UK) or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR increased our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be is a rigorous and time-intensive process that may

increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

The GDPR provides that EEA Member States may make their own further laws and regulations in relation to the processing of genetic, biometric or health data, which could result in differences between Member States, limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition.

The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA and UK not deemed adequate for the transfer of such personal data by competent data protection authorities, or third countries, including the United States. We are subject to evolving and strict rules on the transfer of personal data out of the EEA to third countries such as the United States. Unless the destination country is an adequate country (as recognized by the European Commission), States in certain circumstances unless a derogation exists or we will be required may need to incorporate a GDPR transfer mechanism (such as the European Commission approved standard contractual clauses, or SCCs) SCCs or the UK International Data Transfer Addendum, or IDTA) into our agreements with third parties to govern such transfers of personal data outside and carry out transfer impact assessments. Further, the EEA. The new SCCs may also impact our business as companies based in European Union and United States have adopted its adequacy decision for the EEA may be reluctant to utilize EU-U.S. Data Privacy Framework, or the new clauses to legitimize transfers Framework, which entered into force on July 11, 2023. This Framework provides that the protection of personal data to third countries given the burdensome requirements of transfer impact assessments and the substantial obligations that the new SCCs impose upon exporters.

In addition, further to the UK's exit from transferred between the European Union or EU, on January 31, 2020 the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR into UK law, referred to as the UK GDPR. The UK GDPR and the United States is comparable to that offered in the European Union. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK Data Protection Act 2018 set out transfers to the UK's United States. The Framework could be challenged like its predecessor frameworks. The international transfer obligations under the EEA and UK data protection regime, which is independent from but currently still aligned to the EU's data protection regime. Non-compliance with the UK GDPR regimes will require effort and cost and may result in monetary penalties us needing to make strategic considerations around where EEA/UK personal data is located and which service providers we can utilize for the processing of up to £17.5 million or 4% of worldwide revenue, whichever is higher. EEA/UK personal data.

Although the UK is regarded as a third country under the EU's EU GDPR, the European Commission has now issued a decision an "Adequacy Decision" recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in subject to the EU GDPR to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. It is not subject to the new forms of SCCs but has issued its own transfer mechanism – the UK international data transfer agreement – which, like the SCCs, requires exporters to carry out a transfer impact assessment. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The UK Government has also now introduced a Data Protection and Digital Information Bill, or the UK Bill, into the UK legislative process with the intention for this bill to reform the UK's data protection regime following Brexit. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EU data protection regime and threaten the UK Adequacy Decision from the EU Commission. This may lead to additional compliance costs and could increase our overall risk.

All of these evolving compliance and operational requirements impose potentially significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. If we or third-party CDMOs, CROs or other contractors or consultants fail to comply with U.S. and international data protection laws and regulations, it could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business, financial condition, results of operations and prospects.

The use of new and evolving technologies, such as artificial intelligence, in our business may result in spending material resources and presents risks and challenges that can impact our business including by posing security and other risks to our confidential and/or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability.

We may use and integrate artificial intelligence into our business processes, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the European Union's Artificial Intelligence Act, or the AI Act, the world's first comprehensive AI law, is anticipated to enter into force in Spring 2024 and, with some exceptions, become effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of high risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for European Union ethical principles in their development and use of these systems. If we develop or use AI systems that are governed by the AI Act, it may necessitate ensuring higher standards of data quality, transparency, and human oversight, as well as adhering to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. The rapid evolution of artificial intelligence will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that artificial intelligence is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate artificial intelligence tools into their offerings, and the providers of these artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to

any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Risks Relating to Employee Matters and Managing Growth

Our future success depends on our ability to retain key executives and experienced scientists and to attract, retain, and motivate qualified personnel.

We are highly dependent on many of our key employees and members of our executive management team as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment letter agreements with certain of our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees, including temporary loss due to illness, could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology

companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

In particular, we have experienced a very competitive hiring environment in the greater Boston area of Massachusetts, where we are headquartered. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

We may be unable to adequately protect our information systems and infrastructure from cyberattacks or security compromises, incidents or breaches, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems and infrastructure that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data and other confidential and/or proprietary data, such as names, mailing addresses, email addresses, phone numbers and clinical trial information. A successful cyberattack could result in the theft, destruction or destruction misuse of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks generally are increasing in their

frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, employees, contractors or other third-parties and industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data or compromise the security,

confidentiality, integrity and availability. availability of systems and information. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of protected information or confidential business information, including personal data, financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources designed to protect our information systems and infrastructure, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent or adequately address information security compromises, incidents or breaches that would result in business, legal, financial or reputational harm to it, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches, compromises or incidents or improper access to, use of, or disclosure of protected information, including our clinical data or patients' personal data could result in significant liability through litigation and regulatory investigations and enforcement actions, including under state (e.g., state breach notification and consumer protection laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the GDPR), and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies, vulnerabilities, compromises, incidents or breaches. We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain protected information and our sensitive information. If we or our third-party providers fail to maintain or protect our information technology systems, infrastructure and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems and infrastructure, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks, and any such attacks could result in the losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenue or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or adequately mitigate security breaches, compromises or incidents or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or adequately mitigate the impact of such security or data privacy incidents, compromises or breaches, we could be exposed to litigation and governmental investigations, inquiries, orders, penalties or fines, which could lead to a potential disruption to our business. business and financial penalties or losses. By way of example, the CCPA, which was modified by the CPRA, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties of up to $7,500 per violation, as well as a private right of action for data breaches that has, and is expected to continue to, increase the volume of data breach litigation. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and related litigation filed in other states.California.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of February 28, 2023 February 29, 2024, we had 46 74 full-time employees and no part-time employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly as we function as a public company and in the areas of product development, regulatory affairs and, if any of our product candidates receives regulatory approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

General RisksRisk Factors

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations.

Actual events Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide

liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept placed into receivership. Although

a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB (such as our Company) would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of our lenders or counterparties Subsequent to any such instruments were to be these events, additional financial institutions have experienced similar failures and have been placed into receivership, we may be unable to access such funds. In addition, if any of our customers, suppliers or receivership. It is possible that other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns banks will face similar difficulty in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis. For example, we had significant amounts of cash and cash equivalents held in operating accounts at SVB which were largely uninsured. If we were unable to recover our cash on deposit it could have resulted in material losses to the Company and may have had a material adverse impact on our business.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. future.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to, or reductions in borrowings available under revolving existing credit facilities or other working capital sour and/or delays, inability or reductions in the company's ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require the Company to maintain letters of credit or other credit support arrangements;
- Potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- Potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our customers or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on the Company, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer or supplier bankruptcy or insolvency, or the failure of any customer to make payments when due, or any breach or default by a customer or supplier, or the loss of any significant supplier relationships, could result in material losses to the Company and may have a material adverse impact on our business.

Changes in tax law may adversely affect us or our investors.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law. Prospective investors should consult their tax advisors regarding the potential consequences of changes in tax law on our business and on the ownership and disposition of our common stock.

Our future taxable income may be subject to certain limitations.

As of December 31, 2022 December 31, 2023, we had federal and state net operating loss carryforwards of $69.3 million $88.1 million and $67.7 million $91.7 million, respectively, which respectively. Substantially all of the federal NOLs are not subject to expiration and the state NOLs begin to expire in various amounts in 2037. As of December 31, 2022 December 31, 2023, we also had federal and state research and development tax credit carryforwards of $2.7 million $5.8 million and $1.1 million $1.8 million, respectively, which begin to expire in 2032. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under current law, unused U.S. federal and certain state net operating losses generated for tax years beginning after December 31, 2017 are not subject to expiration and may be carried forward indefinitely. Such U.S. federal net operating losses generally may not be carried back to prior taxable years, except that, net operating losses generated in 2019, 2020 and 2021 may be carried back to each of the five tax years preceding the tax years of such losses. For taxable years beginning after December 31, 2020, the deductibility of U.S. federal net operating losses generated for tax years beginning after December 31, 2017 is limited to 80% of our taxable income in any future taxable year. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs when one or more stockholders or groups of stockholders who each owns at least 5% of a corporation's stock increase their aggregate stock ownership by more than 50 percentage points over their lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change after the merger, our ability

to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase in time. We currently engage, and expect to continue to engage, third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, in 2008, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets and the current COVID-19 pandemic has caused significant volatility and uncertainty in U.S. and international markets. See “Risks Related to the Discovery and Development of Our Product Candidates-The ongoing COVID-19 pandemic, or a similar Candidates-A pandemic, epidemic, or outbreak of an infectious or highly contagious disease may materially and adversely affect our business and financial results and could cause a disruption to the development of our product candidates.” Interest rates in the U.S. have recently increased to levels not seen in decades. In addition, the impact of geopolitical tension, such as a deterioration in the bilateral relationship between the United States and China or an escalation in conflict between Russia and Ukraine and between Israel and Hamas, including any resulting sanctions, export controls or other restrictive actions, also could lead to disruption, instability and volatility in the global markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our products. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements or insider trading.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Other activities subject to these laws include the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourself or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The market price of our common stock is expected to be volatile.

The market price of our common stock following the merger could be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of clinical trials and preclinical studies of our product candidates, or those of our competitors or our existing or future collaborato
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- if we do not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales a marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protect for our technologies;

- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opini regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions or market conditions in the pharmaceutical and biotechnology sectors;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations and continued development of our product candidates;
- trading volume of our common stock;
- announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commer relationships or capital commitments;
- adverse publicity relating to precision medicine product candidates, including with respect to other products in such markets;
- the introduction of technological innovations or new therapies that compete with our products and services; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 or otherwise could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

We will incur additional costs and increased demands upon management as a result of complying with the laws and regulations affecting public companies.

We will incur significant legal, accounting and other expenses as a public company that we did not incur as a private company, including costs associated with public company reporting obligations under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our management team consists of our executive officers prior to the merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to

gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

Once we are no longer an emerging growth company, a smaller reporting company or otherwise no longer qualify for applicable exemptions, we will be subject to additional laws and regulations affecting public companies that will increase our costs and the demands on management and could harm our operating results.

We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition as well as other disclosure and corporate governance requirements. However, as an emerging growth company we may take advantage of exemptions from various requirements such as an exemption from the requirement to have our independent auditors attest to our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002 as well as an exemption from the "say on pay" voting requirements pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. After we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which may allow us to take advantage of some of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive

compensation in our periodic reports and proxy statements. Even after we no longer qualify as an emerging growth company, we expect to still qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Exchange Act, in at least the near term, which will allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10-K and in our periodic reports and proxy statements. Once we are no longer an emerging growth company, a smaller reporting company or otherwise qualify for these exemptions, we will be required to comply with these additional legal and regulatory requirements applicable to public companies and will incur significant legal, accounting and other expenses to do so. If we are not able to comply with the requirements in a timely manner or at all, our financial condition or the market price of our common stock may be harmed. For example, if we or our independent auditor identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses we could face additional costs to remedy those deficiencies, the market price of our stock could decline or we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may discourage any takeover attempts our stockholders may consider favorable, and may lead to entrenchment of management.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws could delay or prevent changes in control or changes in management without the consent of the board of directors. These provisions will include the following:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elec at one time;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- a prohibition on stockholder action by written consent, which means that all stockholder action must be taken at an annual or spe meeting of the stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the Chief Executive Offi or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to the board of directors;
- a requirement that no member of the board of directors may be removed from office by stockholders except for cause and, in additior any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of voting stock then entitled to v in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of voting stock to amend any bylaws by stockholder act or to amend specific provisions of the certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder appro and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

We will also be subject to the anti-takeover provisions contained in Section 203 of the DGCL, or Section 203. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our certificate of incorporation and bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation and bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against it arising pursuant to any provisions of the DGCL, our certificate of incorporation or our bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The exclusive forum provision does not apply to actions arising under the Exchange Act. Our amended and restated bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act. The provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors,

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officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in the certificate of incorporation and bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future.

An active trading market for our common stock may not develop and our stockholders may not be able to resell their shares of common stock for a profit, if at all.

Prior to the merger, there had been no public market for shares of our capital stock. An active trading market for shares of our common stock may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our existing securityholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after legal restrictions on resale discussed in this our Annual Report on Form 10-K for the year ended December 31, 2023 lapse, the trading price of our common stock could decline. As of December 31, 2022 December 31, 2023, we have 17,403,315 had 24,360,233 shares of common stock outstanding. Of the shares of common stock, approximately 11,132,590 shares will be available for sale in the public market beginning 180 days after the closing of the merger as a result of the expiration of lock-up agreements between us on the one hand and certain of our securityholders on the other hand. All other outstanding shares of common stock, other than shares held by our affiliates will be freely tradable, without restriction, in the public market. In addition, shares of common stock that are subject to outstanding options of ours will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these shares are sold, the trading price of our common stock could decline.

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

Our executive officers, directors and principal stockholders, in the aggregate, beneficially own approximately 70% 53% of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our

common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

We will have broad discretion in the use of our cash and cash equivalents and may invest or spend our cash and cash equivalents in ways with which you do not agree and in ways that may not increase the value of your investment.

We will have broad discretion over the use of our cash and cash equivalents . equivalents. You may not agree with our decisions, and our use of our cash and cash equivalents may not yield any return on your investment. Our failure to apply these resources effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our cash resources.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

None. ITEM 1C. CYBERSECURITY

Cyber Risk Management and Strategy

Disc Medicine, under the oversight of the audit committee of the board of directors, has implemented and maintains processes to review and manage enterprise risks, including annual assessments of cybersecurity risks, across the Company.

Our cybersecurity risk management program, which is informed by and incorporates elements of recognized industry standards, is designed to identify, assess, and mitigate critical risks from cybersecurity threats. This program includes, but is not limited to, ongoing monitoring for potential critical risks from cybersecurity threats using automated tools. To support our cybersecurity risk management program, we leverage a managed service provider (MSP) that provides ongoing support for the protection of our information technology infrastructure as well as a virtual Chief Information Security Officer, or vCISO. Our cybersecurity risk management strategy is informed by periodic conversations with, and risk assessments conducted by, our vCISO.

We have an employee security awareness training program, offered upon employee onboarding and on an annual basis, that is designed to raise awareness of cybersecurity threats across functions as well as to encourage consideration of cybersecurity risks across our Company. As part of this employee training program, we periodically conduct phishing simulations designed to raise employee awareness of such risks.

We have also implemented a process to review contractual requirements related to information security obligations included in our agreements with certain third-party vendors and service providers, as appropriate.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition; however, like other companies in our industry, we and our third-party vendors may, from time to time, experience threats and security incidents relating to our and our third-party vendors' information systems and infrastructure. For more information, please see Item 1A - Risk Factors.

Governance Related to Cybersecurity Risks

Our Head of Information Technology (IT), under the oversight of our General Counsel, is responsible for the administration and maintenance of our cybersecurity risk management program, including the day-to-day oversight of the assessment and management of cybersecurity risks. The individual who currently holds the title of Head of IT has more than 20 years of experience in information security and cybersecurity risk management.

Our Head of IT directly reports to, and meets periodically with, our General Counsel to discuss and review our cybersecurity risk management processes, with input from the Company's MSP and vCISO, as appropriate.

Our board of directors has delegated oversight of the Company's cybersecurity program to the audit committee of the board of directors. As provided in the audit committee charter, the audit committee is responsible for reviewing and discussing the Company's information security and risk management programs, controls, and procedures, including high-level review of the threat landscape facing the Company and the Company's strategy to mitigate cybersecurity risks and potential breaches. Under the audit committee charter, the audit committee is also responsible for reviewing the recovery and communication plans for any unplanned outage or security breach.

Our Head of IT, twice a year, provides reports to the audit committee on the status of our cybersecurity program, including measures implemented to monitor and address risks from cybersecurity threats, as appropriate. He also reports on a quarterly basis to the executive committee on cybersecurity and information technology matters. The chair of the audit committee provides periodic reports on cybersecurity risk management to the full board of directors. Our General Counsel, on an annual basis, discusses the results of our enterprise risk assessment processes, including risks related to cybersecurity, with the full board of directors.

ITEM 2. PROPERTIES

Our principal office is located at 321 Arsenal Street, Suite 101, Watertown, MA 02472, where we lease and sublease a total of approximately 7,566 16,847 square feet of office space. The lease term began in November 2021 and sublease terms will end in November 2026. We believe that these facilities will be adequate for our near-term needs. If required, we believe that suitable additional or substitute space will be available in the future on commercially reasonable terms to accommodate any such expansion of our operations.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Certain Information Regarding the Trading of Our Common Stock

Our common stock commenced trading on the Nasdaq Global Market under the symbol "GMTX" on February 8, 2021. Prior to this time, there was no public market for our common stock. On December 29, 2022, we completed our previously announced merger transaction with Gemini in accordance with the terms of the Agreement and Plan of Merger, or the Merger Agreement, dated August 9, 2022, pursuant to which Gemstone Merger Sub, Inc., or Merger Sub, merged with and into Disc Medicine Opco, Inc. (f/k/a Disc Medicine, Inc.), or Disc Opco, with Disc Opco continuing as a wholly owned subsidiary of Gemini and the surviving corporation of the merger. On December 29, 2022, in connection with, and prior to the completion of, the merger, Gemini effected a 1-for-10 reverse stock split of its common stock. In connection with the closing of the merger, Gemini also changed its name to Disc Medicine, Inc. On December 30, 2022, following the completion of the merger, our common stock began trading on the Nasdaq Capital Market under the symbol "IRON."

Holders of Record

As of February 28, 2023 February 29, 2024, there were 66 19 holders of record of shares of our common stock. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

Dividends

We have never declared or paid cash dividends on our common stock, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, then applicable contractual restrictions and any other factors deemed relevant by our board of directors.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Recent Sales of Unregistered Securities

Except as previously disclosed in our Form 8-K filed with the SEC on December 29, 2022, we did not sell any other securities that have not been registered under the Securities Act during the period covered by this Annual Report on Form 10-K.

Use of Proceeds from Initial Public Offering

Not applicable.

Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing at the end of this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of novel treatments for patients suffering from serious hematologic diseases. We have assembled a portfolio of clinical and preclinical product candidates that aim to modify fundamental biological pathways associated with the formation and function of red blood cells, specifically heme biosynthesis and iron homeostasis. Our current pipeline includes bitopertin for the treatment of erythropoietic porphyrias, or EPs, including erythropoietic protoporphyria, or EPP, and X-linked protoporphyria, or XLP, and Diamond-Blackfan Anemia, or DBA; DBA; DISC-0974 for the treatment of anemia of myelofibrosis, or MF, and anemia of chronic kidney disease, or CKD; and MWTX-003 DISC-3405 (formerly MWTX-003) for the treatment of polycythemia vera, or PV, and other hematologic disorders. In addition, our preclinical programs also include DISC-0998, for the treatment of anemia associated with inflammatory diseases. Our approach to product candidate development leverages well-understood molecular mechanisms that have been validated in humans. We believe that each of our product candidates, if approved, has the potential to improve the lives of patients suffering from hematologic diseases.

Bitopertin is the lead product candidate in our heme biosynthesis modulation portfolio. Bitopertin was previously evaluated by F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., or collectively, Roche, in a comprehensive clinical program in over 4,000 individuals in other indications which demonstrated the activity of bitopertin as a glycine transporter 1, or GlyT1, inhibitor and its effect on heme biosynthesis. We are planning to initially develop developing bitopertin for the treatment of EPs, including EPP and XLP. In July 2022, we initiated BEACON, a Phase 2 open-label, parallel-dose clinical trial of bitopertin in EPP and XLP patients that is being conducted at sites in Australia. Separately, in July 2022, we received clearance of our Investigational New Drug application, or IND, from the U.S. Food and Drug Administration, or FDA, for, and in In October 2022, we initiated AURORA, a Phase 2, randomized, double-blind, placebo-controlled clinical trial of bitopertin in EPP patients that is being conducted at sites in the United States. We expect presented interim data from BEACON in the first half of June and December 2023, and we expect topline data from AURORA by year-end 2023. in March or April 2024. Additional analysis of the full population in the BEACON trial is anticipated to be presented in 2024. We entered into a collaborative research and development agreement with the National Institutes of Health, or NIH, to conduct an NIH-sponsored clinical trial of bitopertin in DBA. The FDA authorized the clinical trial to proceed and we expect the trial to begin by mid-year began in July 2023. We are planning additional trials of bitopertin in other indications.

DISC-0974 is the lead product candidate in our iron homeostasis portfolio. portfolio and was in-licensed from AbbVie Deutschland GmbH & Co. KG, or AbbVie. DISC-0974 is designed to suppress hepcidin production and increase serum iron levels. We submitted an IND to the FDA for DISC-0974 in June 2021, received clearance in July 2021, and participants completed a Phase 1 clinical trial in healthy volunteers in the U.S. in June 2022 with results showing an acceptable tolerability profile and evidence of target engagement, iron mobilization and augmented erythropoiesis. We initiated a Phase 1b/2 clinical trial in June 2022 in patients with anemia of MF, and initiated a separate Phase 1b/2 clinical trial in February 2023 in patients with non-dialysis dependent CKD and anemia. We expect presented interim data from both of these trials in 2023. December 2023 and anticipate additional interim data presentations in 2024. In addition, we are developing a preclinical anti-hemojuvelin, or HJV, monoclonal antibody, DISC-0998, which also targets hepcidin suppression and was in-licensed from AbbVie

Deutschland GmbH & Co. KG, or AbbVie. DISC-0998 is designed to increase serum iron levels and has an extended serum half-life as compared to DISC-0974. We believe this profile may be desirable in certain subsets of patients with anemia associated with inflammatory diseases.

Lastly, we are developing MWTX-003, DISC-3405, a monoclonal antibody against Transmembrane Serine Protease 6, or TMPRSS6, that we licensed from Mabwell Therapeutics, Inc., or Mabwell. MWTX-003 DISC-3405 is part of our iron homeostasis portfolio and is designed to induce hepcidin production and reduce serum iron levels. An IND for MWTX-003 has been DISC-3405 was cleared by the FDA, and we plan to initiate a Phase 1 clinical trial in healthy adult volunteers was initiated in October 2023. Interim data is anticipated to be presented in the first and second half halves of 2023. 2024. We expect to develop MWTX-003 DISC-3405 for the treatment of PV and other hematologic disorders.

Reverse Merger with Gemini

On August 9, 2022, Disc Medicine, Inc., a Delaware corporation, or Private Disc, entered into an Agreement and Plan of Merger and Reorganization, or the Merger Agreement, with Gemini Therapeutics, Inc., a Delaware corporation, or Gemini, Gemstone Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Gemini, or Merger Sub.

On December 29, 2022, Private Disc completed the merger with Gemini, or the merger. Gemini changed its name to Disc Medicine Inc., and Private Disc changed its name to Disc Medicine Opco, Inc., a wholly-owned subsidiary of Disc Medicine, Inc. On December 30, 2022, our common stock began trading on The Nasdaq Capital Market under the ticker symbol “IRON.”

Financial Operations Overview

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future, if at all. If our development efforts are successful and result in commercialization of one or more product candidates or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales, payments from such collaboration or license agreements or a combination thereof.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of our product candidates. These expenses include:

- employee-related expenses, including salaries, benefits, and stock-based compensation expense, for personnel engaged in research a development functions;
- expenses incurred in connection with our research and development activities, including under agreements with third parties such consultants, contractors and CROs;

- costs related to contract development and manufacturing organizations, or CDMOs, that are primarily engaged to provide drug substa and product for our preclinical studies, clinical trials and research and development programs, as well as investigative sites a consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- the costs of acquiring and manufacturing preclinical study and clinical trial materials, including manufacturing registration and valida batches;
- costs related to compliance with quality and regulatory requirements; and
- payments made under third-party licensing agreements.

We expense research and development costs as incurred. Costs incurred for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and may be reflected in our consolidated financial statements as prepaid or accrued expenses. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses and expensed as the related goods are delivered or the services are performed or when it is no longer expected that the goods will be delivered or the services rendered.

We typically use our employee and infrastructure resources across product candidates and development programs. We track outsourced external development costs by product candidate or development program, but we do not allocate personnel costs or other internal costs to specific product candidates or development programs.

We expect that our research and development expenses will increase substantially as we advance our programs into and through clinical development. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any product candidates we may develop. A change in the outcome of any number of variables with respect to product candidates we may develop could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any

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product candidates we may develop. The successful development of any product candidate is highly uncertain. This is due to the numerous risks and uncertainties associated with product development, including the following:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the ability to raise additional funds necessary to complete clinical development of and commercialize our product candidates;
- our ability to establish new licensing or collaboration arrangements and the progress of the development efforts of third parties with wh we may enter into such arrangements;

- our ability to maintain our current research and development programs and to establish new programs;
- the successful initiation, enrollment and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to FDA or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities for any product candidates;
- the availability of raw materials for use in production of our product candidates;

- establishing agreements with third-party manufacturers for supply of product candidate components for our clinical trials;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally
- our ability to protect our other rights in our intellectual property portfolio;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- obtaining and maintaining third-party insurance coverage and adequate reimbursement for any approved products.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, corporate and business development, and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters, including noncapitalizable transaction costs; professional fees for accounting, auditing, tax compliance and administrative consulting services; investor and public relations expenses; director and officer insurance costs and other insurance costs; and facility related expenses including maintenance and allocated expenses for rent and other operating costs.

We anticipate that our general and administrative expenses will increase substantially in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also expect that we will incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services, director and officer insurance costs and investor and public relations expenses.

Other Income

Interest Income

Interest income primarily consists of interest earned on cash equivalents, consisting of money market fund accounts. funds, U.S. treasury notes and certificates of deposit.

Change in Fair Value of Contingent Value Right Liability

In December 2022, we entered into the CVR Agreement, described in more detail in Notes 1 and 4 to our consolidated financial statements, which provided a CVR to Gemini's pre-merger common stockholders to receive common stock from the Company upon its receipt of certain proceeds, calculated in accordance with the CVR Agreement, resulting from a disposition of Gemini's pre-merger assets within one year after the closing of the merger. The disposition period ended December 29, 2023 and no dispositions of Gemini's pre-merger assets were made during the disposition period. Therefore, there were no CVR payments made to the holders and there will not be any future CVR payments to the holders. The CVR liability was measured at fair value as of each reporting date and the change in the fair value for the period was recorded in the consolidated statements of operations and comprehensive loss in the change in fair value of contingent value right liability.

Change in Fair Value of Derivative Liability

In May 2021, we entered into the Roche Agreement, described in more detail in Notes 4 and 8 to our consolidated financial statements, which included an obligation to issue a variable number of shares of our common stock to Roche for no additional consideration upon the completion of a Roche Qualified Transaction as defined by the Roche Agreement. The liability is was measured

at fair value as of each reporting date and the change in the fair value for the period is was recorded in the consolidated statements of operations and comprehensive loss in the change in fair value of derivative liability. The liability was settled upon the completion of the merger on December 29, 2022.

Results of Operations

Comparison of the Years Ended December 31, 2022 December 31, 2023 and 2021 2022

The following table summarizes our results of operations for the years ended December 31, 2022 December 31, 2023 and 2021 2022 (in thousands):

	Year Ended December 31,			Year Ended December 31,		
	2022	2021	CHANGE	2023	2022	Change
Operating expenses:						
Research and development	$ 33,437	$ 25,170	$ 8,267	$ 69,264	$ 33,437	$ 35,827
General and administrative	14,038	5,763	8,275	21,861	14,038	7,823
Total operating expenses	47,475	30,933	16,542	91,125	47,475	43,650
Loss from operations	(47,475)	(30,933)	(16,542)	(91,125)	(47,475)	(43,650)
Other income (expense), net:						
Interest income	709	14	695	14,797	709	14,088
Change in fair value of derivative liability	(61)	(5,050)	4,989	—	(61)	61
Other expense				(2)	—	(2)
Total other income (expense), net	648	(5,036)	5,684	14,795	648	14,147
Loss before income taxes				(76,330)	(46,827)	(29,503)
Income tax expense				(99)	—	(99)
Net loss	$ (46,827)	$ (35,969)	$ (10,858)	$ (76,429)	$ (46,827)	$ (29,602)

Research and Development Expenses

The following table summarizes our research and development expenses for the years ended December 31, 2022 December 31, 2023 and 2021 2022 (in thousands):

	Year Ended December 31,			Year Ended December 31,		
	2022	2021	CHANGE	2023	2022	Change
DISC-3405				$ 20,168	$ —	$ 20,168
Bitopertin	$ 8,783	$ 8,354	$ 429	17,271	8,783	8,488
DISC-0974	10,241	7,019	3,222	9,136	10,241	(1,105)

Other research programs and expenses				7,066	5,236	1,830
Personnel-related (including equity-based compensation)	9,177	4,709	4,468	15,623	9,177	6,446
Other research programs and expenses	5,236	5,088	148			
Total research and development expenses	33,437	25,170	$ 8,267	$ 69,264	$ 33,437	$ 35,827

Research and development expenses were $69.3 million for the year ended December 31, 2023, compared to $33.4 million for the year ended December 31, 2022, compared to $25.2 million for the year ended December 31, 2021. The increase of $8.3 million $35.8 million in research and development expenses was primarily due to a $4.5 million $20.2 million increase related to the DISC-3405 program which incurred $15.0 million in upfront and milestone license fees in 2023, a $8.5 million increase in bitopertin development expense related to increased clinical study and drug manufacturing activity, and a $6.4 million increase in personnel-related costs related to higher research and development headcount, and $3.2 million including an increase of $1.2 million in the DISC-0974 program as a result of increased clinical CRO spend. stock-based compensation.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the years ended December 31, 2022 December 31, 2023 and 2021 2022 (in thousands):

	Year Ended December 31,			Year Ended December 31,		
	2022	2021	CHANGE	2023	2022	Change
Personnel-related (including equity-based compensation)	$ 6,983	$ 2,692	$ 4,291	$ 10,481	$ 6,983	$ 3,498
Legal, consulting and professional fees	6,252	2,661	3,591	7,448	6,252	1,196
Other expenses	803	410	393	3,932	803	3,129
Total general and administrative expenses	14,038	5,763	$ 8,275	$ 21,861	$ 14,038	$ 7,823

General and administrative expenses were $21.9 million for the year ended December 31, 2023, compared to $14.0 million for the year ended December 31, 2022, compared to $5.8 million for the year ended December 31, 2021. The increase of $8.3 million $7.8 million in general and administrative expenses was primarily due to a $4.3 million an increase of $3.5 million in personnel-related costs related due to higher general and administrative headcount, including an increase of $2.3 million in stock-based compensation, and a $3.6 million an increase

of $3.1 million in legal, audit and other services primarily due to the recognition of $2.2 million of deferred transaction costs in legal and consulting fees expenses related to increased costs as a planned equity financing that was superseded by the merger. public company.

Other Income (Expense), Net

Other income, net was $14.8 million for the year ended December 31, 2023, compared to other income, net of $0.6 million for the year ended December 31, 2022, compared to other expense of $5.0 million for the year ended December 31, 2021. The change of $5.7 million $14.1 million in other income (expense), net was primarily due to the change an increase in fair value of our derivative liability of $5.0 million related to the Roche Agreement. interest income based on a larger cash and cash equivalents balance and higher interest rates.

100 Income Tax Expense

Income tax expense was $0.1 million for the year ended December 31, 2023, compared to no expense for the year ended December 31, 2022. The increase in expense relates to state income tax resulting from an increase in interest income.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses. We expect to continue to incur significant expenses and operating losses for in the foreseeable future as we advances advance the clinical development of our product candidates. We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials and manufacturing for our product candidates to support commercialization and providing general and administrative support for our operations, including the costs associated with operating as a public company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources. See “Risk Factors” for additional risks associated with our substantial capital requirements.

To date, we have funded our operations primarily with proceeds from the sale of our convertible preferred stock and common stock, and the proceeds from the merger with Gemini. Gemini, proceeds from at-the-market offerings, proceeds from a registered direct offering and proceeds from a follow-on public offering. Through December 31, 2022 December 31, 2023, we have received gross net proceeds of $145.0 million $144.5 million from sales of our Series Seed, Series A and Series B convertible preferred stock, gross proceeds of $89.5 million from the merger with Gemini, $53.5 million from sales of common stock in a pre-closing private financing, $62.4 million from sales of common stock and gross proceeds pre-funded warrants in a registered direct offering, $147.9 million from sales of $97.4 million common stock and pre-funded warrants in a public follow-on offering and $26.4 million from the merger with Gemini. at-the-market offerings. As of December 31, 2022 December 31, 2023, we had cash and cash equivalents of $194.6 million $360.4 million.

We have incurred significant operating losses since inception and, as of December 31, 2022 December 31, 2023, had an accumulated deficit of $112.2 million $188.6 million. In addition, we expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future. We believe that our current cash resources will enable us to fund our current planned operating expense and capital expenditure requirements for at least twelve months from the date of issuance of these consolidated financial statements, March 31, 2023. well into 2026. We may also pursue additional cash resources through public or private equity offerings, collaborations or debt financings.

Cash Flows

The following table provides information regarding our cash flows for each period presented (in thousands):

Year Ended December 31,		Year Ended December 31,	
2022	2021	2023	2022

Net cash provided by (used in):				
Operating activities	$ (42,252)	$ (27,534)	$ (73,462)	$ (42,252)
Investing activities	(151)	(68)	(89)	(151)
Financing activities	148,978	89,929	239,379	148,978
Net increase in cash and cash equivalents and restricted cash	$ 106,575	$ 62,327		
Net increase in cash, cash equivalents and restricted cash			$ 165,828	$ 106,575

Operating Activities

Our cash flows from operating activities are greatly influenced by our use of cash for operating expenses and working capital requirements to support our business. We have historically experienced negative cash flows from operating activities as we

invested in developing our portfolio, drug discovery efforts, conducting clinical trials and manufacturing, and related infrastructure. The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges and changes in components of operating assets and liabilities, which are primarily the result of increased expenses and timing of vendor payments.

During the year ended December 31, 2023, net cash used in operating activities of $73.5 million was primarily due to our net loss of $76.4 million and changes in operating assets and liabilities of $3.0 million, offset by non-cash expenses of $5.9 million primarily related to stock-based compensation expense of $5.5 million.

During the year ended December 31, 2022, net cash used in operating activities of $42.3 million was primarily due to our net loss of $46.8 million, offset by non-cash expenses of $2.4 million and changes in operating assets and liabilities of $2.1 million primarily related to accounts payable and accrued expenses assumed in the merger.

During the year ended December 31, 2021, net cash used in operating activities of $27.5 million was primarily due to our net loss of $36.0 million, offset by non-cash expenses of $7.2 million and changes in operating assets and liabilities of $1.3 million. Non-cash expenses included $6.5 million of expense related to non-cash license expense for Roche and the change in the fair value of the Roche liability.

Investing Activities

During the years ended December 31, 2022 December 31, 2023 and 2021, 2022, net cash used in investing activities was due to purchases of property and equipment.

Financing Activities

During the year ended December 31, 2023, net cash provided by financing activities of $239.4 million consisted primarily of net proceeds of $147.9 million from sales of common stock and pre-funded warrants in a public follow-on offering, net proceeds of $62.4 million from sales of common stock and pre-funded warrants in a registered direct offering and aggregate net proceeds of $26.4 million from the at-the-market offerings.

During the year ended December 31, 2022, net cash provided by financing activities of $149.0 million consisted primarily of $97.4 million of net cash proceeds from the completion of the merger with Gemini and $53.5 million of net cash proceeds from the pre-closing

financing.

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During the year ended December 31, 2021, net cash provided by financing activities of $89.9 million consisted primarily of net proceeds from the sale and issuance of our Series B convertible preferred stock in September 2021.

Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates into and through clinical development and operate as a public company. Our funding requirements and the timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates or any future prod candidates we may develop;
- the costs, timing and outcome of regulatory review of our product candidates;
- changes in laws or regulations applicable to any product candidates we may develop, including but not limited to clinical trial requireme for approvals;
- the cost and timing of obtaining materials to produce adequate product supply for any preclinical or clinical development of any prod candidate we may develop;
- the effect of competing technological and market developments;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of su arrangements;
- the payment or receipt of milestones, royalties and other collaboration-based revenues, if any;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for a product candidate we may develop for which we obtain marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receives rece marketing approval; and
- the legal costs involved in prosecuting patent applications and enforcing patent claims and other intellectual property claims.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial

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success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Market volatility resulting from the COVID-19 pandemic or other factors could also adversely impact our ability to access capital as and

when needed. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourself. ourselves.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of December 31, 2022 December 31, 2023 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods (in thousands):

	Payments Due by Period					Payments Due by Period				
	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years
Operating lease commitments(1)	$ 1,485	$ 373	$ 677	$ 633	$ —	$ 2,424	$ 845	$ 1,579	$ —	$ —
Total	$ 1,485	$ 373	$ 677	$ 633	$ —	$ 2,424	$ 845	$ 1,579	$ —	$ —

(1) Amounts reflect payments due for our leased and subleased office space spaces in Watertown, Massachusetts as of December 31, 2022 December 31, 2023. The lease term terms began in November 2021 and will June 2023, and both end in November 2026.

We enter into contracts in the normal course of business with CROs, CDMOs and other third parties for preclinical studies, clinical trials and manufacturing services. These contracts typically do not contain minimum purchase commitments and are generally cancelable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation and, in the case of certain arrangements with CROs and CDMOs, may include non-cancelable fees. These payments are not included in the table above as the amount and timing of such payments are not fixed and estimable.

We have also entered into license agreements under which we are obligated to make specified milestone and royalty payments. We have not included future payments under these agreements in the table of contractual obligations above since the payment obligations under these agreements are contingent upon future events such as regulatory milestones or generating product sales. We are unable to estimate the timing or likelihood of achieving these milestones or generating future product sales. For additional information about our license agreements and amounts that could become payable in the future under such agreements, see our consolidated financial statements. See also “Licensing Agreements.”

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of our

consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Contract Costs and Accruals

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued and prepaid research and development expenses. This process involves reviewing open contracts and purchase orders, communicating

with applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and makes adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical studies and clinical trials; and
- CDMOs in connection with the production of preclinical study and clinical trial materials.

The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our

estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period.

Fair Value of Derivative Liability

In May 2021, we entered into a license agreement (the “Roche Agreement”) with F. Hoffmann-La Roche Agreement Ltd. and Hoffmann-La Roche Inc. (together, “Roche”) pursuant to which Roche granted us an exclusive and sublicensable worldwide license under certain patent rights and know-how to develop, manufacture and commercialize certain compounds (the “Compounds”) as further described in Notes 4 and 8 to our consolidated financial statements. Note 8. We recognized a liability in connection with the Roche Agreement which includes included an obligation to issue a variable number of shares of our common stock to Roche for no additional consideration upon our completion of an initial public offering or certain merger transactions a (a “Roche Qualified Transaction.” The number of shares of common stock to be issued to Roche was estimated to be approximately 2.85% of the outstanding shares of our common stock as of immediately after the completion of a Roche Qualified Transaction. We had determined that the obligation to issue common stock upon completion of a Roche Qualified Transaction represented a liability classified financial instrument. The liability was measured at fair value as of each reporting date and the change in the fair value for the period was recorded in the consolidated statements of operations in the change in fair value of derivative liability. Transaction”). Prior to its settlement in Q4 2022, the fair value measurement of the derivative liability was classified as Level 3 under the fair value hierarchy as it had been was valued using certain unobservable inputs. These inputs included: (1) our estimated shares outstanding and fair value per share upon completion of a Roche Qualified Transaction and (2) the probability of us completing a Roche Qualified Transaction. The probability number of us completing shares of common stock to be issued to Roche was estimated to be approximately 2.85% of the outstanding shares of common stock of the combined company as of immediately after the completion of a Roche Qualified Transaction, was low double-digits upon including the execution exercise by the underwriters thereof of the Roche Agreement and was adjusted periodically based on our progress towards a Roche Qualified Transaction. We settled the derivative liability by issuing common stock to Roche immediately following the completion of the merger. any overallotment option, if applicable. We remeasured the derivative liability based on the stock price of our its publicly-traded common stock on December 29, 2022. The change in the fair value for the period was recorded in the consolidated statements of operations and comprehensive loss in the change in fair value of derivative liability. We then reclassified Upon completion of the resulting amount merger, we issued 482,313 shares of common stock to Roche, thereby settling the derivative liability, to with the fair value of the common stock at the time of issuance recorded as additional paid-in capital.

Stock-Based Compensation Expense

We measure stock-based awards granted to employees, directors, and nonemployees based on their fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. For stock-based awards with service-based vesting conditions, we recognize compensation expense using the straight-line method. For stock-based awards with performance-based vesting conditions, we use the accelerated attribution method to expense the awards over the implicit service period based on the probability of achieving the performance conditions. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the fair value of our common stock, the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the expected dividend yield. Due to the lack of company-specific historical and implied volatility data, we determine the volatility for awards granted based on an analysis of reported data for a group of guideline companies that issued options with substantially similar terms. The expected volatility has been determined using a weighted average of the historical volatility measures of this group of guideline companies. We expect to continue to do so until such time that we have adequate historical data regarding the volatility of our own traded stock price. The expected term of our stock options granted to employees has been determined utilizing the “simplified” method for awards that qualify as “plain-vanilla” options, using the average between the vesting date and the contractual term. The fair value of each restricted common stock award is estimated on the date of grant based on the estimated fair value of our common stock on the date of grant.

Determination of the Fair Value of Common Stock

Prior to the merger closing, the estimated fair value of our common stock had been determined by our board of directors as of the date of each option grant with input from management, considering our most recently available third-party valuation of common stock, and our board of directors' assessment of additional objective and subjective factors that we believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

Our common stock valuations were prepared using either an option pricing method, or OPM, or a hybrid method, both of which used market approaches to estimate our enterprise value. The OPM treats common stock and convertible preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the convertible preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

The hybrid method is a probability-weighted expected return method, or PWERM, by which the equity value in one or more scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common

stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock.

The assumptions underlying these valuations were highly complex and subjective and represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and stock-based compensation expense could be materially different.

Upon closing of the merger, a public trading market for our common stock has been established and it is no longer necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock is now determined based on the quoted market price of our common stock.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued and certain recently adopted accounting pronouncements that have or may potentially impact our financial position and results of operations is included in Note 2 to our consolidated financial statements.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company under Section 107 of the JOBS Act, which provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to avail ourselves of the extended transition period and, therefore, while we are an emerging growth company, we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies, unless we choose to early adopt a new or revised

accounting standard. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering which occurred in August 2020, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Additionally, we are a “smaller reporting company” as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our common stock held by non-affiliates exceeds $250 million as of the prior June 30, or (ii) our annual revenues exceed $100 million during such completed fiscal year and the market value of our common stock held by non-affiliates exceeds $700 million as of the prior June 30.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As of December 31, 2022 December 31, 2023 and 2021, 2022, we had cash and cash equivalents of $194.6 million $360.4 million and $88.0 million $194.6 million, respectively, which consisted of cash, and money market funds. funds and U.S. treasury notes. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in market interest rates would not have a material effect on the fair market value of our cash or cash equivalents.

Our employees and operations are primarily located in the United States. We have, from time to time, engaged in contracts with contractors or other vendors in a currency other than the U.S. dollar. To date, we have had minimal exposure to fluctuations in foreign currency exchange rates as the time period between the date that transactions are initiated, and the date of payment or receipt of payment is generally of short duration. Accordingly, we believe it does we do not have a material exposure to foreign currency risk.

Inflation generally affects us by increasing our cost of labor. labor and contract research. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the twelve months ended December 31, 2022 December 31, 2023 and 2021. 2022.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

DISC MEDICINE, INC.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors of Disc Medicine, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Disc Medicine, Inc. (the Company) as of December 31, 2022 December 31, 2023 and 2021, 2022, the related consolidated statements of operations and comprehensive loss, shareholders' convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2022 December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 December 31, 2023 and 2021, 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022 December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2020.

Boston, Massachusetts
March 31, 2023 21, 2024

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

	December 31,		December 31,	December 31,
	2022	2021	2023	2022
Assets				
Current assets:				
Cash and cash equivalents	194,61	88,03		
	$ 1	$ 6	$ 360,382	$ 194,611
Prepaid expenses and other current assets	3,880	2,448	5,280	3,880
Total current assets	198,49	90,48		
	1	4	365,662	198,491
Property and equipment, net	168	106	170	168
Right-of-use assets, operating leases	1,430	1,641	1,930	1,430
Other assets	116	180	234	116
Total assets	200,20	92,41		
	$ 5	$ 1	$ 367,996	$ 200,205
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)				
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	$ 16,162	$ 2,559	$ 12,629	$ 16,162
Accrued expenses	6,109	4,096	8,145	6,109
Derivative liability	—	6,450		
Operating lease liabilities, current	307	319	665	307
Total current liabilities		13,42		
	22,578	4	21,439	22,578
Operating lease liabilities, non-current	1,027	1,334	1,436	1,027
Total liabilities		14,75		
	23,605	8	22,875	23,605
Commitments and contingencies (Note 14)				

Series Seed convertible preferred stock, $0.0001 par value; no shares and 5,000,000 shares authorized at December 31, 2022 and 2021, respectively; no shares and 5,000,000 shares issued and outstanding as of December 31, 2022 and 2021, respectively; (liquidation preference of $0 and $5,000 as of December 31, 2022 and 2021, respectively)	—	2,350		
Series A convertible preferred stock, $0.0001 par value; no shares and 41,666,666 shares authorized as of December 31, 2022 and 2021, respectively; no shares and 41,666,666 shares issued and outstanding as of December 31, 2022 and 2021, respectively; (liquidation preference of $0 and $50,000 as of December 31, 2022 and 2021, respectively)	—	49,762		
Series B convertible preferred stock, $0.0001 par value; no shares and 37,499,999 shares authorized as of December 31, 2022 and 2021, respectively; no shares and 37,499,999 shares issued and outstanding as of December 31, 2022 and 2021, respectively; (liquidation preference of $0 and $90,000 as of December 31, 2022 and 2021, respectively)	—	89,744		
Stockholders' equity (deficit):				
Common stock, $0.0001 par value; 100,000,000 and 108,108,833 shares authorized as of December 31, 2022 and 2021, respectively; 17,405,231 and 919,588 shares issued December 31, 2022 and 2021, respectively; and 17,403,315 and 909,418 shares outstanding as of December 31, 2022 and 2021, respectively	2	—		
Stockholders' equity:				
Common stock, $0.0001 par value; 100,000,000 shares authorized as of December 31, 2023 and 2022; 24,360,233 and 17,405,231 shares issued as of December 31, 2023 and 2022, respectively; and 24,360,233 and 17,403,315 shares outstanding as of December 31, 2023 and 2022, respectively			2	2
Additional paid-in capital	288,814	1,186	533,764	288,814

Accumulated deficit	(112,216)	(65,389)	(188,645)	(112,216)
Total stockholders' equity (deficit)	176,600	(64,203)		
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 200,205	$ 92,411		
Total stockholders' equity			345,121	176,600
Total liabilities and stockholders' equity			$ 367,996	$ 200,205

The accompanying notes are an integral part of these consolidated financial statements.

DISC MEDICINE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Operating expenses:				
Research and development	$ 33,437	$ 25,170	$ 69,264	$ 33,437
General and administrative	14,038	5,763	21,861	14,038
Total operating expenses	47,475	30,933	91,125	47,475
Loss from operations	(47,475)	(30,933)	(91,125)	(47,475)
Other income (expense), net:				
Interest income	709	14	14,797	709
Change in fair value of derivative liability	(61)	(5,050)	—	(61)
Other expense			(2)	—
Total other income (expense), net	648	(5,036)	14,795	648
Loss before income taxes			(76,330)	(46,827)
Income tax expense			(99)	—
Net loss and comprehensive loss	$ (46,827)	$ (35,969)	$ (76,429)	$ (46,827)
Net loss attributable to common stockholders-basic and diluted	$ (46,827)	$ (35,969)	$ (76,429)	$ (46,827)
Weighted-average common shares outstanding-basic and diluted	1,039,490	878,407	22,315,877	1,039,490

Net loss per share attributable to common stockholders-basic and diluted	$ (45.05)	$ (40.95)	$ (3.42)	$ (45.05)

The accompanying notes are an integral part of these consolidated financial statements.

DISC MEDICINE, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK

AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share and per share amounts)

	Convertible Preferred Stock										
	Series Seed $0.0001 Par Value		Series A $0.0001 Par Value		Series B $0.0001 Par Value		Common Stock $0.0001 Par Value		Additional Paid-In	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	(Deficit)
Balance at December 31, 2020	5,000,000	$ 2,350	41,666,666	$ 49,762	—	$ —	843,587	$ —	$ 611	$ (29,420)	$ (28,809)

Convertible Preferred Stock										
Series Seed $0.0001 Par Value		Series A $0.0001 Par Value		Series B $0.0001 Par Value		Common Stock $0.0001 Par Value		Additional Paid-In	Accumulated	Total Stockholders'
Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit

Issuance of Series B convertible preferred stock, net of issuance costs of $256	—	—	—	—	37,499,999	89,744	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	51,061	—	68	—	68
Vesting of restricted common stock	—	—	—	—	—	—	14,770	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	507	—	507
Net loss	—	—	—	—	—	—	—	—	—	(35,969)	(35,969)
Balance at December 31, 2021	5,000,000	$ 2,350	41,666,666	$ 49,762	37,499,999	$ 89,744	909,418	$ —	$ 1,186	$ (65,389)	$ (64,203)

Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	53,224	—	219	—	219	—	—	—	—	—	—	53,224	—	219	—	219
Vesting of restricted common stock	—	—	—	—	—	—	8,254	—	—	—	—	—	—	—	—	—	—	8,254	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	2,089	—	2,089	—	—	—	—	—	—	—	—	2,089	—	2,089
Issuance of common stock for cash in pre-closing financing	—	—	—	—	—	—	2,336,092	—	53,500	—	53,500	—	—	—	—	—	—	2,336,092	—	53,500	—	53,500
Conversion of preferred stock to common stock	(5,000,000)	(2,350)	(41,666,666)	(49,762)	(37,499,999)	(89,744)	9,224,653	1	141,855	—	141,856	(5,000,000)	(2,350)	(41,666,666)	(49,762)	(37,499,999)	(89,744)	9,224,653	1	141,855	—	141,856
Issuance of common stock to Gemini shareholders in reverse recapitalization	—	—	—	—	—	—	4,389,361	1	91,390	—	91,391	—	—	—	—	—	—	4,389,361	1	91,390	—	91,391

Reverse recapitalization transaction costs	—	—	—	—	—	—	—	—	(7,936)	—	(7,936)	—	—	—	—	—	—	—	—	(7,936)	—	(7,936)
Issuance of common stock to Roche	—	—	—	—	—	—	482,313	—	6,511	—	6,511	—	—	—	—	—	—	482,313	—	6,511	—	6,511
Net loss	—	—	—	—	—	—	—	—	—	(46,827)	(46,827)	—	—	—	—	—	—	—	—	—	(46,827)	(46,827)
Balance at December 31, 2022	—	$ —	—	$ —	—	$ —	17,403,315	2	$ 288,814	$ (112,216)	$ 176,600	—	$ —	—	$ —	—	$ —	$ 17,403,315	$ 2	$ 288,814	$ (112,216)	$ 176,600

	Convertible Preferred Stock										
	Series Seed $0.0001 Par Value		Series A $0.0001 Par Value		Series B $0.0001 Par Value		Common Stock $0.0001 Par Value		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance at December 31, 2022	—	$ —	—	$ —	—	$ —	17,403,315	$ 2	$ 288,814	$ (112,216)	$ 176,600
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	254,432	—	2,763	—	2,763

Vesting of restricted common stock	—	—	—	—	—	—	1,916	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	5,530	—	5,530
Sale of common stock in registered direct offering, net of issuance costs of $80	—	—	—	—	—	—	1,488,166	—	34,148	—	34,148
Sale of pre-funded warrants in registered direct offering, net of issuance costs of $66	—	—	—	—	—	—	—	—	28,206	—	28,206
Sale of common stock in at-the-market offerings, net of issuance costs of $742	—	—	—	—	—	—	967,264	—	26,422	—	26,422

Sale of common stock in follow-on public offering, net of issuance costs of $9,272	—	—	—	—	—	—	3,015,919	—	138,508	—	138,508
Sale of pre-funded warrants in follow-on public offering, net of issuance costs of $627	—	—	—	—	—	—	—	—	9,373	—	9,373
Issuance of common stock upon exercise of warrants	—	—	—	—	—	—	1,229,221	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	(76,429)	(76,429)
Balance at December 31, 2023	—	$ —	—	$ —	—	$ —	24,360,233	$ 2	$ 533,764	$ (188,645)	$ 345,121

The accompanying notes are an integral part of these consolidated financial statements.

DISC MEDICINE, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Cash flows from operating activities				
Net loss	$ (46,827)	$ (35,969)	$ (76,429)	$ (46,827)
Adjustments to reconcile net loss to net cash used in operations:				
Depreciation and amortization	89	32	100	89
Stock-based compensation	2,089	507	5,530	2,089
Change in fair value of derivative liability	61	5,050	—	61
Noncash license expense	—	1,400		
Noncash lease expense	211	160	290	211
Changes in operating assets and liabilities:	—			
Prepaid expenses and other current assets	352	(1,366)	(1,166)	352
Other assets	64	(64)	—	64
Accounts payable	526	1,315	(3,741)	526
Accrued expenses	1,502	1,542	2,008	1,502
Operating lease liabilities	(319)	(141)	(54)	(319)
Net cash used in operating activities	(42,252)	(27,534)	(73,462)	(42,252)
Cash flow from investing activities				
Purchases of property and equipment	(151)	(68)	(89)	(151)
Net cash used in investing activities	(151)	(68)	(89)	(151)
Cash flow from financing activities				
Proceeds from sale of common stock in offerings, net of issuance costs paid			199,078	—
Proceeds from sale of pre-funded warrants in offerings, net of issuance costs paid			37,579	—
Proceeds from the issuance of common stock in pre-closing financing	53,500	—	—	53,500
Cash acquired in connection with the reverse recapitalization	97,403	—	—	97,403
Payment of reverse recapitalization transaction costs	(2,144)	—	—	(2,144)
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	89,861		
Proceeds from stock option exercises	219	68	2,722	219
Net cash provided by financing activities	148,978	89,929	239,379	148,978
Net increase in cash, cash equivalents and restricted cash	106,575	62,327	165,828	106,575

Cash, cash equivalents and restricted cash, beginning of period	88,213	25,886	194,788	88,213
Cash, cash equivalents and restricted cash, end of period	$ 194,788	$ 88,213	$ 360,616	$ 194,788
Supplemental cash flow information				
Cash paid for income taxes	$ —	$ —	$ 112	$ —
Supplemental disclosure of non-cash activities				
Purchases of property and equipment included in accounts payable and accrued expenses	$ —	$ 10	$ 13	$ —
Right-of-use assets obtained in exchange for new operating lease liabilities	$ —	$ 1,670	$ 1,106	$ —
Decrease in right-of-use assets related to lease modification	$ —	$ 896		
Decrease in operating lease liabilities due to lease modification	$ —	$ 896		
Deferred issuance costs on Series B convertible preferred stock in accounts payable and accruals	$ —	$ 117		
Deferred offering costs included in accounts payable and accruals at end of period	$ 5,792	$ 656		
Net decrease in right-of-use assets related to lease modifications and reassessment events			$ 317	$ —
Net decrease in operating lease liabilities due to lease modifications and reassessment events			$ 287	$ —
Receivable for proceeds from stock option exercises included in other current assets			$ 41	$ —
Deferred issuance costs on sale of common stock and pre-funded warrants in offerings included in accounts payable and accrued expenses			$ 225	$ 5,792
Settlement of derivative liability upon issuance of common stock to Roche	$ 6,511	$ —	$ —	$ 6,511

The accompanying notes are an integral part of these consolidated financial statements.

DISC MEDICINE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Nature of the Business

Disc Medicine, Inc. (together with its subsidiaries, the “Company”) is a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of novel treatments for patients suffering from serious hematologic diseases. The Company has assembled a portfolio of clinical and preclinical product candidates that aim to modify fundamental biological pathways associated with the formation and function of red blood cells, specifically heme biosynthesis and iron homeostasis. The Company's Company’s current pipeline includes, bitopertin for the treatment of erythropoietic porphyrias ("EPs" (“EPs”) including erythropoietic protoporphyria ("EPP" (“EPP”), and X-linked protoporphyria ("XLP" (“XLP”), and Diamond-Blackfan Anemia ("DBA" (“DBA”); DISC-0974 for the treatment of anemia of myelofibrosis ("MF" (“MF”), and anemia of chronic kidney disease ("CKD" (“CKD”); and MWTX-003 DISC-3405 for the treatment of polycythemia vera ("PV" (“PV”), and other hematologic disorders. In addition, the Company's Company’s preclinical programs also include DISC-0998, for the treatment of anemia associated with inflammatory diseases. The Company's Company's approach to product candidate development leverages well-understood molecular mechanisms that have been validated in humans. The Company believes that each of its product candidates, if approved, has the potential to improve the lives of patients suffering from hematologic diseases. The Company was founded in October 2017. The Company's Company’s principal offices are in Watertown, Massachusetts.

The Company is subject to a number of risks and uncertainties common to development stage companies in the biotechnology industry, including, but not limited to, risks associated with completing preclinical studies and clinical trials, receiving regulatory approvals for product candidates, development by competitors of new biopharmaceutical products, dependence on key personnel, reliance on third-party organizations, protection of proprietary technology, compliance with government regulations, the impact of the COVID-19 pandemic public health crises such as pandemics and the ability to secure additional capital to fund operations. The Company’s research and development programs will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

Reverse Merger with Gemini

On August 9, 2022, Gemini Therapeutics, Inc., a Delaware corporation (“Gemini”), Gemstone Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Gemini (“Merger Sub”), and Disc Medicine, Inc., a Delaware corporation (“Private Disc”), entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”). The merger was completed on December 29, 2022. In accordance with the Merger Agreement, the Merger Sub merged with and into Private Disc, with Private Disc surviving as a wholly-owned subsidiary of the Company (the “merger”). Gemini changed its name to Disc Medicine Inc., and Private Disc, which remains as a wholly-owned subsidiary of the Company, changed its name to Disc Medicine Opco, Inc. On December 30, 2022, the combined company’s common stock began trading on The Nasdaq Capital Market under the ticker symbol “IRON.”

Except as otherwise indicated, references herein to “Disc,” the “Company,” or the “combined company”, refer to Disc Medicine, Inc. on a post-merger basis, and the term “Private Disc” refers to the business of privately-held Disc Medicine, Inc., prior to completion of the merger. References to Gemini refer to Gemini Therapeutics, Inc. prior to completion of the merger.

Pursuant to the terms of the Merger Agreement, at the effective time of the merger (the “Effective Time”), each then outstanding share of Private Disc common stock (including shares of common stock issued upon conversion of the Company's Company’s preferred stock (see Note 9) and shares of the Company's Company’s common stock issued in the Private Disc pre-closing financing defined below) was exchanged for 0.1096 shares of Gemini's Gemini’s common stock (the “Exchange Ratio”), after taking into account the Reverse Stock Split, as defined below. In addition, each option to purchase Private Disc shares that was outstanding and unexercised immediately prior to the Effective Time was converted into an option to purchase shares of Gemini based on the Exchange Ratio. Immediately following the merger, stockholders of Private Disc owned approximately 74% of the outstanding common stock of the combined company. The merger was intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

At the Effective Time, each person who as of immediately prior to the Effective Time was a stockholder of record of Gemini or had the right to receive Gemini’s common stock received a contractual contingent value right (“CVR”) issued by Gemini subject to and in accordance

with the terms and conditions of a Contingent Value Rights Agreement between Gemini, the holder's representative and the rights agent (the "CVR Agreement"), representing the contractual right to receive consideration from the post-closing combined company upon the receipt of certain proceeds from a disposition of Gemini's pre-merger assets (specifically, Gemini's intellectual property assets ("Gemini IP"), which the Company assumed in the merger) during the period that is one year after the closing of the merger, calculated in accordance with the CVR Agreement. In accordance with the CVR Agreement, the holders of the CVRs would receive proceeds from any disposition of the Gemini pre-merger assets, net of costs incurred by the Company in performance of its obligations under the CVR Agreement in excess of $250,000, paid in the form of common stock in

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the Company based on the weighted average stock price of the Company for the five trading days prior to the issuance of the payment to the holders of the CVRs.

112 To satisfy its obligations with respect to the CVRs and the Gemini IP, the Company hired an outside firm to attempt to sell the Gemini IP, which firm previously was unsuccessful in finding a buyer for the Gemini IP. In June 2023, the Company received an offer for the Gemini IP and recorded a $1.5 million liability representing the estimated fair value of the Company's obligation to the holders of the CVRs based on the offer. However, the counterparty and the Company were unable to come to an agreement on the terms of the offer.

The disposition period ended December 29, 2023 and no dispositions of Gemini's pre-merger assets were made during the disposition period. Therefore, there were no CVR payments made to the holders and there will not be any future CVR payments to the holders (See Note 4). As such, the Company's obligations under the CVR Agreement have expired and the CVRs are valueless. In December 2023, the Company recognized the reversal of the $1.5 million liability in the consolidated statements of operations and comprehensive loss within the change in fair value of contingent value right liability.

The Company has no additional obligations or plans with respect to Gemini's pre-merger assets. The Company has generated no revenue from Gemini's pre-merger assets and has incurred approximately $1.6 million in aggregate costs (including maintenance of license agreements, storage, legal and other fees) for the twelve months ended December 31, 2023, to maintain Gemini's pre-merger assets solely in order to fulfill the Company's obligations under the CVR Agreement.

In connection with the Merger Agreement, certain third parties entered into a subscription agreement with Private Disc to purchase shares of Private Disc's Disc's common stock for an aggregate purchase price of $53.5 million (the "pre-closing financing"). Shares of Private Disc's Disc's common stock issued pursuant to the pre-closing financing were converted into shares of the Company's Company's common stock based on the Exchange Ratio.

The merger was accounted for as a reverse recapitalization in accordance with U.S. GAAP. For accounting purposes, Private Disc was considered to be acquiring the assets and liabilities of Gemini in the merger based on the terms of the Merger Agreement and other factors, including: (i) Private Disc's stockholders own a majority of the voting rights in the combined company; (ii) Private Disc designated a majority (eight of nine) of the initial members of the board of directors of the combined company; (iii) Private Disc's executive management team became the management of the combined company; (iv) the pre-combination assets of Gemini were primarily cash and cash equivalents and other non-operating assets (the in-process research and development assets potentially remaining as of the combination were considered to be of de minimis value); and (v) the combined company was named Disc Medicine, Inc. and is headquartered in Private Disc's Disc's office in Watertown, Massachusetts. Accordingly, the merger was treated as the equivalent of Private Disc issuing stock to acquire the net assets of

Gemini. As a result of the merger, the net assets of Gemini were recorded at their acquisition-date fair value in the financial statements of the Company and the reported operating results prior to the merger are those of Private Disc.

Pursuant to the terms of the Roche Agreement (see Note 8) 4), immediately following the Effective Time, the Company issued 482,313 shares of the combined company to Roche for no consideration.

Reverse Stock Split and Exchange Ratio

On December 29, 2022, in connection with, and prior to the completion of, the merger, Gemini effected a one-for-ten reverse stock split of its then outstanding common stock (the "Reverse Stock Split"). The par value and the authorized shares of the common stock were not adjusted as a result of the Reverse Stock Split. All of Gemini's issued and outstanding common stock have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented.

All issued and outstanding Private Disc common stock, convertible preferred stock and options prior to the effective date of the merger have been retroactively adjusted to reflect the 0.1096 Exchange Ratio, which reflects the impact of the reverse stock split, for all periods presented.

Liquidity and Capital Resources

The Company's consolidated financial statements have been prepared on the basis of the Company continuing as a going concern. The Company expects that its existing cash and cash equivalents as of December 31, 2022 December 31, 2023 of $194.6 360.4 million will enable the Company to fund its planned operating expense and capital expenditure requirements for at least twelve months from the date of issuance of these consolidated financial statements. The Company has incurred recurring losses and negative cash flows from operations since inception. As of December 31, 2022 December 31, 2023, the Company had an accumulated deficit of $112.2 188.6 million. The Company expects its operating losses and negative operating cash flows to continue into the foreseeable future. The future viability of the Company is dependent on its ability to generate cash from operating activities or to raise additional capital to finance its operations. There can be no assurance that the Company will ever earn revenues or achieve profitability, or if achieved, that the revenues or profitability will be sustained on a continuing basis. In addition, the Company's preclinical and clinical development activities, manufacturing and commercialization of the Company's product candidates, if approved, will require significant additional financing.

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2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The Company's consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative accounting principles generally accepted in the United States as found in the Accounting Standard Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of the Company's consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Significant estimates

and assumptions reflected in these consolidated financial statements include, but are not limited to accrued research and development expenses; stock-based compensation expense; the fair value of the common stock prior to the effective date of the merger; the fair value determinations for instruments accounted for at fair value including contingent amounts payable to third parties upon the consummation of specified transactions, including a Roche Qualified Transaction (see Note 8) 4); the fair value of Gemini's development programs underlying at the Effective Time; the fair value of the CVR; the incremental borrowing rate for determining lease liabilities and right-of-use assets and income taxes. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it has concluded to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ materially from those estimates or assumptions.

Segment Information

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions, resulting in a single reportable segment. The Company has assembled a portfolio of clinical and preclinical product candidates that aim to modify fundamental biological pathways associated with the formation and function of red blood cells, specifically heme biosynthesis and iron homeostasis. The Company has determined that its chief operating decision maker is its Chief Executive Officer. The Company's chief operating decision maker reviews the Company's financial information on a consolidated basis for purposes of allocating resources and assessing financial performance. All of the Company's tangible assets are held in the United States.

Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains deposits in a federally insured financial institution institutions in excess of federally insured limits and limits its exposure to cash risk by placing its cash with a high credit quality accredited financial institution. institutions. The Company has concluded that it is not subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company relies, and expects to continue to rely, on a small number of vendors to manufacture supplies and to process its product candidates for its development programs. These programs could be adversely affected by a significant interruption in the manufacturing process or supply chain.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents include cash in readily available checking and money market accounts. accounts and U.S. treasury notes with original maturities of three months or less at the date of purchase. Cash equivalents are reflected at fair value based on quoted market prices as further described in Note 4.

Restricted Cash

The Company maintained maintains letters of credit totaling $0.2 million for the benefit of its landlords related to its current leased and subleased office space in Cambridge, Watertown, Massachusetts and Watertown, Massachusetts. which is classified within other assets. The Company was is required to maintain a separate cash balances balance to secure its letters of credit.

Due to the lease termination in September 2021, the

The Company maintained a letter of credit related to the of less than $0.1 million for leased office space in Cambridge, Massachusetts, is which was classified within prepaid expenses prepaids and other current assets as of December 31, 2022 (see Note 15). This lease was terminated in 2021 and the letter of credit was subsequently returned and released from restricted cash.

Deferred Transaction Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred transaction costs until such financings are consummated. After consummation of an equity financing, these costs are recorded as a reduction of the proceeds from the transaction, either as a reduction of the carrying value of the preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the transaction. Should the in-process equity financing be abandoned, the deferred transaction costs would be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss.

As of December 31, 2021, Private Disc had capitalized deferred transaction costs of $1.7 million related to a planned equity financing. During 2022, Private Disc concluded not to proceed with the planned equity financing and expensed the related deferred transaction costs of $2.2 million to general and administrative expenses. During 2022, the Company capitalized deferred transaction costs related to the merger of $7.9 million. At the Effective Time, the Company reclassified the capitalized deferred transaction costs to reduce additional paid-in capital generated as a result of the merger. As of December 31, 2023, the Company capitalized deferred costs related to its at-the-market program and shelf registration of $0.5 million.

Fair Value Measurements

The Company categorizes its assets and liabilities measured at fair value in accordance with the authoritative accounting guidance that establishes a consistent framework for measuring fair value and expands disclosures for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1—Quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2—Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable; and
- Level 3—Unobservable inputs in which little or no market activity exists, therefore requiring an entity to develop its own assumptions about the assumptions that market participants would use in pricing.

The fair value of the Company's cash equivalents are determined according to the fair value hierarchy described above (see Note 4). The carrying values of the Company's prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. Depreciation on leasehold improvements is recognized over the shorter of the useful life of the assets or the estimated remaining term of the associated lease.

	ESTIMATED USEFUL LIFE
Computer equipment	3.0 years
Furniture and fixtures	3.0 years

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated in accordance with the above guidelines once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are expensed as incurred.

The Company capitalizes internal costs incurred to develop software for internal use during the application development stage. The Company includes capitalized internally developed software subject to a cloud computing arrangement within other assets. Amortization of capitalized internally developed software costs is recorded in depreciation expense over the estimated useful life of the related asset of 3.0 years.

Impairment of Long-lived Assets

As required under the applicable accounting guidance, the Company periodically reevaluates the original assumptions and rationale used in the establishment of the carrying value and estimated lives of all of its long-lived assets, including property and equipment. The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when the total of estimated future undiscounted cash flows, expected to result from the use of the asset and its eventual disposition, are less than its carrying amount. Impairment, if any, would be assessed using discounted cash flows or other appropriate measures of fair value. There were no impairments for the twelve months ended December 31, 2022 December 31, 2023 and 2021. 2022.

Leases

Effective January 1, 2020, Private Disc adopted and The Company accounts for its leases under ASC 842, using the modified retrospective transition approach. 842. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease. Leases with a term greater than one year are recognized on the consolidated balance sheet as a right-of-use (“ROU”) asset and current and non-current lease liabilities, as applicable. The Company has made an accounting policy election, known as the short-term lease recognition exemption, which allows the Company to not recognize ROU assets and lease liabilities that arise from short-term leases (12 months or less) for any class of underlying asset. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew or options to cancel a lease are not included in the Company’s assessment unless there is reasonable certainty that the Company will renew or will not cancel, respectively. The Company monitors its material leases on a quarterly basis.

Leases are classified at their lease commencement date, which is defined as the date on which the lessor makes the underlying asset available for use by the lessee, as either operating or finance leases based on the economic substance of the

agreement. All of the Company's leases are classified as operating leases. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected remaining lease term. Fixed lease cost for operating leases is recognized on a straight-line basis over the lease term as an operating expense. Variable lease costs, such as common area maintenance expenses, are recognized in the period incurred. Certain adjustments to the ROU asset may be required for items such as lease prepayments or incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its estimated incremental borrowing rate, which reflects the estimated fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

The Company has elected to account for the lease and non-lease components together for existing classes of underlying assets.

Preferred Stock

The Company applies the guidance of ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480"), when determining the classification and measurement of its preferred stock. Preferred stock subject to mandatory redemption (if any) are classified as liability instruments and are measured at fair value. The Company classifies contingently redeemable preferred stock (if any), which includes preferred stock that features redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity. At all other times, the Company classifies its preferred stock in stockholders' equity (deficit).

Prior to the merger, Private Disc classified its convertible preferred stock as temporary equity due to terms that allowed for redemption of the shares upon the occurrence of a contingent event that was not solely within the Private Disc's control. Private Disc did not accrete the carrying values of the preferred stock to the redemption values since the contingent event was not considered probable as of December 31, 2021. prior to their conversion to common stock at the Effective Time.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, depreciation, external costs of vendors engaged to conduct preclinical development activities and clinical trials, manufacturing expenses, as well as the costs of licensing technology.

Nonrefundable prepayments for goods or services that will be used or rendered for future research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

If the Company acquires an asset or group of assets under an in-licensing arrangement that does not meet the definition of a business under ASC Topic 805, *Business Combinations*, and the acquired in-process research and development does not have an alternative future use, any related upfront license payment is expensed as incurred in accordance with guidance in ASC Topic

730, *Research and Development*. In general, contingent payments are recognized when it becomes probable the payment will be required. Any contingent payments that qualify as a derivative liability are recognized at fair value on the Company's consolidated balance sheets. Annual maintenance fees under license agreements are expensed in the period in which they are incurred. Contingent payments for assets acquired are expensed as incurred or capitalized and amortized based on the nature of the associated asset at the date the payment is recognized. Royalties owed on sales of the products licensed pursuant to license agreements are expensed in the period the related revenues are recognized.

The Company has entered into various research, development and manufacturing contracts with research institutions and other companies primarily in the United States, including contracts with third-party contract research organizations and contract development and manufacturing organizations. These agreements are generally cancelable, and related costs are recorded as research and development expenses as incurred. The Company records accrued liabilities for estimated ongoing research, development and manufacturing costs and prepaid expenses for payments made in advance of work performed. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations to those third parties as of period end. Any accrual estimates are based on a number of factors, including the Company's knowledge of the progress towards completion of the research, development and manufacturing activities, invoicing to date under the contracts, communication from the research institutions and other companies of any actual costs incurred during the period that have not yet been invoiced and the costs included in the contracts. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results may differ from the estimates made by the Company.

Patent Costs

The Company expenses all costs as incurred in connection with patent applications, including direct application fees, and the legal and consulting expenses related to making such applications due to the uncertainty about the recovery of the expenditure. These costs are included in general and administrative expenses within the Company's consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

The Company accounts for all stock-based awards granted to employees and non-employees as stock-based compensation expense at fair value. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the fair value of the Company's common stock on the date of grant, the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option and the Company's expected dividend yield. The fair value of each restricted stock award is estimated on the date of grant based on the fair value of the Company's common stock on that same date. Due to the lack of company-specific historical and implied volatility data, the Company determines the volatility for awards granted based on an analysis of reported data for a group of guideline companies that issued options with substantially similar terms. The expected volatility has been determined using a weighted-average of the historical volatility measures of this group of guideline companies. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options granted to employees has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common stock; therefore, the expected dividend yield is assumed to be zero.

The Company recognizes compensation expense for employees and non-employees over the requisite service period, which is generally the vesting period of the respective award, based on the grant date fair value of the award. For awards that include performance-

based vesting conditions expense is recognized using the accelerated attribution method when the performance condition is deemed to be probable. The Company accounts for forfeitures as they occur.

The Company classifies stock-based compensation expense in the consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

See Note 11 for a summary of the stock-based award activity under the Company's stock-based compensation plan.

Determination of Fair Value of Common Stock on Grant Dates

Prior to the merger, due to the absence of an active market for Private Disc's common stock, Private Disc and its Board were required to determine the fair value of Private Disc's common stock at the time of each grant of a stock-based award. Private Disc estimated the fair value of its common stock utilizing methodologies in accordance with the framework of the American Institute of Certified Public Accountants' Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued*

as Compensation. In determining the exercise prices for options granted, Private Disc considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including prices paid for Private Disc's convertible preferred stock and the rights, preferences, and privileges of Private Disc's Preferred Stock and common stock; Private Disc's stage of development and status of technological developments within Private Disc's research; the illiquid nature of securities in a private company; the prospects of a liquidity event; and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Private Disc's common stock valuations were prepared using either an option pricing method ("OPM"), or a hybrid method, both of which used market approaches to estimate our enterprise value. The OPM treats common stock and convertible preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeds the value of the convertible preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

The hybrid method is a probability-weighted expected return method ("PWERM"), by which the equity value in one or more scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for

the common stock. In addition to a scenario using the OPM, the hybrid method also considers an initial public offering scenario in which the shares of convertible preferred stock are assumed to convert to common stock. The future value of the common stock in the initial public offering scenario was discounted back to the valuation date at an appropriate risk adjusted discount rate. In the hybrid method, the present

value indicated for each scenario was probability weighted to arrive at an indication of value for the Private Disc's common stock. Private Disc utilized significant estimates and assumptions in determining the fair value of its equity and equity-based awards.

Substantially all of the awards granted by the Company are either new hire grants or routine annual grants. Management evaluates its award grants and modifications contemporaneously and if any are determined to be spring-loaded, the Company will adjust the fair value.

Comprehensive Loss

Comprehensive loss includes net loss, as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. The Company's comprehensive loss was equal to net loss for the twelve months ended December 31, 2022 December 31, 2023 and 2021.2022.

Income Taxes

Income taxes have been accounted for using the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates applicable to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. A valuation allowance against deferred tax assets is recorded if, based upon the weight of all available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Since the Company has generated operating losses and expects to continue to incur future losses, the net deferred tax assets have been fully offset by a valuation allowance.

The Company accounts for income taxes in accordance with authoritative accounting guidance which states the impact of an uncertain income tax position is recognized at the largest amount that is "more likely than not" to be sustained upon audit by the relevant taxing authority. There are no unrecognized tax benefits included in the Company's consolidated balance sheets at December 31, 2022 December 31, 2023 or 2021. 2022. The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company has not recognized interest or penalties related to income tax matters in its consolidated statements of operations and comprehensive loss since inception.

The Company files income tax returns in the United States and in Massachusetts. The Company's income tax returns are subject to review and tax assessment from an income tax examination. As of December 31, 2022 December 31, 2023, the Company was not under examination by the Internal Revenue Service or other jurisdictions for any tax year.

Net Loss Per Share

Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. The Company's Preferred Stock contains contained participation rights in any dividend paid by the Company and is was deemed to be a participating security. Net income attributable to common stockholders and participating preferred shares, if applicable, are allocated to each share as if all of the earnings for the period had been distributed. The participating securities do did not include a contractual obligation to share in losses of the

Company and are were not included in the calculation of net loss per share in the periods in which a net loss is recorded. Net loss attributable to common stockholders is equal to the net loss for the period.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the treasury stock method and if-converted method. The Company allocates earnings first to preferred stockholders, if applicable, based on dividend rights and then to common and preferred stockholders, if applicable, based on ownership interests. The weighted-average number of common shares included in the computation of diluted net loss gives effect to all potentially dilutive common equivalent shares, including outstanding stock options and Preferred Stock. Common stock equivalent shares are excluded from the computation of diluted net loss per share if their effect is antidilutive. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is generally the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Subsequent Events

The Company considers events or transactions that occur after the consolidated balance sheet date but prior to the issuance of the consolidated financial statements to provide additional evidence for certain estimates or to identify matters that require additional disclosure. The Company has evaluated events occurring after the date of its consolidated balance sheet, through March 31, 2023 March 21, 2024, the date these consolidated financial statements were available to be issued. See issued (see Note 16.17).

Emerging growth company status Growth Company Status

The Company qualifies as an “emerging growth company” (“EGC”), as defined in the Jumpstart Our Business Startups Act (“JOBS Act”), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act, which provides that an EGC can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to avail itself of the extended transition period and, therefore, while the Company is an EGC it will not be subject to new or revised accounting standards the same time that they become applicable to other public companies that are not EGCs, unless it chooses to early adopt a new or revised accounting standard. As a result of this election, the consolidated financial statements may not be comparable to companies that comply with public company FASB standards’ effective dates.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Topic 350): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. This standard requires capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The Company adopted ASU 2018-15 on January 1, 2021 using the prospective method. The adoption of this standard did not have a material effect on the Company’s financial position, results of operations or disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This standard removes certain exceptions for investments, intra-period allocations and interim calculations, and adds guidance to reduce complexity in accounting for income taxes. The Company adopted ASU 2019-12 on January 1, 2021 using the prospective method. The adoption of this standard did not have a material effect on the Company’s financial position, results of operations or disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*. This standard amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity’s own equity and improves and amends the related earnings per share guidance for both subtopics. The Company early adopted ASU 2020-06 on

January 1, 2021 using a modified retrospective approach. The adoption of this standard did not have a material effect on the Company's financial position, results of operations or disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which has been subsequently amended by ASU 2018-19, ASU 2019-04, ASU 2019-05, ASU 2019-10, ASU 2019-11, ASU 2020-03, and ASU 2022-02 ("ASU 2016-13"). This standard requires that credit losses be recorded using an expected losses model rather than the incurred losses model that was previously used and establishes additional credit risk disclosures associated with financial assets. The amendments in this standard should be applied on a modified retrospective basis to all periods presented. For public business entities The Company adopted ASU 2016-13 on January 1, 2023 using the modified retrospective approach. The adoption of this standard did not have a material effect on the Company's financial position, results of operations or disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

Other accounting standards that meet the definition of a U.S. Securities and Exchange Commission ("SEC") filer, excluding entities eligible to be smaller reporting companies as defined have been issued or proposed by the SEC, the standard is effective for fiscal calendar years beginning January 1, 2020, including interim periods within those fiscal years. For all FASB or other entities, the standard is effective for fiscal calendar years beginning January 1, 2023. Early standards-setting bodies that do not require adoption is permitted. The Company does until a future date are not expect that this standard will expected to have a material impact on its the Company's consolidated financial statements and disclosures. upon adoption.

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3. Reverse Merger with Gemini

As described in Note 1, Private Disc merged with Gemini on December 29, 2022. The merger was accounted for as a reverse recapitalization with Private Disc as the accounting acquirer. The primary pre-combination assets of Gemini were cash and cash equivalents. Under reverse recapitalization accounting, the assets and liabilities of Gemini were recorded at their fair value which approximated book value due to the short-term nature of the accounts. No goodwill or intangible assets were recognized. Consequently, the consolidated financial statements of the Company reflect the operations of Private Disc for accounting purposes, together with a deemed issuance of shares equivalent to the shares held by the former stockholders of Gemini, the legal acquirer, and a recapitalization of the equity of Private Disc, the accounting acquirer.

As part of the reverse recapitalization, the Company acquired $97.4 million of cash and cash equivalents. The Company also obtained prepaids and other assets of $1.8 million and assumed accounts payable and accrued expenses of $7.8 million. Gemini's Gemini's development programs had ceased prior to the merger and were deemed to be de minimis in value at the transaction date.

In addition, the Company recognized $0.6 million in share-based compensation expense as a result of the acceleration of vesting of stock options, performance stock units and restricted stock units at the time of merger. This amount was recorded in general and administrative expense in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31,

2022. The Company also incurred transaction costs of $7.9 million and this amount is recorded in additional paid-in capital in the accompanying consolidated statements of convertible preferred stock and stockholders' equity (deficit) for the year ended December 31, 2022.

4. Fair Value Measurements

The following tables present information about the Company's assets and liabilities that are regularly measured and carried at fair value on a recurring basis and indicate the level within the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value, which is described further within Note 2.

Financial assets and liabilities measured at fair value on a recurring basis are summarized as follows (in thousands):

	December 31, 2022			December 31, 2023		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Assets						
Money market funds in cash and cash equivalents	$ 40,783	$ —	$ —			
Cash equivalents:						
Money market funds				$ 55,001	$ —	$ —
U.S. Treasury notes				—	255,419	—
Total	$ 40,783	$ —	$ —	$ 55,001	$ 255,419	$ —
Liabilities						
Derivative liability	$ —	$ —	$ —			
Total	$ —	$ —	$ —			

	December 31, 2021			December 31, 2022		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Assets						
Money market funds in cash and cash equivalents	$ 86,119	$ —	$ —			
Cash equivalents:						
Money market funds				$ 40,783	$ —	$ —
Total	$ 86,119	$ —	$ —	$ 40,783	$ —	$ —
Liabilities						
Derivative liability	$ —	$ —	$ 6,450			
Total	$ —	$ —	$ 6,450			

The fair value of the Company's Level 1 cash equivalents, consisting of money market funds, is based on quoted market prices in active markets with no valuation adjustment. The fair value of the Company's Level 2 cash equivalents, consisting of U.S. Treasury notes with original maturities of three months or less, is determined through third-party pricing services. The amortized cost of the U.S. treasury notes approximates the fair value. There have been no impairments of the Company's assets measured and carried at fair value during the twelve months ended December 31, 2022 December 31, 2023 and 2021. 2022. In addition, there were no changes in valuation techniques or transfers between Level 1, Level 2 and Level 2 3 financial assets during the twelve months ended December 31, 2022 December 31, 2023 and 2021. 2022. The Company did not have any non-recurring fair value measurements on any assets or liabilities during the twelve months ended December 31, 2022 December 31, 2023 and 2021.2022.

In May 2021, Private Disc the Company entered into a license agreement (the “Roche Agreement”) with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (together, “Roche”) pursuant to which Roche granted Private Disc the Company an exclusive and sublicensable worldwide license under certain patent rights and know-how to develop, manufacture and commercialize certain compounds (the “Compounds”) as further described in Note 8. Private Disc The Company recognized a liability in connection with the Roche Agreement which included an obligation to issue a variable number of shares of the Company's Company’s common stock to Roche for no additional

consideration upon Private Disc’s the Company’s completion of an initial public offering or certain merger transactions a (a “Roche Qualified

Transaction.” The number of shares of common stock to be issued to Roche was estimated to be approximately 2.85% of the outstanding shares of common stock of the combined company as of immediately after the completion of a Roche Qualified Transaction. Private Disc determined that the obligation to issue common stock upon completion of a Roche Qualified Transaction represented a liability classified financial instrument. The liability was measured at fair value as of each reporting date and the change in the fair value for the period is recorded in the consolidated statements of operations and comprehensive loss in the change in fair value of derivative liability. Transaction”). Prior to settlement in Q4 2022, the fair value measurement of the derivative liability was classified as Level 3 under the fair value hierarchy as it was valued using certain unobservable inputs. These inputs included: (1) the Company’s estimated shares outstanding and fair value per share upon completion of a Roche Qualified Transaction and (2) the probability of the Company completing a Roche Qualified Transaction. The Company settled the derivative liability by issuing number of shares of common stock to be issued to Roche was estimated to be approximately 2.85% of the outstanding shares of common stock of the combined company as of immediately following after the completion of a Roche Qualified Transaction, including the merger. exercise by the underwriters thereof of any overallotment option, if applicable. The Company remeasured the derivative liability based on the stock price of its publicly-traded common stock on December 29, 2022. The change in the fair value for the period was recorded in the consolidated statements of operations and comprehensive loss in the change in fair value of derivative liability. The Upon completion of the merger, the Company then reclassified the resulting amount issued 482,313 shares of common stock to Roche, thereby settling the derivative liability, to with the fair value of the common stock at the time of issuance recorded as additional paid-in capital.

The following table provides a summary of changes in fair value of the Level 3 liabilities related to the Roche Agreement (in thousands):

	Level 3 Rollforward
Balance at December 31, 2021	$ 6,450
Change in fair value of derivative liability	61
Settlement of derivative liability upon issuance of common stock to Roche	(6,511)
Balance at December 31, 2022	$ —

	Year Ended December 31, 2022
	Derivative liability

Balance at the beginning of the year	$	6,450
Change in fair value of derivative liability		61
Settlement of derivative liability upon issuance of common stock to Roche		(6,511)
Balance at the end of the year	$	—

As described in Note 1, in connection with the merger, the stockholders of Gemini at the Effective Time received a CVR to receive consideration from the Company upon its receipt of certain proceeds, resulting from a disposition of Gemini's pre-merger assets within one year after the closing of the merger, calculated in accordance with the CVR Agreement. The disposition period ended December 29, 2023 and no dispositions of Gemini's pre-merger assets were made during the disposition period. Therefore, there were no CVR payments made to the holders and there will not be any future CVR payments to the holders. The fair value of the CVR liability was zero and de minimis as of December 31, 2023 and 2022, respectively. The fair value of the CVR liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company used a discounted cash flow approach to value the CVR liability. As inputs into the valuation, the Company considered the probabilities of success of certain potential payments, the amount of the payments, and a discount rate of 13.2% determined using an implied credit spread adjusted based on companies with similar credit risk.

5. Cash, Cash Equivalents and Restricted Cash

Cash, cash equivalents and restricted cash consisted of the following (in thousands):

	December 31,		December 31,	December 31,
	2022	2021	2023	2022
Cash and cash equivalents	194,61	88,03		
	$ 1	$ 6	$ 360,382	$ 194,611
Restricted cash	177	177	234	177
Total cash, cash equivalents and restricted cash as shown on the consolidated	194,78	88,21		
statements of cash flows	$ 8	$ 3	$ 360,616	$ 194,788

6. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31,		December 31,	December 31,
	2022	2021	2023	2022
Computer equipment			$ 231	$ 169
Furniture and fixtures	$ 144	$ 93	184	144
Computer equipment	169	69		
Less: Accumulated depreciation	(145)	(56)	(245)	(145)
Property and equipment, net	$ 168	$ 106	$ 170	$ 168

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,		December 31,	December 31,
	2022	2021	2023	2022
Accrued employee-related expenses	$ 3,623	$ 1,177	$ 5,790	$ 3,623
Accrued research and development	1,817	2,297	1,986	1,817
Accrued professional fees	463	601	317	463
Accrued other	206	21	52	206
Total accrued expenses	$ 6,109	$ 4,096	$ 8,145	$ 6,109

8. Development and License Agreements

License Agreement and Master Service Agreement with Aurigene Discoveries Technology Limited ("Aurigene")

In February 2018, Private Disc the Company entered into a license agreement with Aurigene, pursuant to which Aurigene granted Private Disc the Company an exclusive worldwide license, with the right to grant sublicenses, to certain Aurigene intellectual property. Concurrent with the execution of the Aurigene license agreement, the parties entered into a master services agreement, which provided for Aurigene to provide future development services to the Company on a full-time equivalent cost basis and consumable costs incurred basis. In December 2022, The Company terminated the master service agreement was terminated. effective in March 2023.

Pursuant to the license agreement, Private Disc the Company agreed to pay an upfront fee of $0.1 million and annual maintenance fees up to $0.2 million for the licensed intellectual property. The Company may also be obligated to make future milestone payments of up to $7.1 million for the first licensed product based on the achievement of certain development and regulatory milestones. The term of the license agreement expires on a licensed product-by-licensed product and country-by-country basis on the expiration of the last-to-expire valid claim under the licensed intellectual property rights in such country. The Company can terminate the agreement, for convenience, with 90 days' notice to Aurigene. The agreement can also be terminated by either party due to insolvency or by Aurigene due to a material breach after a specified cure period.

During the twelve months ended December 31, 2022 December 31, 2023 and 2021, 2022, the Company recorded research and development expense of $0.8 0.3 million and $1.7 0.8 million, respectively, related to its arrangements with Aurigene.

License and Stock Purchase Agreement with AbbVie Deutschland GmbH & Co. KG ("AbbVie")

In September 2019, Private Disc entered into an agreement with AbbVie, pursuant to which AbbVie granted Private Disc an exclusive license, with the right to grant sublicenses, to certain AbbVie intellectual property.

Under this agreement, Private Disc paid a non-refundable, non-creditable upfront fee of $0.6 million. The Company is also obligated to make future payments upon the achievement of certain development, commercialization and sales-based milestones up to $18.0 million, $45.0 million and $87.5 million, respectively on a licensed product-by-licensed product basis. In addition, the Company is also obligated to pay

royalties based on net sales of the licensed products on a licensed product-by-licensed product and country-by-country basis. As of December 31, 2022 December 31, 2023, none of the milestones had been achieved.

The Company's royalty obligation expires on a licensed product-by-licensed product and country-by-country basis upon the expiration of the last-to-expire valid claim under the licensed intellectual property rights in such country. Unless terminated earlier, the agreement expires upon the expiration of the Company's royalty obligation for all licensed products. AbbVie can terminate the agreement if the Company fails to make any payments within a specified period after receiving written notice of such failure, or in the event of a material breach by the Company and failure to cure such breach within a certain period of time.

License Agreement with Roche

In connection with the Roche Agreement, Private Disc the Company paid Roche an upfront, non-refundable exclusivity payment of $0.5 million in March 2021. Upon execution of the Roche Agreement in May 2021, Private Disc the Company paid Roche an additional upfront, non-refundable payment of $4.0 million.

The Company is obligated to make contingent payments to Roche totaling up to an aggregate of $205.0 50.0 million upon in development and regulatory milestone payments for development and approval in a first indication and up to an aggregate of $35.0 million in development and regulatory milestone payments for development and approval in a second indication. The Company is also obligated to make contingent payments to Roche up to an aggregate of $120.0 million based on achievement of certain development, regulatory and commercial milestones. thresholds for annual net sales of licensed products. As of December 31, 2023, none of the milestones had been achieved. Roche is also eligible to receive tiered royalties on net sales of commercialized products, at rates ranging from high single-digits to high teens.

In addition, Private Disc was obligated to issue shares

A description of the Company to Roche in connection with the completion of a Roche Qualified Transaction as defined by the Roche Agreement. The number of shares of common stock to be issued to Roche was estimated to be approximately 2.85% of the outstanding shares of common stock of the combined company as of immediately after the completion of a Roche Qualified Transaction, including the exercise by the underwriters thereof of any overallotment option, if applicable. Private Disc had determined that the obligation to issue common stock upon completion of a Roche Qualified Transaction represented a derivative liability classified financial instrument. The resulting liability was initially recorded at fair value in research and development expense, with gains and losses arising from changes in fair value recognized in other income (expense), net in the consolidated statement of operations and comprehensive loss at each period while the instrument was outstanding.

During the twelve months ended December 31, 2022, the Company recorded research and development expense of $0.3 million for a material transfer per the Roche Agreement. During the twelve months ended December 31, 2021, Private Disc recorded research and development expense of $5.9 million related to the Roche agreement settled in 2022 is included in Note 4.

License Agreement comprised of with Mabwell

In January 2023, the Company entered into an exclusive license agreement with Mabwell Therapeutics, Inc. ("Mabwell"), pursuant to which Mabwell granted the Company an exclusive and sublicensable license to certain Mabwell intellectual property.

In connection with the agreement, the Company paid Mabwell an upfront payment of $4.5 10.0 million and in March 2023. In October 2023, the initial fair value Company dosed the first patient in the Phase 1 clinical trial of the derivative liabilitypolycythemia vera for DISC-3405,

resulting in a milestone payment of $1.4 5.0 million due to Mabwell. In addition, the Company is obligated to pay certain development and regulatory milestone payments for the licensed products, for up to three indications, up to a maximum aggregate amount of $127.5 million, as well as certain commercial milestone payments for certain licensed product net sales achievements, up to a maximum aggregate amount of $275.0 million. During the twelve months ended December 31, 2022 and 2021, The Company is further obligated to pay a tiered percentage of revenue that the Company recorded expense of less than $0.1 million and $5.1 million, respectively, within other income (expense), net, related receives from its sublicensees ranging from a low third decile percentage to the change in fair value of the derivative liability.

Upon completion of the merger, a low first decile percentage. In addition, the Company issued 482,313 shares is obligated to pay Mabwell a royalty on annual net sales of common stock all licensed products at a tiered rate ranging from low single-digits to Roche, thereby settling the derivative liability, with the fair value of the common stock at the time of issuance recorded as additional paid-in capital. high single-digits.

9. Convertible Preferred Stock

As of December 31, 2022, December 31, 2023 and 2022, the Company was authorized to issue up to 10,000,000 shares of preferred stock at a par value of $0.0001, with no shares issued or outstanding.

Immediately prior to the Effective Time, each share of Private Disc's preferred stock was converted into a share of Private Disc's common stock. At the closing of the merger, the shares of Private Disc's Disc's common stock were converted into shares of the Company's Company's common stock based on the Exchange Ratio.

As of December 31, 2021, the Preferred Stock authorized, issued and outstanding consisted of the following (in thousands, except share amounts):

	December 31, 2021				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series Seed	5,000,000	5,000,000	$ 2,350	$ 5,000	5,000,000
Series A	41,666,666	41,666,666	49,762	50,000	41,666,666
Series B	37,499,999	37,499,999	89,744	90,000	37,499,999
Total	84,166,665	84,166,665	$ 141,856	$ 145,000	84,166,665

The Preferred Stock as of December 31, 2021 had the following rights and preferences:

Dividends

The holders of the Preferred Stock were entitled to receive noncumulative dividends when and if declared by the Board at the rate per annum of eight percent (8%) of the applicable Original Issue Price, which is $1.00 per share for the Series Seed Preferred Stock, $1.20 per share for the Series A Preferred Stock, and $2.40 per share for the Series B Preferred Stock. Preferred Stock dividends would have been paid in preference and in priority to any dividends on common stock. If Private Disc had declared, paid or set aside, on the same date, a dividend on shares of more than one class or series of capital stock of Private Disc, the dividend payable to the holders of the Preferred Stock would have been based on the number of common shares the Preferred Stock would convert into. There have been no dividends declared by the Board to date.

Liquidation Preference

In the event of any liquidation, dissolution, or winding up of Private Disc ("Liquidation Event"), the holders of Series A and Series B Preferred Stock were entitled to receive prior and in preference to the holders of common stock and Series Seed Preferred Stock, an amount equal to the Original Issue Price plus all declared and unpaid dividends on the Series A and Series B Preferred Stock. If the assets and funds available to be distributed to all holders of Series A and Series B Preferred Stock were insufficient to permit the payment, in full, of any of the liquidation preferences, then the entire assets and funds legally available for distribution to the Series A and Series B Preferred Stock would have been distributed ratably among the holders of Series A and Series B Preferred Stock at the time outstanding, ratably in proportion to the full amounts to which they would otherwise be respectively entitled.

After the payment of the full liquidation preference of the Series A and Series B Preferred Stock as set forth above, the holders of shares of Series Seed Preferred Stock were entitled to receive an amount per share of Series Seed Preferred Stock equal to the Original Issue Price plus all declared and unpaid dividends on the Series Seed Preferred Stock. If the assets and funds available to be distributed to all holders of Series Seed Preferred Stock were insufficient to permit the payment, in full, of any of the liquidation preferences, then the entire assets and funds legally available for distribution to the Series Seed Preferred Stock would have been distributed ratably among the holders of Series Seed Preferred Stock at the time outstanding, ratably in proportion to the full amounts to which they would otherwise be respectively entitled or when the remaining capital is distributed.

After the payment of all preferential amounts related to the holders of Preferred Stock, the remaining assets of Private Disc would have been distributed pro rata to the holders of the Preferred Stock and common stock as if the Preferred Stock had converted at the time of the Liquidation Event. Preferential amounts to the holders of Preferred Stock were capped at 2.5 times the applicable Original Issue Price per share plus any dividends declared but unpaid or the amount such holder would have received if all shares had been converted to common stock immediately prior to the Liquidation Event.

Conversion

As of December 31, 2021, the shares of Preferred Stock were convertible into equal shares of common stock, at the conversion price in effect at the time of such conversion, (a) at any time upon the written consent of the holders of a majority of the outstanding shares of the Preferred Stock and at least one holder of Series B Preferred Stock that owned at least 4,166,666 shares of Series B Preferred Stock and that had not purchased any shares of Series A Preferred Stock as part of the Series A Agreement or (b) immediately upon the closing of a Qualified Public Offering. The conversion ratio for the shares of Preferred Stock was 1:1, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization.

Voting Rights

The Preferred Stock vote together with the common stock on an as-converted basis, and not as a separate class, except for matters as defined by the Certificate of Incorporation which required the written consent or affirmative votes of the holders of a majority of the outstanding shares of the Preferred Stock and at least one holder of Series B Preferred Stock that owned at least 4,166,666 shares of Series B Preferred Stock and that had not purchased any shares of Series A Preferred Stock as part of the Series A Agreement. For any transactions that affect the priority of the Series A or Series B Preferred Stock, a majority of Series A or Series B Preferred Stock was required, respectively.

Redemption

The Preferred Stock was not redeemable at the option of the holders thereof. However, the Preferred Stock was redeemable upon the occurrence of certain contingent events, unless otherwise determined by the holders.

As it relates to the redemption upon the occurrence of a contingent event, Private Disc evaluated the Preferred Stock in accordance with the guidance in ASC 480 and determined that the redemption upon the occurrence of a contingent event was not solely within Private Disc's

control and accordingly classified the Preferred Stock in temporary equity. The Preferred Stock was not currently redeemable, nor was it probable that the instruments would have become redeemable, and therefore the instruments were not being accreted to redemption value.

10. Common Stock

At the closing of the merger, the shares of Private Disc's Disc's common stock were converted into shares of the Company's Company's common stock based on the Exchange Ratio.

As of December 31, 2022 December 31, 2023, the authorized capital stock of the Company included 100,000,000 shares of common stock, $0.0001 par value per share. Prior to the merger, the holders of Private Disc's Disc's common stock were subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth above. Stock. Each share of common stock entitles the holder to one vote on all matters submitted to the stockholders for a vote.

As of December 31, 2022 December 31, 2023 and 2022, the Company has reserved 2,459,037 and 2,640,590, respectively, of common stock for the following exercise of stock options and 204,081 shares of common stock were reserved for potential conversion of outstanding Preferred Stock and the exercise of pre-funded warrants.

Registration Statements Resulting from the Merger

In January 2023, as a result of the merger, the Company filed a resale registration statement on Form S-3 with the Securities and Exchange Commission ("SEC"), which covered the proposed resale or other disposition by certain stockholders of up to an aggregate of 12,635,956 shares of the Company's common stock. The Company also filed a registration statement on Form S-8 with the SEC, which registered 1,672,599 shares of common stock options: issuable with respect to Private Disc options assumed by the Company pursuant to the Merger Agreement as well as 2,035,103 additional shares of common stock reserved and available for future issuance under the 2021 Plan and 180,894 additional shares of common stock reserved and available for future issuance under the 2021 Employee Stock Purchase Plan (the "2021 ESPP").

ATM Program

In January 2023, the Company filed a shelf registration statement on Form S-3 with the SEC, which covered the offering, issuance and sale by the Company of up to an aggregate of $300.0 million of the Company's common stock, preferred stock, debt securities, warrants or units (the "January 2023 Shelf"). Subsequently in January 2023, the Company entered into a Sales Agreement (the "Sales Agreement") with SVB Securities LLC, as sales agent, to provide for the offering, issuance and sale by the Company of up to $100.0 million of the Company's common stock from time to time in "at-the-market" ("ATM") offerings under the January 2023 Shelf. Effective June 12, 2023, the ATM program with SVB Securities LLC was suspended. Following the date of the ATM suspension, the Company did not make any further sales of its common stock pursuant to the Sales Agreement. The Sales Agreement was terminated effective September 28, 2023. In connection with the ATM suspension, the Company recognized the remaining

	December 31,	
	2022	2021
Series Seed convertible preferred stock	—	5,000,000

Series A convertible preferred stock	—	41,666,666
Series B convertible preferred stock	—	37,499,999
Stock options	2,640,590	1,456,551
Total	2,640,590	85,623,216

capitalized issuance costs of $0.3 million as general and administrative expense in the consolidated statements of operations and comprehensive loss for the nine months ended September 30, 2023.

As of September 30, 2023, the Company had sold an aggregate of 825,350 shares of common stock in ATM offerings under the January 2023 Shelf and pursuant to the Sales Agreement. Aggregate gross proceeds from the transactions were $20.0 million and the Company received $19.5 million in net proceeds, after deducting placement agent fees and offering expenses.

In October 2023, the Company entered into an Open Market Sale Agreement with Jefferies LLC as sales agent (the “ATM Agreement”) to provide for the offering, issuance and sale by the Company of up to $59.7 million of the Company’s common stock from time to time in ATM offerings under the January 2023 Shelf.

In November 2023, the Company filed a shelf registration statement on Form S-3 with the SEC, which covered the offering, issuance and sale by the Company of up to an aggregate of $400.0 million of the Company’s common stock, preferred stock, debt securities, warrants or units (the “November 2023 Shelf”). On December 5, 2023, the Company and Jefferies LLC entered into an amendment to the ATM Agreement to increase the aggregate offering price of the shares of common stock that the Company may offer under the ATM Agreement from $59.7 million to $200.0 million. The material terms and conditions of the ATM Agreement otherwise remained unchanged.

As of December 31, 2023, the Company had sold an aggregate of 141,914 shares of common stock in ATM offerings under the November 2023 Shelf and pursuant to the ATM Agreement. Aggregate gross proceeds from the transactions were $7.2 million and the Company received $7.0 million in net proceeds, after deducting placement agent fees and offering expenses.

Registered Direct Offering

In February 2023, the Company entered into a securities purchase agreement, with certain investors. Pursuant to the securities purchase agreement, the Company sold an aggregate of 1,488,166 shares of the Company’s common stock, at a purchase price of $23.00 per share, and with respect to a certain investor, in lieu of shares of the Company’s common stock, pre-funded warrants to purchase an aggregate of 1,229,224 shares of the Company’s common stock, at a purchase price of $22.9999 per pre-funded warrant, for aggregate net proceeds of $62.4 million, after deducting offering expenses of $0.1 million.

The pre-funded warrants provide that the holder will not have the right to exercise any portion of its warrants if such holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of the Company’s common stock outstanding immediately after giving effect to such exercise (the “Beneficial Ownership Limitation”); provided, however, that the holder may increase or decrease the Beneficial Ownership Limitation by giving 61 days’ notice, but not to any percentage in excess of 19.99%. The investors or their affiliates are beneficial holders of more than 5% of the Company’s capital stock. The pre-funded warrants meet the condition for equity classification and were therefore recorded as a component of stockholders’ equity within additional paid-in capital at the time of their issuance.

During the twelve months ended December 31, 2023, all of the pre-funded warrants were exercised in a cashless transaction which resulted in 1,229,221 shares of common stock being issued to the investor.

Follow-On Public Offering

In June 2023, the Company issued 3,015,919 shares of its common stock upon the completion of its public follow-on offering, which included the exercise in full by the underwriters of their option to purchase up to 420,000 additional shares of common stock, at a public offering price of $49.00 per share. The Company also sold, in lieu of shares of the Company’s common stock, pre-funded warrants to purchase an aggregate of 204,081 shares of common stock at a price of $48.9999 per pre-funded warrant. The Company received aggregate

net proceeds of $147.9 million, after deducting offering expenses of $9.9 million. As of December 31, 2023, none of the 204,081 pre-funded warrants had been exercised.

The pre-funded warrants provide that the holder will not have the right to exercise any portion of its warrants if such holder, together with its affiliates, would beneficially own in excess of 24.99% of the number of shares of Common Stock outstanding immediately after giving effect to the exercise (the "Ownership Limit"). Purchasers of the pre-funded warrants may also elect to set the initial Ownership Limit at 4.99%, 9.99% or 19.99%. Upon at least 61 days' prior notice from the holder to the Company, the holder may increase or decrease the Ownership Limit up to 24.99%, provided however that purchasers that select an Ownership Limit of 19.99% or less will only be allowed to increase the Ownership Limit above 19.99% if such increase would not result in a change of control under the rules and regulations of the Nasdaq Stock Market LLC. The pre-funded warrants meet the condition for equity classification and were therefore recorded as a component of stockholders' equity within additional paid-in capital.

11. Stock-Based Compensation

2017 Stock Option and Grant Plan

Private Disc adopted the 2017 Stock Option and Grant Plan (the "Private Disc Plan") in November 2017 reserving shares of common stock for issuance to employees, directors, and consultants. The Private Disc Plan allowed for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards and other stock awards. Recipients of stock options or stock appreciation rights were eligible to purchase shares of Private Disc's common stock at an exercise price equal to the estimated fair market value of such stock on the date of grant. The exercise price could have been less than fair market value if the stock award was granted pursuant to an assumption or substitution for another stock award in the event of a merger or sale of Private Disc. The maximum term of options granted under the Private Disc Plan was ten years, and stock options typically vested over a four-year period. The Board could have assigned vesting terms to the stock options

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grants as deemed appropriate. Private Disc also had the right of first refusal to purchase any proposed disposition of shares issued under the Private Disc Plan. As it relates to restricted stock awards, Private Disc had the option to repurchase any unvested shares at the original purchase price upon any voluntary or involuntary termination. At the discretion of the Board, unvested shares held by employees, directors and consultants could have accelerated vesting in the event of a change of control of Private Disc unless assumed or substituted by the acquirer or surviving entity.

The number of shares of common stock reserved for issuance as of December 31, 2022 December 31, 2023 and 2021 2022 was1,505,624 and 1,672,599 and 1,777,309shares, respectively. Options available for grant were As of December 31, 2023 and 2022, there are no options and 247,896 options at December 31, 2022 and 2021, respectively. available for grant. Upon completion of the merger, the Company ceased granting awards under the Private Disc Plan.

2021 Stock Option and Incentive Plan

In February 2021, Gemini adopted the 2021 Stock Option and Incentive Plan ("the 2021 Plan") reserving shares of common stock to grant incentive stock options or nonqualified stock options for the purchase of common stock, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, cash-based awards and dividend equivalent rights to employees, officers, directors and consultants. Upon approving the 2021 Plan in February 2021, Gemini ceased granting awards under its then existing 2017 Stock Option and Grant Plan. Incentive stock options may only be granted to employees. The 2021 Plan is administered by the plan administrator, which is the compensation committee of the Company's board of directors, provided therein, which has discretionary authority, subject only to the express provisions of the 2021 Plan, to interpret the 2021 Plan; determine eligibility for and grant awards; determine form of settlement of awards (whether in cash, shares of stock, other property or a combination of the foregoing), determine, modify or waive the terms and conditions of any award; prescribe forms, rules and procedures; and otherwise do all things necessary to carry out the purposes of the 2021 Plan. As of December 31, 2022 December 31, 2023, 1,031,615 1,561,926 shares remained available for future issuance under the 2021 Plan. The number of shares of common stock reserved for issuance under the 2021 Plan automatically increases on January 1 of each calendar year, starting on January 1, 2022 and continuing through January 1, 2031, in an amount equal to 4% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Company's board of directors.

The exercise price of each stock option granted under the 2021 Plan is 100% of the fair market value of the underlying stock subject to the award, determined as of the date of the grant, or such higher amount as the plan administrator may determine in connection with the grant, and the term of stock option may not be greater than ten years. The vesting and other restrictions are determined at the discretion of the plan administrator.

2021 Employee Stock Purchase Plan

In July 2021, Gemini's board of directors approved the 2021 Employee Stock Purchase Plan (the "2021 ESPP"). The first offering period under the 2021 ESPP began on December 1, 2021. As of December 31, 2022 December 31, 2023, 179,898 222,953 shares remained available for future issuance under the 2021 ESPP. The number of shares of common stock reserved for issuance under the 2021 ESPP automatically increases on January 1 of each calendar year, starting on January 1, 2023 and continuing through January 1, 2031, in an amount equal to the least of (a) 1% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, (b) 43,055 shares of common stock, or (c) such number of shares determined by the Company's board of directors.

2021 Inducement Plan

In February 2021, Gemini's board of directors approved the 2021 Inducement Plan. The 2021 Inducement Plan is a non-stockholder approved stock plan under which equity awards are granted to induce highly-qualified prospective officers and employees who are not currently employed by the Company to accept employment and provide them with a proprietary interest in the Company. Upon From the completion of the merger through December 31, 2023, the Company ceased granting had not granted awards under the 2021 Inducement Plan. As of December 31, 2023, 153,712 shares remained available for future issuance under the plan.

Reverse Merger with Gemini

In connection with the merger, each option to purchase shares of Private Disc common stock that was outstanding and unexercised under the Private Disc Plan immediately prior to the Effective Time, whether or not vested, was converted into an option to purchase shares of Gemini common stock and became eligible to be registered on Form S-8. Gemini assumed the

Private Disc Plan, as amended, and each such outstanding option to purchase shares of Private Disc common stock in accordance with the terms (as in effect as of the date of the Merger Agreement) of the Private Disc Plan and the terms of the stock option agreement by which such option to purchase shares of Private Disc common stock is evidenced.

On December 29, 2022, Gemini's shareholders approved amendments to the 2021 Plan and the 2021 ESPP to (i) increase the number of shares of common stock reserved for issuance under the 2021 Plan to a number of shares representing approximately 9% of the fully diluted capitalization of the Company, determined as of immediately following the merger and (ii) increase the number of shares of common stock reserved for issuance under the 2021 ESPP to a number of shares representing approximately 0.84% of the fully diluted capitalization of the Company, determined as of immediately following the merger.

Stock Options

For purposes of calculating stock-based compensation, the Company estimates the fair value of stock options using the Black-Scholes option-pricing model. This model incorporates various assumptions, including the expected volatility, expected term, and interest rates.

Prior to the merger, Private Disc lacked company-specific historical and implied volatility information. Therefore, Private Disc estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer public companies and the Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the option. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected dividend yield of 0% is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table summarizes stock option activity for the year ended December 31, 2022 December 31, 2023.

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value (In Thousands)	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value (In Thousands)
Outstanding at December 31, 2021	1,456,551	$ 5.48	8.98	$ 13,027				
Assumed in reverse recapitalization	303,497	$ 71.56						
Outstanding at December 31, 2022					2,640,590	$ 16.19	8.08	$ 25,513
Granted	978,539	$ 13.94			236,503	43.42		
Exercised	(53,224)	$ 4.12			(254,432)	11.09		
Forfeited	(44,773)	$ 8.25			(21,173)	17.90		

Outstanding at December 31, 2022	2,640,590	$	16.19	8.08	$	25,513				
Exercisable at December 31, 2022	1,010,939	$	24.53	6.33	$	11,037				
Expired							(142,451)	111.15		
Outstanding at December 31, 2023							2,459,037	$ 13.82	7.81	$ 109,078
Exercisable at December 31, 2023							1,271,208	$ 9.78	7.08	$ 61,992

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the common stock as of the end of the period. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2022 December 31, 2023 and 2021 2022 was $8.3 million and $0.6 million, and $0.3 million, respectively.

The weighted-average assumptions used to estimate the fair value of stock options granted were as follows:

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Risk-free interest rate	3.54%	0.95%	4.03%	3.54%
Expected term (in years)	5.94	6.00	6.88	5.94
Expected volatility	60%	59%	59%	60%
Expected dividend yield	0%	0%	0%	0%
Fair value per share of common stock	$ 13.94	$ 9.26	$ 43.42	$ 13.94

The weighted-average grant date fair value of options granted in the years ended December 31, 2022 December 31, 2023 and 2021 2022 was $26.54 and $8.13 and $4.98per share, respectively.

The total fair value of options vested during the years ended December 31, 2022 December 31, 2023 and 2021 2022 was $3.7 million and $1.9 million, and $ respectively.

0.4 127

million, respectively.

Shares of Restricted Common Stock

As of December 31, 2022 December 31, 2023, the Company had issued a total of 63,061 shares of restricted common stock to the founders of Private Disc pursuant to subscription agreements and to certain key employees pursuant to the Private Disc Plan at $0.0001 per share. The stock restrictions relate to the sale and transferability of the stock and lapse over the defined vesting period in the restricted stock

agreement. The vesting period is generally contingent upon continued employment or consulting services being provided to the Company. In the event of termination, the Company has the right, but not the obligation to repurchase the unvested shares at the original purchase price. As of December 31, 2023, all awards of restricted common stock were fully vested.

A summary of restricted common stock activity is as follows:

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Unvested at the beginning of the year	10,170	24,940	1,916	10,170
Vested	(8,254)	(14,770)	(1,916)	(8,254)
Unvested at the end of the year	1,916	10,170		
Unvested at the end of the period			—	1,916

As of December 31, 2022, the unrecognized stock-based compensation expense related to restricted common stock is expected to be recognized over a weighted-average period of 0.25 years.

Stock-Based Compensation Expense

Total stock-based compensation expense recorded as research and development and general and administrative expenses, respectively, for employees, directors and non-employees is as follows (in thousands):

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Research and development	$ 581	$ 223	$ 1,767	$ 581
General and administrative	1,508	284	3,763	1,508
Total stock-based compensation expense	$ 2,089	$ 507	$ 5,530	$ 2,089

As of December 31, 2022 December 31, 2023, the total unrecognized stock-based compensation expense related to outstanding awards was $10.0 11.5 million and is expected to be recognized over a weighted-average period of 2.98 2.63 years.

12. Income Taxes

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Federal statutory income tax rate	21.0%	21.0%	21.0%	21.0%
State income taxes, net of federal benefit	6.3	7.3	8.0	6.3
Federal and state research and development tax credits	3.5	1.3	4.0	3.5
Stock-based compensation			1.3	(0.4)

Other	(0.3)	(0.3)	(0.7)	0.1
Change in deferred tax asset valuation allowance	(30.5)	(29.3)	(33.6)	(30.5)
Effective income tax rate	0%	0%	0%	0%

For the twelve months ended December 31, 2022 and 2021, no December 31, 2023, the Company recorded income tax expense was of $0.1 million due to state income tax resulting from higher interest income. For the twelve months ended December 31, 2022, the Company recordedno income tax expense due to the Company's net operating loss ("NOL") and full valuation allowance.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The significant components of the Company's net deferred income taxes are as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 18,882	$ 15,128
Research and experimental expenditures	7,608	—
Tax credits	3,550	1,639
Capitalized licenses	3,142	3,214
Accrued expenses	2,416	—
Stock-based compensation	565	34
Operating lease liabilities	359	452
Total deferred tax assets	36,522	20,467
Valuation allowance	(36,102)	(19,997)
Total deferred tax assets, net of valuation allowance	420	470
Deferred tax liabilities:		
Operating right-of-use assets	(385)	(448)
Depreciation	(35)	(22)
Total deferred tax liabilities	(420)	(470)
Net deferred tax assets	$ —	$ —

	December 31,	
	2023	2022
Deferred tax assets:		

Net operating loss carryforwards	$ 24,312	$ 18,882
Research and experimental expenditures	20,598	7,608
Tax credits	7,202	3,550
Capitalized licenses	6,890	3,142
Accrued expenses	1,513	2,416
Stock-based compensation	1,234	565
Operating lease liabilities	574	359
Total deferred tax assets	62,323	36,522
Valuation allowance	(61,768)	(36,102)
Total deferred tax assets, net of valuation allowance	555	420
Deferred tax liabilities:		
Operating right-of-use assets	(527)	(385)
Depreciation	(28)	(35)
Total deferred tax liabilities	(555)	(420)
Net deferred tax assets	$ —	$ —

The Company has had no Company's income tax expense due provision for the twelve months ended December 31, 2023 related to operating losses incurred since inception. The Company's losses before state and foreign income taxes consist solely of losses from domestic operations. taxes. The Company has evaluated the positive and negative evidence bearing upon the reliability of its deferred tax assets. Based on this, the Company has provided a valuation allowance for the full amount of the net deferred tax assets as the realization of the deferred tax assets is not determined to be more likely than not. During the year ended December 31, 2022 December 31, 2023, the valuation allowance increased by $16.1 25.7 million primarily due to the increase in the Company's net operating loss, capitalized expenditures and tax credit carryforwards during the period.

As of December 31, 2022 December 31, 2023, the Company had $69.3 88.1 million and $67.7 91.7 million of federal and state operating loss carryforwards, respectively. The pre-merger net operating loss carryforwards of Gemini were written off in the transaction as these would be permanently restricted from use as a result of Section 382 of the Internal Revenue Code of 1986 ("Section 382"). Substantially all of the federal NOLs are not subject to expiration and the state NOLs begin to expire in 2037. These loss carryforwards are available to reduce future federal taxable income, if any. As of December 31, 2022 December 31, 2023, the Company also had federal and state research and development tax credit carryforwards of $2.7 5.8 million and $1.1 1.8 million respectively, to offset future income taxes, which will begin to expire beginning in December 2032. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities.

Utilization of the Company's NOL carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382 as well as similar state provisions. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change as defined by Section 382 results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. Since its formation, the Company has raised capital through the issuance of capital stock on several occasions. These financings could result in a change of control as defined by Section 382. The Company has not yet conducted an analysis under Section 382 to determine if historical changes in ownership through December 31, 2022 December 31, 2023, would limit or otherwise restrict its ability to utilize its NOL and research and development credit carryforwards. In addition, future changes in ownership occurring after December 31, 2022 December 31, 2023 could affect the limitation in future years, and any limitation may result in expiration of a portion of the NOL or research and development credit carryforwards before utilization.

Beginning in 2022, the Tax Cuts and Jobs Act ("TCJA") amended Section 174 and now requires U.S.-based and non-U.S.-based research and experimental expenditures to be capitalized and amortized over a period of five or 15 years, respectively, for amounts paid in tax years starting after December 31, 2021. Prior to the TCJA amendment, Section 174 allowed taxpayers to immediately deduct research and experimental expenditures in the year paid or incurred. The Company has applied this required change in accounting method beginning in 2022 and the computation may be adjusted pending future IRS guidance.

On December 18, 2015, the Protecting Americans from Tax Hikes ("PATH") Act of 2015 was signed into law. The PATH Act has created several research and development credit provisions, including allowing a qualified small business to utilize the research credit against the employer portion of payroll tax (i.e., FICA tax) not exceeding $0.3 million per year. This provision is

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available for credits generated in tax years beginning after 2015. The Company qualifies does not qualify as a small business for 2022 2023 and will not elect to make a small business election.

The Company follows the provisions of ASC Topic 740-10, *Accounting for Uncertainty in Income Taxes*, which specifies how tax benefits for uncertain tax positions are to be recognized, measured, and recorded in financial statements; requires certain disclosures of uncertain tax matters; specifies how reserves for uncertain tax positions should be classified on the consolidated balance sheets; and provides transition and interim period guidance, among other provisions. As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company has not recorded any amounts for uncertain tax positions. The Company's policy is to recognize interest and penalties accrued on any uncertain tax positions as a component of income tax expense, if any, in its consolidated statements of operations and comprehensive loss. As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company had no reserves for uncertain tax positions. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, no estimated interest or penalties were recognized on uncertain tax positions.

The Company's tax returns for the years ended December 31, 2019 to December 31, 2022 December 31, 2023 remain open and subject to examination by the Internal Revenue Service and state taxing authorities.

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13. Net Loss Per Share

Basic and diluted net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average common shares outstanding. The weighted-average common shares outstanding used in the basic and diluted net loss per share calculation includes the pre-funded warrants issued in connection with the Company's follow-on public offering in June 2023 and registered direct offering in February 2023 as the pre-funded warrants are exercisable for nominal cash consideration. In September 2023, 1,229,224 of the pre-funded warrants were exercised in a cashless transaction which resulted in 1,229,221 shares of common stock being issued to the investor. As of December 31, 2023, 204,081 pre-funded warrants were outstanding. The following table sets forth the computation of the Company's basic and diluted net loss per share (in thousands, except share and per share data):

	Year Ended December 31,	
	2022	2021
Numerator:		

Net loss attributable to common stockholders-basic and diluted	$ (46,827)	$ (35,969)
Denominator:		
Weighted-average common shares outstanding-basic and diluted	1,039,490	878,407
Net loss per share attributable to common stockholders-basic and diluted	$ (45.05)	$ (40.95)

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss attributable to common stockholders-basic and diluted	$ (76,429)	$ (46,827)
Denominator:		
Weighted-average common shares outstanding-basic and diluted	22,315,877	1,039,490
Net loss per share attributable to common stockholders-basic and diluted	$ (3.42)	$ (45.05)

The Company's potentially dilutive securities have been excluded from the computation of diluted Company has generated a net loss per share as in all periods presented, so the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is are the same. same, as the inclusion of the potentially dilutive securities would be anti-dilutive. The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	December 31,	
	2022	2021
Series Seed convertible preferred stock	—	5,000,000
Series A convertible preferred stock	—	41,666,666
Series B convertible preferred stock	—	37,499,999
Unvested restricted common stock	1,916	10,170
Options to purchase common stock	2,640,590	1,456,551

	December 31,	
	2023	2022
Unvested restricted common stock	—	1,916
Options to purchase common stock	2,459,037	2,640,590
Employee stock purchase program	4,878	—

14. Commitments and Contingencies

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to its vendors, lessors, contract research organizations, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its Board that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the

Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the twelve months ended December 31, 2022 December 31, 2023 and 2021 2022 and, to the best of its knowledge, no material legal proceedings are currently pending or threatened.

Payments Upon Termination

The Company enters into contracts in the normal course of business with CROs, CDMOs and other third parties for preclinical studies, clinical trials and manufacturing services. These contracts typically do not contain minimum purchase commitments and are generally cancelable by the Company upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including noncancelable obligations of the Company's service providers, up to the date of cancellation and, in the case of certain arrangements with CROs and CDMOs, may include noncancelable fees. Under such agreements, the exact amounts owed by the Company in the event of termination will be based on the timing of the termination and the exact terms of the agreement.

15. Leases

In September 2021, Private Disc and its landlord jointly entered a termination agreement to provide an early termination date in November 2021 for its operating lease in Cambridge, Massachusetts. In addition, the landlord provided an incentive of $0.1 million. On the modification date, Private Disc decreased the lease liability and corresponding right-of-use asset to zero. Private Disc recognized the incentive as a reduction to lease expense over the remaining lease term. As of December 31, 2022 and

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2021, the Company had a security deposit in the form of an irrevocable standby letter of credit in the amount of $0.1 million related to this lease, which was recorded as prepaid expenses and other current assets on the Company’s consolidated balance sheets as of December 31, 2022 and 2021.

In October 2021, Private Disc entered into a five-year lease through November 2026 of 7,566 square feet of office space located at 321 Arsenal Street, Watertown, Massachusetts to be used as its corporate headquarters. In June 2023, the lease was amended to allow the landlord to perform certain maintenance activities expected to be completed by the end of 2023 and to provide rent abatement of $0.2 million. The Company’s landlord is amendment was accounted for as a related party modification resulting in a new incremental borrowing rate and a reduction to the right-of-use asset and lease liability of $0.2 million. In September 2023, the Company recognized a reassessment event which was accounted for as a modification resulting in a new incremental borrowing rate and a reduction to the right-of-use asset and lease liability of an additional $0.2 million. In November 2023, the Company recognized another reassessment event which was accounted for as a modification resulting in an increase to the right-of-use asset and lease liability of $0.1 million.

In June 2023, the Company entered into a sublease for a term of approximately three and a half years through November 2026, consisting of 9,281 square feet of office space on the second floor of the Company due to its equity ownership. The lease term

began corporate headquarters in November 2021 and will end in November 2026, unless terminated earlier. The lease contains a five-year renewal option, which the Company is not reasonably certain to exercise. Watertown, Massachusetts. Fixed lease payments include base rent, subject to annual rent increases, and a management fee. Variable lease payments include the Company's allocated share of costs incurred for real estate taxes, utilities, and other operating expenses applicable to the leased premises. In connection with the lease, a security deposit was delivered to the landlord in the form of an irrevocable standby letter of credit in the amount of $0.1 million, which is recorded as other assets (non-current) on the Company's consolidated balance sheet as of December 31, 2022. Pursuant to the lease, the Company is also obligated to pay for certain administrative costs, taxes and operating expenses.

The components of lease expense were as follows (in thousands):

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Operating lease costs	$ 422	$ 187	$ 422	$ 422
Short-term lease costs	—	—		
Variable lease costs	177	42	159	177
Total lease expense	$ 599	$ 229	$ 581	$ 599

Other information related to the Company's leases is as follows (in thousands, except term and discount rate amounts):

	Year Ended December 31,		Year Ended December 31,	
	2022	2021	2023	2022
Weighted average remaining lease term	3.91 years	4.91 years	2.92 years	3.91 years
Weighted average discount rate	5.5%	5.5%	10.0%	5.5%
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows used in operating leases	$ 480	$ 250	$ 186	$ 480

A maturity analysis of the annual undiscounted cash flows reconciled to the carrying value of the operating lease liabilities as of December 31, 2022 December 31, 2023, reflective of the Company's election to account for lease and non-lease components together, is as follows (in thousands):

Year Ending December 31,	Operating Leases	Operating Leases
2023	$ 373	
2024	382	845
2025	394	850
2026	336	729
2027	—	
Total minimum lease payments	1,485	2,424
Less imputed interest	(151)	(323)
Present value of lease liabilities	$ 1,334	$ 2,101

16. Related Party Transactions

The landlord of the Company's leased office space in Watertown, Massachusetts is a related party of the Company due to its equity ownership.

In February 2023, certain existing investors participated in the Company's registered direct offering (see Note 10).

In March 2023, the Company executed a promissory note for an aggregate principal amount of $0.5 million from an existing investor. The Company did not use these funds and repaid the note four days later, recording a de minimis amount of interest expense based on the then Federal funds rate for short term loans of 4.5% per annum.

In June 2023, an existing investor participated in the Company's follow-on offering (see Note 10).

17. Subsequent Events

The Company has completed an evaluation of all subsequent events after the audited consolidated balance sheet date of December 31, 2022 December 31, 2023 through March 31, 2023, the date these consolidated financial statements were issued to ensure that these consolidated financial statements include appropriate disclosure of events both recognized in the consolidated financial statements as of December 31, 2022 December 31, 2023, and events which occurred subsequently but were not recognized in the consolidated financial statements. Non-recognizable subsequent events through March 31, 2023 are summarized below.

Registration Statements Resulting from the Merger

In January 2023, as a result of the merger, the Company filed a resale registration statement on Form S-3 with the SEC, which covered the proposed resale or other disposition by certain stockholders of up to an aggregate of 12,635,956 shares of the Company's common stock. The Company also filed a registration statement on Form S-8 with the SEC, which registered 1,672,599 shares of common stock issuable with respect to Private Disc options assumed by the Company pursuant to the Merger Agreement as well as 2,035,103 additional shares of common stock reserved and available for future issuance under the 2021 Plan and 180,894 additional shares of common stock reserved and available for future issuance under the 2021 ESPP.

Exclusive License Agreement with Mabwell Therapeutics, Inc.

In January 2023, the Company entered into an exclusive license agreement with Mabwell Therapeutics, Inc. ("Mabwell"), pursuant to which Mabwell granted the Company an exclusive and sublicensable license to certain Mabwell intellectual property.

The Company is obligated to pay Mabwell an upfront payment of $10.0 million, and certain development and regulatory milestone payments for the licensed products, for up to three indications, up to a maximum aggregate amount of $127.5 million, as well as certain commercial milestone payments for certain licensed product net sales achievements, up to a maximum aggregate amount of $275 million. The Company is further obligated to pay a tiered percentage of revenue that the Company receives from its sublicensees ranging from a low third decile percentage to a low first decile percentage. In addition, the Company is obligated to pay Mabwell a royalty on annual net sales of all

licensed products at a tiered rate ranging from low single-digits to high single-digits. The Company paid the upfront payment of $10.0 million to Mabwell in March 2023.

ATM Program

In January 2023, the Company filed a shelf registration statement on Form S-3 with the SEC, which covered the offering, issuance and sale by the Company of up to an aggregate of $300.0 million of the Company's common stock, preferred stock, debt securities, warrants or units. Subsequently in January 2023, the Company entered into a Sales Agreement with SVB Securities LLC, as sales agent, to provide for the offering, issuance and sale by the Company of up to $100.0 million of the Company's common stock from time to time in "at-the-market" offerings under the shelf.

As of March 31, 2023 March 21, 2024, the issuance date of these consolidated financial statements, the Company has sold an aggregate of 608,050 234,449 shares of common stock in at-the-market ATM offerings under the shelf for gross proceeds of $15.0 million.

Registered Direct Offering

In February November 2023 the Company entered into a securities purchase agreement (the "Purchase Agreement"), with certain investors. Pursuant Shelf and pursuant to the Purchase ATM Agreement the Company sold an aggregate of 1,488,166 shares of the Company's common stock, at a purchase price of $23.00 per share, and with respect to certain investors, in lieu of shares of the Company's common stock, pre-funded warrants to purchase an aggregate of 1,229,224 shares of the Company's common stock, at a purchase price of $22.9999 per pre-funded warrant, for aggregate gross proceeds of $62.5 15.3 million. The pre-funded warrants provide that the holder will not have the right to exercise any portion of its warrants if such holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise (the "Beneficial Ownership Limitation"); provided, however, that the holder may increase or decrease the Beneficial Ownership Limitation by giving 61 days' notice, but not to any percentage in excess of 19.99%. The investors or their affiliates are beneficial holders of more than 5% of the Company's capital stock.

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Principal Executive Officer (our Chief Executive Officer) and Principal Financial Officer (our Chief Financial Officer), has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2022 December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is

accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2022 December 31, 2023, our Principal Executive Officer and Principal Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control Over Financial Reporting

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. We maintain a system of internal control that is designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Notwithstanding that we do not qualify for Management assessed the relief afforded by Instruction 1 to Item 308 effectiveness of Regulation S-K to newly public companies, management has not assessed nor attested to our internal control over financial reporting as is set forth of December 31, 2023. In making this assessment, it used the criteria established in Item 308 Internal Control—Integrated Framework (2013) issued by the Committee of Regulation S-K promulgated under the Securities Exchange Act 1934, as amended, and Section 404 Sponsoring Organizations of the Sarbanes-Oxley Act as of December 31, 2022, the end of Treadway Commission (COSO). Based on such assessment, management has concluded that our last fiscal year. We will do so initially internal control over financial reporting was effective as of December 31, 2023.

We were unable to conduct the required assessment primarily due to the merger that closed on December 29, 2022 and the substantial change in operational focus, management and the internal control environment following the merger and due to the fact the internal controls of the legal acquirer no longer existed as of the required assessment date and during that period. Since completion of the merger, we engaged an external consulting firm to assist in the implementation of ICFR best practices to position management to report on its assessment of internal controls for 2023.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

Other than as discussed above, there have not been any changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three twelve months ended December 31, 2022 December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

The following table discloses any officer (as defined in Rule 16a-1(f) under the Exchange Act) or director who entered into, modified or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K) during the three months ended December 31, 2023:

None.

Name and Title	Type of Trading Arrangement	Action Taken (Date of Action)	Duration or End Date	Aggregate Number of Securities to be Sold	Description of Trading Arrangement
William White *Director*	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c)	Adoption (December 13, 2023)	End Date (December 31, 2024)	16,572	Sale
William Savage *Chief Medical Officer*	Trading plan intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c)	Adoption (December 20, 2023)	End Date (August 30, 2024)	23,341	Sale

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth the name, age and position of each of the individuals who serve as executives and directors of our company as of February 28, 2023 February 29, 2024.

Name	Age	Position
Executive Officers:		
John Quisel, J.D., Ph.D.	51 52	Chief Executive Officer and Director
Joanne Bryce, CPA Jean Franchi	57	Chief Financial Officer
Jonathan Yu, MBA	43	Chief Operating Officer
William Savage, MD, Ph.D.	49	Chief Medical Officer
Pamela Stephenson, MPH	56	Chief Financial Officer
Jonathan Yu	42	Chief Business Officer
William Savage, MD, Ph.D.	48	Chief Medical Officer

Brian MacDonald, MB, Ch.B., Ph.D.	63	Chief Innovation Commercial Officer
Rahul Khara, Pharm.D., J.D.	41 42	General Counsel
Non-Employee Directors:		
Donald Nicholson, Ph.D.	65 66	Executive Chairman and Director
Mona Ashiya, Ph.D.	54	Director
Jay Backstrom, M.D., M.P.H	68 55	Director
Kevin Bitterman, Ph.D.	46 47	Director
Mark Chin, MS, MBA	41	Director
Georges Gemayel, Ph.D.	62 63	Director
Liam Ratcliffe, MD, Ph.D.	59 60	Director
William White, MPP, J.D.	50 51	Director

Each executive officer serves at the discretion of the board and will hold office until his or her successor is duly elected and qualified or until his or her earlier resignation or removal. There are no family relationships among any of our directors or executive officers.

Executive Officers

John Quisel, J.D., Ph.D. has served as our President, Chief Executive Officer and as a member of our board of directors since February 2020. Previously, from October 2006 through February 2020, Dr. Quisel served in various positions at Acceleron Pharma Inc., or Acceleron, a biopharmaceutical company, most recently as Chief Business Officer. Prior to joining Acceleron, Dr. Quisel worked as an associate at the law firms of Ropes & Gray and Foley Hoag. Since November 2023, Dr. Quisel serves as a board member of Gossamer Bio, Inc. (Nasdaq: GOSS). Dr. Quisel holds an AB A.B. from Harvard University, an MS M.S. from Stanford University, a Ph.D. from the Massachusetts Institute of Technology, and a J.D. from Harvard Law School. Dr. Quisel is qualified to serve as a member of our board because of his significant scientific industry and management experience, including the experience gained from prior service as a Chief Business Officer.

Joanne Bryce, CPA ***Jean Franchi***has served as our Chief Financial Officer since September 2021. February 2024. Previously, she Ms. Franchi served as a part-time consultant for us acting as our Chief Financial Officer from November 2017 to September 2021. Ms. Bryce was previously the Chief Financial Officer of Arkuda Therapeutics, Replimune Group, Inc. (Nasdaq: REPL), a biotechnology company, having served from February 2018 December 2019 to September 2021. Additionally, she previously June 2023. From August 2017 to May 2019, Ms. Franchi served as a consultant to Dyne Therapeutics, a muscle disease company, acting as head of finance, from January 2018 to March 2020, and was also previously the Chief Financial Officer of Quartet Medicine, Merrimack Pharmaceuticals, Inc., a biotechnology company, from November 2016 biopharmaceutical company. From August 2015 to November 2018. Prior to Quartet, Ms. Bryce held July 2017, she served as Chief Financial Officer, roles Treasurer and Secretary at Dimension Therapeutics, Inc., a number of technology companies, including Speedy Packets from October 2014 biotechnology company. From February 2012 to November 2016 and WiTricity from September 2008 to June 2014. July 2015, Ms. Bryce was Interim Chief Executive Officer at Jingle Networks from November 2005 to November 2008 and Franchi served as an independent consultant for multiple organizations between 2001 and 2005. Ms. Bryce was also Chief Financial Officer at Narrative Communications, later acquired by At Home Corporation, from January 1997 Good Start Genetics, Inc., a molecular genetics information company. From 1995 to July 2000. 2011, Ms. Bryce began her career Franchi held various positions at Arthur Andersen & Co. Sanofi S.A., an accounting firm. including Senior Vice President of Corporate Finance, Senior Vice President of Business Unit Finance, and Vice President of Finance and Controller, Product Line and International Group. Ms. Bryce Franchi holds a B.S. B.B.A. from Babson College and is a certified public accountant licensed in the Commonwealth of Massachusetts.Hofstra University.

Jonathan Yu, MBA has served as our Chief Business Operating Officer since August 2021, February 2024, and was previously our Chief Business Officer from August 2021 to February 2024, and our Senior Vice President of Corporate Development from July 2020 to August 2021. Previously, he Mr. Yu co-founded Qpex Biopharma, a biotechnology company, where he served as the Vice President of Corporate Strategy, Finance and Operations from October 2018 to July 2020. Prior to Qpex, Mr. Yu served in various leadership roles at The Medicines Company, a pharmaceutical company, from July 2013 to July 2018, most recently serving as Vice President of Strategic Planning and Corporate Development. Mr. Yu has also held a variety of roles at SR One, Acceleron Pharma and Johnson & Johnson, spanning commercial planning and assessment, business development and finance. Mr. Yu holds an AB A.B. from Harvard College and an MBA M.B.A. from the Wharton School of the University of Pennsylvania.

William Savage, MD, M.D., Ph.D. has served as our Chief Medical Officer since August 2021 and was previously our Vice President, Head of Clinical Development from August 2020 to August 2021. Previously, he served as Senior Medical Director at

Magenta Therapeutics, a biotechnology company, from July 2019 to July 2020. Prior to Magenta Therapeutics, he was the Global

Clinical Development Lead in Hematology at Shire plc and Takeda Pharmaceutical Company, following its acquisition of Shire, both pharmaceutical companies, from January 2017 to July 2019. Dr. Savage was also an Assistant Professor of Pathology at Harvard Medical School/Brigham and Women's Hospital from July 2012 to January 2017. He Dr. Savage started his career at Johns Hopkins University School of Medicine, where he was Associate Medical Director, Transfusion Medicine and Assistant Professor of Pediatric Hematology. Dr. Savage holds a BA B.A. from Columbia University, an MD M.D. with honors in research from Weill Cornell Medical College and a Ph.D. from the Johns Hopkins Bloomberg School of Public Health.

Brian MacDonald, MB, Ch.B., Ph.D., Pamela Stephenson, MPH has served as our Chief Innovation Commercial Officer since September 2021 and February 2024. Previously, Ms. Stephenson served as Chief Commercial Officer at Albireo Pharma, Inc., a biopharmaceutical company, from March 2019 to April 2023. Prior to that, she served as a member Vice President at Vertex Pharmaceuticals, Inc. (Nasdaq:VRTX), a biotechnology company, from July 2008 to March 2019. Prior to Vertex, she held roles of our board of directors from February 2020 until September 2021. Dr. MacDonald was our founding and Interim Chief Executive Officer increasing strategic importance at Pfizer Inc. (Nasdaq: PFE), a pharmaceutical company, from October 2017 through February 2020, 1998 to June 2008. Ms. Stephenson holds a B.A. from Brown University and has founded another company engaged in the discovery an M.P.H. from Boston University School of hepcidin-targeting therapeutics, Merganser Biotech, Inc., where he was the Chief Executive Officer from September 2011 through July 2016. Prior to that, he spent six years as Chief Executive Officer of Zelos Therapeutics from October 2005 through September 2011. He was also previously Head of Regulatory Affairs at Tetralogic from 2004 to 2005, Vice President, Development at 3-Dimensional Pharmaceuticals, Inc. from 2002 to 2003 and Group Director, Emerging Therapeutic Areas, at GSK from 2000 to 2002. Dr. MacDonald received his MB, Ch.B. and Ph.D. from the University of Sheffield, and is a member of the Royal College of Physicians.Public Health.

Rahul Khara, Pharm.D., J.D., has served as our General Counsel since December 2021 and as our Compliance Officer and Secretary since December 2022. Dr. Khara previously served as Vice President, Legal and Chief Compliance Officer at Acceleron Pharma Inc. from August 2018 until to December 2021. Prior to joining Acceleron, he Dr. Khara was a Senior Associate at the law firm Arnold & Porter LLP from March 2015 until to August 2018. Prior to that, Dr. Khara was a Senior Associate at the law firm Sidley Austin LLP from September 2008

until to March 2015. Dr. Khara received his J.D. from the University of Michigan Law School. He School and earned a Pharm.D. from Rutgers University.

Non-Employee Directors

Donald Nicholson, Ph.D. has served as Executive Chairman of our board of directors since April 2019. Dr. Nicholson is the former chief executive officer of Nimbus Therapeutics, LLC, or Nimbus, a biotechnology company, serving from August 2014 to October 2018. Prior to joining Nimbus, Dr. Nicholson held various strategic, leadership and operational roles in diverse therapeutic areas, including respiratory, inflammation, immunology, bone, endocrine, urology, infectious disease and neurosciences at Merck from April 1998 to July 2013. Dr. Nicholson has co-authored more than 150 publications in peer-reviewed scientific and medical journals and is internationally recognized for his contributions to the field of apoptotic cell death. He also serves as a member on the board of directors of Generation Bio (Nasdaq: GBIO), Jnana Therapeutics, Muna Therapeutics, Matchpoint Therapeutics and NodThera. Dr. Nicholson previously served on the board of directors of Kymera Therapeutics, Inc. (Nasdaq: KYMR) from November 2017 to November 2022. Dr. Nicholson received his Ph.D. and an Honors B.Sc. degree in Biochemistry from the University of Western Ontario, and trained as a Medical Research Council postdoctoral fellow at the University of Munich in Germany. Dr. Nicholson is qualified to serve as a member of our board of directors due to his extensive experience in leadership positions throughout the life sciences industry and his strong scientific background.

Mona Ashiya, Ph.D. has served as a member of our board of directors since September 2021. Dr. Ashiya is currently a Partner at OrbiMed Advisors LLC, an investment firm, where she has been employed since October 2010. She Dr. Ashiya currently serves on the board of directors of several private companies. Dr. Ashiya also previously served on the board of directors of Prevail Therapeutics Inc. (Nasdaq: PRVL), from October 2017 to March 2019, and Sierra Oncology, Inc. (Nasdaq: SRRA), from November 2019 to July 2022. Dr. Ashiya received her B.A. from the University of California, Berkeley and her Ph.D. in Cellular, Molecular and Developmental Biology from the University of Pittsburgh. Dr. Ashiya is qualified to serve on our board of directors based on her roles on public and private boards of directors as well as her extensive experience in investing in healthcare companies.

Jay Backstrom, M.D., **M.P.H.** has served as a member of our board of directors since December 2021. Dr. Backstrom is currently Chief Executive Officer of Scholar Rock, a position that he assumed in October 2022. Dr. Backstrom previously served as Executive Vice President, Research and Development at Acceleron Pharma Inc. from December 2019 through December 2021. Dr. Backstrom previously served as Chief Medical Officer of Celgene Corporation from April 2016 until November 2019. Prior to that he served as Senior Vice President, Clinical R&D and Regulatory Affairs at Celgene where he was responsible for the late stage clinical and regulatory programs across the Hematology & Oncology portfolio. Dr. Backstrom joined Celgene in March 2008 as Vice President, Clinical R&D after serving as Vice President, Global Medical Affairs and Safety for Pharmion from 2002 to 2008. Prior to joining Pharmion, Dr. Backstrom was with Marion Merrell Dow and its successor companies including Hoechst Marion Roussel. Dr. Backstrom received his M.D. from Temple University School of Medicine. He did his post graduate training in Internal Medicine at Temple University Hospital and earned a Masters degree in Public Health from Saint Louis University School of Public Health. Dr. Backstrom is qualified to serve on our board of directors due to his extensive clinical development background.

Kevin Bitterman, Ph.D. has served as a member of our board of directors since November 2017. Dr. Bitterman currently serves as a partner at venture firm Atlas Venture Life Science Advisors, LLC, or Atlas, a venture capital firm, where he has been employed since June 2017 and where he focuses on investments in life science companies. Prior to joining Atlas, Dr. Bitterman was a partner at Polaris

Partners, an investment firm, as a member of the healthcare team from July 2004 to June May 2017. Dr. Bitterman serves on the boards of Resonance Medicine, Nvelop Therapeutics, Judo Bio, Kinaset Therapeutics, Mariana Oncology, and Remix Therapeutics. He is board chair at Chroma Medicine and at Vedere Bio II following Novartis' acquisition of Vedere Bio. Dr. Bitterman was the founding CEO of Editas Medicine (NASDAQ: (Nasdaq: EDIT), Morphic Therapeutics (NASDAQ: (Nasdaq: MORF) and Wisterra (acquired by Otsuka), and co-founded Genocea Biosciences(NASDAQ: Biosciences (Nasdaq: GNCA). He Dr. Bitterman previously served as a director of Akero Therapeutics, Inc. (Nasdaq:

AKRO), Kala Pharmaceuticals, Inc. (Nasdaq: KALA) and Taris Biomedical (acquired by Johnson & Johnson) among other ventures. Dr. Bitterman also serves as board chair of the New England Venture Capital Association. Dr. Bitterman received a B.A. in biology from Rutgers College and a Ph.D. in genetics from Harvard Medical School. Dr. Bitterman is qualified to serve on our board of directors due to his extensive experience investing in, guiding, and leading start-up and early phase companies, as well as his experience as a director of other companies.

Mark Chin, MS, MBA M.S., M.B.A. has served as a member of our board of directors since September 2021. Mr. Chin has served as managing director partner at Arix Bioscience PLC, Avoro Capital, a biotechnology-focused venture capital investment firm, since July 2021. November 2023. From April 2020 to November 2023 and August 2016 to April 2020, Mr. Chin served as a managing director and, an investment director, respectively, at Arix Bioscience.

Bioscience PLC, or Arix Bioscience, a biotechnology-focused venture capital firm. Prior to Arix Bioscience, he Mr. Chin was a principal at Longitude Capital, a healthcare venture capital firm, from September 2012 to August 2016, where he focused on investments in both private and public biotechnology and medical technology companies. Prior to Longitude Capital, Mr. Chin was a consultant at the Boston Consulting Group, a global management consulting firm, from January 2011 to September 2012, where he managed strategy and corporate development projects for pharmaceutical and biotechnology companies, and prior to Boston Consulting Group, he worked in corporate development at Gilead Sciences, a biotechnology company, and in market planning at Genentech, a biotechnology company. Mr. Chin currently serves as a member of the boards of directors of Harpoon Therapeutics, Inc. (Nasdaq: HARP), Imara Inc. (Nasdaq: IMRA), and Iterum Therapeutics plc (Nasdaq: ITRM) and a number of private biotechnology companies. Mr. Chin received a BS B.S. from the University of California at San Diego, an MS a M.S. from the University of Pennsylvania, and an MBA a M.B.A. from The Wharton School at the University of Pennsylvania. We believe Mr. Chin is qualified to serve on our board of directors based on his extensive experience investing in, guiding, and leading start-up and early phase companies, as well as his experience as a director of other companies.

Georges Gemayel, Ph.D. has served as a member of our board of directors since December 2022. Prior to that, Dr. Gemayel served as Gemini's Gemini Therapeutics' Interim President and Chief Executive Officer from February 2022 to December 2022, Executive Chairperson of the Board from November 2021 to December 2022 and Chairperson of the Board from May 2021 to November 2021. Dr. Gemayel has over 30 years of experience in the pharmaceutical industry, including management and executive positions in the U.S., Europe and the Middle East. Dr. Gemayel currently serves on the board of directors of Supernus Pharmaceuticals, Inc., and is the chair of the boards of Dynacure, Flamingo, Enterome SA, and GlycoEra. Previously, Dr. Gemayel served as Executive Chair of FoldRx Pharmaceuticals and of Syndexa Pharmaceuticals, as Chair of Oxthera AB, Dimension Therapeutics, Orphazyme A/S, Epitherapeutics and Epitherapeutics Dynacure, and as Director of Prosensa, Raptor Pharmaceuticals, NPS Pharma, Momenta Pharmaceuticals and Adolor. From 2008 to 2009, Dr. Gemayel was President and Chief Executive Officer of Altus Pharmaceuticals Inc., a publicly traded pharmaceutical company. From 2003 to 2008, he Dr. Gemayel was Executive Vice President at Genzyme Corporation where he was responsible for the company's global therapeutics, transplant, renal and biosurgery businesses. From 1998 to 2003, he Dr. Gemayel held progressively senior roles at Hoffmann Ltd. and Roche Labs, most recently as Vice President, National Specialty Care, responsible for its U.S. business for dermatology, oncology, transplantation, hepatitis and HIV. Dr. Gemayel completed his doctorate in pharmacy at St. Joseph University in Beirut, Lebanon, and earned a Ph.D. in pharmacology at University in Paris, France. Our board of directors has concluded that Dr. Gemayel possesses the expertise and extensive professional experience and knowledge that qualifies him to serve as a member of our board.

Liam Ratcliffe, MD, M.D., Ph.D. has served as a member of our board of directors since September 2019. Dr. Ratcliffe has served as Head of Biotechnology at Access Industries, a privately held industrial group, since April 2019. Previously, he Dr. Ratcliffe spent 10 years at

New Leaf Venture Partners, a venture capital firm, from September 2008 through March 2019, culminating his career there as Managing Director, where he focused on investing in therapeutic and therapeutic platform companies. Prior to joining New Leaf Venture Partners, Dr. Ratcliffe was Worldwide Head of Clinical Research and Development at Pfizer Inc. (Nasdaq: PFE), where he spent 12 years of his career. Dr. Ratcliffe currently serves as a member of the boards of directors of Arvinas Inc. (Nasdaq: ARVN) since October 2015, Passage Bio Inc. (Nasdaq: PASG) since September 2019, Recludix Pharma, Inc. since December 2019, and Eliem Therapeutics Inc. (Nasdaq: ELYM) since October 2019. Previously, he Dr. Ratcliffe served as a board member at Edge Therapeutics, Inc. (now PDS Biotechnology Corp., Nasdaq: PDSB) from October 2015 to November 2018, Unum Therapeutics Inc. (formerly listed on Nasdaq) from March 2018 to April 2019, Deciphera Pharmaceuticals Inc. (Nasdaq: DCPH) from September 2017 to March 2019, Aptinyx Inc. (Nasdaq: APTX) from June 2018 to April 2019, and RallyBio Corporation (Nasdaq: RLYB) from April 2018 to March 2019. Dr. Ratcliffe received a MBChB M.B.Ch.B. and a Ph.D. in immunology from University of Cape Town and an MBA M.B.A. from the University of Michigan. Dr. Ratcliffe is qualified to serve on our board of directors because of his extensive clinical development and venture capital experience in the life sciences industry.

William White, MPP, M.P.P., J.D., has served as a member of our board of directors since December 2020. Mr. White has served as the Executive Vice President, Chief Financial Officer and Head of Corporate Development and Treasurer at Akero Therapeutics, Inc. (Nasdaq: AKRO), a biotechnology company, since April 2019. Previously, Mr. White served as a Managing Director and Head of US Life Sciences Investment Banking at Deutsche Bank, a financial service provider, from September 2017

until to March 2019. Prior to that, position, Mr. White was a Managing Director in Healthcare Investment Banking at Citigroup from May 2006 until to September 2017. Previously, he Mr. White served as an associate and later as a Vice President in Healthcare Investment Banking at Goldman, Sachs & Co. from November 2000 to March 2006. Mr. White also serves as a member of the board of directors and Chair of the Audit Committee of Ventyx Bioscience (Nasdaq: VTYX). Mr. White received an AB A.B. from Princeton University, an MPP M.P.P. from Harvard University and a J.D. from Columbia University. Mr. White also serves as a board member and Audit Committee Chair of Ventyx Bioscience (Nasdaq: VTYX). Mr. White is qualified to serve on our board of directors because of his extensive financial and investment experience in the life sciences industry.

Corporate Governance

Corporate Governance Guidelines

Our corporate governance guidelines assist our board of directors in the exercise of its duties and responsibilities and to serve the best interests of our company and our stockholders. These guidelines, which provide a framework for the conduct of our board's business, provide that:

- the principal responsibility of the directors is to oversee our management;
- a majority of the members of the board shall be independent directors, unless otherwise permitted by Nasdaq rules;
- the independent directors meet at least once a year;
- directors have full and free access to management and, as necessary and appropriate, independent advisors; and
- at least annually, the nominating and corporate governance committee oversees a self-evaluation by the board to assess the effectiveness of the board and its committees.

Our board of directors is responsible for managing or supervising the management of our business and affairs. This includes appointing our chief executive officer, advising management on strategic issues, approving our business and other plans and monitoring our performance against those plans and against our operating and capital budgets. In addition, our board of directors also receives and considers recommendations from our various committees with respect to matters such as the following:

- the compensation of our directors;
- criteria for board and committee membership;
- persons to be nominated for election as directors and to each of the board of director's committees; and
- matters relating to our code of business conduct and ethics and corporate governance guidelines. Our board of directors does not have written mandate.

Code of Business Conduct and Ethics

We have also adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is posted on the "Investors & Media— Corporate Governance" section of our website, which is located at ***www.discmedicine.com***. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a Current Report on Form 8-K to be filed with the SEC. Employees are required to annually certify compliance with the code.

Determination of Independence

Our common stock is listed on The Nasdaq Global Market, or Nasdaq. Under the Nasdaq listing rules, independent directors must comprise a majority of a listed company's board of directors within twelve months from the date of listing. In addition, the Nasdaq listing rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A 3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C 1 under the Exchange Act. Under Nasdaq listing rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered independent for purposes of Rule 10A 3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board of directors committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board of directors service; or (2) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C 1, the board of

directors must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

Our board of directors has determined that each of our directors, with the exception of Dr. Quisel, who serves as our Chief Executive Officer, and Georges Gemayel, who served as the chief executive officer of Gemini prior to our merger with Gemini, is an "independent director" within the meaning of the director independence standards established by the SEC and Nasdaq. Our

board of directors also determined that Mark Chin, Liam Ratcliffe and William White who comprise our audit committee, Mona Ashiya, Kevin Bitterman and Donald Nicholson, who comprise our compensation committee, and Mona Ashiya, Kevin Bitterman, Donald Nicholson and Liam Ratcliffe, who comprise our nominating and corporate governance committee, satisfy the independence standards for such committees established by the SEC and Nasdaq, as applicable. In making such determinations, our board of directors evaluated, and will evaluate at least on an annual basis, all relationships that each such non-employee director has with our company in light of all facts and circumstances our board of directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

The non-management directors meet at regularly scheduled executive sessions without management participation, and at least once each year an executive session with only independent directors present is held. In 2022, 2023, there were four executive sessions at which only the independent directors were present.

Board Self-Assessment; Director Candidates; and Criteria

Our board of directors performs an annual self-assessment. During this self-assessment, the board of directors considers many factors, including, but not limited to, the expertise of existing board of director members and the expertise of directors we need in our transition from a clinical development stage company to becoming a commercial enterprise. The board of director's annual self-assessment is conducted by a survey in which each director is asked to comment on the effectiveness and contribution of the board of directors as a whole.

Our board of directors is responsible for selecting its own members. The board of directors delegates the selection and nomination process to our nominating and corporate governance committee, with the expectation that other members of the board of directors, and of management, will be requested to take part in the process as appropriate.

Generally, our Our nominating and corporate governance committee identifies candidates for director nominees in consultation with management, through the use of independent director search firms, through recommendations submitted by stockholders or through such other methods as the nominating and corporate governance committee deems to be helpful to identify candidates. Once candidates have been identified, the nominating and corporate governance committee confirms that the candidates meet the minimum qualifications for director nominees established by set forth in the nominating and corporate governance committee. committee charter. These criteria include, among other things, the skills of the candidate, his or her depth and breadth of business experience and other background characteristics, his or her independence and the needs of the board of directors.

The nominating and corporate governance committee may gather information about the candidates through meetings from time to time, questionnaires or background checks to evaluate biographical information and background material relating to potential candidates, and interviews of selected candidates by members of the committee and our board of directors. The nominating and corporate governance committee then meets as a group to discuss and evaluate the qualities and skills of each candidate, both on an individual basis and taking into account the overall composition and needs of our board of directors. Based on the results of the evaluation process, the nominating and corporate governance committee recommends candidates for the board of directors' approval as director nominees for election to the board of directors.

The board of directors does not believe that limits on the number of consecutive terms a director may serve or on the directors' ages are appropriate for the company at this stage. time. Instead, each director's performance and their continued service is assessed by the nominating and corporate governance committee in light of the needs of the board of directors and other relevant factors.

Stockholders may recommend individuals to our nominating and corporate governance committee for consideration as potential director candidates by providing timely notice and meeting the other requirements set forth in our by-laws, including our advanced notice provision, and the rules and regulations of the SEC. Assuming such requirements have been met, the nominating and corporate governance committee will evaluate stockholder-recommended candidates by following substantially the same process, and applying substantially the same criteria, as it follows for candidates submitted by others. If the board of directors determines to nominate a stockholder-recommended candidate and recommends his or her election, then his or her name will be included in our proxy card for the next annual meeting.

The company conducts an orientation program for each new director, which generally includes conversations with individual members of management. The orientation is designed to familiarize the new director with the company's business and strategic plans, key policies and practices, principal officers and management structure, auditing and compliance processes and its

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code of business conduct and ethics. New directors have access to historical published information about the company, its articles and by-laws, the corporate governance guidelines and the charters of the board of director's committees and other relevant information. The nominating and corporate governance committee is responsible for providing materials or briefing sessions for continuing directors on topics that will assist them in discharging their duties. In addition, management makes regular presentations to the board of directors on the main areas of the company's business and new developments in the industry.

Communication from Stockholders

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The board of directors will give appropriate attention to written communications that are submitted by stockholders and will respond if and as appropriate. The chairman of the board of directors is primarily responsible for monitoring communications from stockholders and for providing copies or summaries to the other directors as he considers appropriate.

Communications are forwarded to all directors if they relate to important substantive matters and include suggestions or comments that the chairman of the board of directors considers to be important for the directors to know. In general, communications relating to corporate governance and corporate strategy are more likely to be forwarded than communications relating to ordinary business affairs, personal grievances and matters as to which we receive repetitive or duplicative communications.

Composition of the Board of Directors

Our board of directors currently consists of nine eight members, divided into three staggered classes, with one class to be elected at each annual meeting to serve for a three-year term.

Board Diversity

Our nominating and corporate governance committee has a written board diversity policy and believes that our board of directors, taken as a whole, should embody a diverse set of skills, experience, knowledge and backgrounds, including an appropriate number of women directors. The board of directors has not adopted targets for the number or proportion of directors who are female directors or other designated groups, as the company is committed to a merit-based system for board composition, which reflects a diverse and inclusive culture where directors believe that their views are heard, their concerns are attended to and they serve in an environment where bias, discrimination and

harassment on any matter are not tolerated. When identifying suitable candidates for appointment to the board of directors, the company considers candidates on merit against objective criteria and the needs of the board of directors and considers the need to increase the number of women directors on the board of directors to meet the company's goal. directors. When recruiting new candidates for appointment, search protocols will go beyond the networks of existing board of director members and will incorporate diversity, including identification of female candidates, as a component. Any search firm engaged to assist the board of directors or the nominating and corporate governance committee in identifying candidates for appointment to the board of directors shall be directed to include women candidates and women candidates will be included in the board of director's evergreen list of potential board of director nominees.

The company has not adopted targets for the number or proportion of directors who are members of a visible minority, Indigenous peoples or persons with a disability, or the designated groups, or for other diversity characteristics at this time. For now, the board of directors has chosen to focus on gender in exclusion to other diversity characteristics and the nominating and corporate governance committee does not specifically consider the level of representation of members of designated groups on the board of directors in identifying and nominating candidates for election or re-election to the board of directors.

The below board diversity matrix reports self-identified diversity statistics for the board of directors.

Board Diversity Matrix (As of February 28, 2023 February 29, 2024)

Total Number of Directors	**9**			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	1	8		
Part II: Demographic Background				
African American or Black				
Alaskan Native or Native American				
Asian	1	1		
Hispanic or Latinx				
Native Hawaiian or Pacific Islander				
White		7		
Two or More Races or Ethnicities				

LGBTQ+	
Persons with disabilities	
Visible minorities	
Indigenous peoples	
Did Not Disclose Demographic Background	

Total Number of Directors	**8**			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	1	7		
Part II: Demographic Background				

African American or Black				
Alaskan Native or Native American				
Asian	1	1		
Hispanic or Latinx				
Native Hawaiian or Pacific Islander				
White		6		
Two or More Races or Ethnicities				
LGBTQ+				
Persons with disabilities				
Visible minorities				
Indigenous peoples				
Did Not Disclose Demographic Background				

The company does not consider the level of representation of women or other designated groups in executive officer positions and has not adopted targets for the number or proportion of directors executive officers who are women female or members of other designated groups as the company seeks to promote individuals solely based on merit. Currently one two of the executive officers is a woman, are women, two of the executive officers are visible minorities and none of the executive officers are Indigenous peoples or persons with a disability.

Board and Committee Meetings

The Disc board of directors held 14 10 meetings during 2022. 2023. During 2022, 2023, each of the Disc directors then in office attended at least 75% of the aggregate of all meetings of the board of directors and all meetings of the committees of the board of directors on which such director then served. A director's attendance rate is considered by the nominating and corporate governance committee when making recommendations for re-appointment of the director. Continuing directors and nominees for election as directors in a given year are required to attend the annual meeting of stockholders, barring significant commitments or special circumstances.

Committees of the Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Each of these committees operates under a charter that has been approved by our board of directors. We believe that the composition and functioning of all of our committees comply with the applicable requirements of Nasdaq, the Sarbanes-Oxley Act of 2002 and SEC rules and regulations that are applicable to us. We intend to comply with future requirements to the extent they become applicable to us. A copy of each charter can be found under the "Investors & Media—Corporate Governance" section of our website, which is located at ***www.discmedicine.com***. The board of directors has not adopted position descriptions for the chairperson of each committee. However, each committee chairperson understands that the responsibilities of the committee chairperson include responsibility for providing leadership to the committee, including chairing meetings in a manner that facilitates open discussions and expressions of competing views, and reporting to the board of directors on the work of the committee and any recommendations for approval by the board of directors. The committee chairperson

also ensures that the committee receives the information required for the performance of its responsibilities. The board of directors may also establish other committees from time to time to assist the company and the board of directors.

Audit Committee

The primary purpose of our audit committee is to discharge the responsibilities of the board of directors with respect to our accounting, financial, and other reporting and internal control practices and to oversee our independent registered accounting firm.

Specific responsibilities of our audit committee include:

- selecting a qualified firm to serve as the independent registered public accounting firm to audit our financial statements
- helping to ensure the independence and performance of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with manageme and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing policies on risk assessment and risk management;
- reviewing related party transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes its internal qu control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by appli law; and
- approving (or, as permitted, pre-approving) all audit and all permissible non-audit service to be performed by the independent regist public accounting firm.

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The members of the Audit Committee are William White, Liam Ratcliffe and Mark Chin. William White is the chair of the Audit Committee and our board of directors has determined that he qualifies as an “audit committee financial expert” within the meaning of SEC regulations. To qualify as independent to serve on our audit committee, listing standards of Nasdaq and the applicable SEC rules require that a director not accept any consulting, advisory or other compensatory fee from us, other than for service as a director, or be an affiliated person of the company. During the fiscal year ended December 31, 2022 December 31, 2023, the Disc audit committee met four times. We believe that the composition of the audit committee complies with the applicable requirements of the rules and regulations of Nasdaq and the SEC.

Compensation Committee

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The primary purpose of our compensation committee is to discharge the responsibilities of the board of directors to oversee our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate.

Specific responsibilities of our compensation committee include:

- reviewing and approving, or recommending that the board of directors approve, the compensation of our executive officers;
- reviewing and recommending to our board of directors the compensation of our directors;

- administering our stock and equity incentive plans;
- selecting independent compensation consultants and assessing whether there are any conflicts of interest with any of the committe compensation advisors;
- reviewing and approving, or recommending that the board of directors approve, incentive compensation and equity plans, severanc agreements, change-of-control protections and any other compensatory arrangements for our executive officers and other senior management, as appropriate;
- reviewing and establishing general policies relating to compensation and benefits of our employees; and
- reviewing our overall compensation philosophy.

The members of the Compensation Committee are Donald Nicholson, Mona Ashiya and Kevin Bitterman. Dr. Nicholson is the chair of the Compensation Committee. Each member of our compensation committee will be a “non-employee” director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. During the fiscal year ended December 31, 2022 December 31, 2023, the Disc compensation committee met three four times. We believe that the composition of the compensation committee complies with the applicable requirements of the rules and regulations of Nasdaq and the SEC.

Compensation Consultants

In fiscal year 2022, 2023, our compensation committee engaged Pearl Meyer & Partners, LLC, or Pearl Meyer, to provide compensation consulting services. During fiscal year 2022, 2023, Pearl Meyer’s services included advising on equity compensation programs and the development of the Company’s peer group and providing support and analysis regarding executive and director compensation. Our compensation committee has assessed the independence of Pearl Meyer consistent with SEC rules and Nasdaq listing standards and has concluded that the engagement of Pearl Meyer does not raise any conflict of interest.

Nominating and Corporate Governance Committee

Specific responsibilities of our nominating and corporate governance committee include:

- identifying, evaluating and selecting, or recommending that the board of directors approve, nominees for election to the board of directors;
- evaluating the performance of the board of directors and of individual directors;
- reviewing developments in corporate governance practices;
- evaluating the adequacy of our corporate governance practices and reporting;
- reviewing management succession plans; and
- developing and making recommendations to the board of directors regarding corporate governance guidelines and matters.

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The members of the Nominating and Corporate Governance Committee are Kevin Bitterman, Mona Ashiya, Donald Nicholson and Liam Ratcliffe. Dr. Bitterman is the chair of the Nominating and Corporate Governance Committee. During the fiscal year ended December 31, 2022 December 31, 2023, the Disc nominating and corporate governance committee did not meet. We believe that the composition the nominating and corporate governance committee meets the requirements for independence under, and the functioning of such nominating and corporate governance committee complies with, any applicable requirements of the rules and regulations of Nasdaq and the SEC.

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Policy on Trading, Pledging and Hedging of Company Stock

Certain transactions in our securities (such as purchases and sales of publicly traded put and call options, and short sales) create a heightened compliance risk or could create the appearance of misalignment between management and stockholders. In addition, securities held in a margin account or pledged as collateral may be sold without consent if the owner fails to meet a margin call or defaults on the loan, thus creating the risk that a sale may occur at a time when an officer or director is aware of material, non-public information or otherwise is not permitted to trade in Company securities. Our insider trading policy expressly prohibits derivative transactions of our stock by our executive officers, directors, employees, consultants and designated contractors. Our insider trading policy expressly prohibits purchases of any derivative securities that provide the economic equivalent of ownership.

Compensation Committee Interlocks and Insider Participation

Each member of the compensation committee is a “non-employee” director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. None of our executive officers serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers who serves on our board of directors or compensation committee.

Board Leadership Structure

Our board of directors is currently chaired by Donald Nicholson, an independent director. Currently, the role of chairman of the board of directors is separated from the role of chief executive officer. Separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing the chairperson of the board of directors to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. The board of directors has not adopted a position description for the chairperson. However, there is a shared understanding on the board of directors of the chairperson’s responsibilities. The chairperson’s primary role is to provide leadership to the board of directors and its committees, including chairing meetings in a manner that facilitates open discussions and expressions of competing views. The chairperson is also responsible for, among other things, assisting the board of directors in obtaining information required for the performance of their duties, retaining appropriately qualified and independent advisors as needed, working with the board to support board development and to ensure a proper committee structure is in place, providing a link between the board of directors and management and acting in an advisory capacity to the chief executive officer in all matters concerning the interests and management of the company. Our board of directors recognizes the time, effort and energy that the chief executive officer must devote to his position in the current business environment, as well as the commitment required to serve as the chairperson of the board of directors, particularly as the board of directors’ oversight responsibilities continue to grow. Our board of directors also believes that this structure ensures a greater role for the non-management directors in the oversight of our company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our board of directors. Our board of directors believes its administration of its risk oversight function has not affected its leadership structure. Although our by-laws do not require our chairperson of the board and chief executive officer positions to be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time. The board of directors has not adopted a separate position description for our chief executive officer. The role and responsibilities of the chief executive officer is delineated by frequent discussion and interaction between the board chairperson and the chief executive officer.

Oversight of Risk

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our financial condition, development and commercialization activities, operations, strategic direction and intellectual property as more fully discussed under “Risk Factors” in this Annual Report on Form 10-K. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of

risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

Our board of directors regularly discusses with management our major risk exposures, the potential impact of these risks on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board of

director committees and members of senior management to enable our board of directors to understand the company's risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.

The audit committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors, and

discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating and corporate governance committee manages risks associated with the independence of the board of directors, corporate disclosure practices, and potential conflicts of interest. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board as a whole.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors and officers and holders of more than 10% of our common stock to file with the SEC, initial reports of ownership of our common stock and other equity securities on a Form 3 and reports of changes in such ownership on a Form 4 or Form 5. Directors and officers and holders of 10% of our common stock are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. The SEC has designated specific deadlines for these reports, and we must identify those persons who did not file these reports when due. To our knowledge, based solely on a review of copies of such forms furnished to us, and written representations made by our directors and officers regarding their filing obligations, we believe all Section 16(a) filing requirements were satisfied on a timely basis with respect to the year ended December 31, 2022 December 31, 2023.

Ownership of Our Common Stock

The information in this section is set forth below in "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters".

Policy for Recoupment of Incentive Company (Clawback Policy)

On September 19, 2023, we adopted a policy for recoupment of incentive compensation (the "Clawback Policy") in compliance with the requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act, final SEC rules and applicable Nasdaq listing standards (the "final clawback rules"), which covers our current and former executive officers, including all of our named executive officers. Under the

Clawback Policy, in the event that we are required to prepare a restatement of our previously issued financial statements due to our material noncompliance with any financial reporting requirement under securities laws, we are required to recover (subject to certain limited exceptions described in the Clawback Policy and permitted under the final clawback rules) any cash or equity incentive-based compensation received by any current or former executive officer after the effective date of the Clawback Policy and in the three years prior to the date we are required to restate our financial statements that is in excess of the amount that would have been received based on the restated financial statements. In addition, under our Clawback Policy, in the event that we are required to restate our financial statements due to material noncompliance with any financial reporting requirement under securities laws, we must use reasonable efforts to recover (i) any cash or equity incentive compensation received by any other current or former employee of the Company in the three years prior to the date we are required to restate our financial statements that is in excess of the amount that would have been received based on the restated financial statements if we determine that the employee committed certain acts or omissions that materially contributed to the circumstances requiring the restatement and (ii) up to 100% of the cash and equity incentive compensation received by any current or former employee in the three years prior to the date we are required to restate our financial statements if we determine that the employee committed certain acts or omissions that materially contributed to the circumstances requiring the restatement.

ITEM 11. EXECUTIVE COMPENSATION

Our executive compensation programs are designed to attract, motivate, incentivize and retain our executive officers, who contribute to our long-term success. Pay that is competitive, rewards performance and effectively aligns the interests of our executive officers with those of our long-term stockholders is key to our compensation program design and decisions. We structure our executive compensation programs to be heavily weighted towards long-term equity incentives that correlate with the growth of sustainable long-term value for our stockholders.

The compensation provided to our named executive officers for the fiscal years ended December 31, 2022 December 31, 2023 and 2021, 2022, as applicable, is detailed in the 2022 2023 Summary Compensation Table and accompanying footnotes and narrative that follow. Our named executive officers for the fiscal year ended December 31, 2022 December 31, 2023, which consisted of our Chief Executive Officer and our four two most highly compensated executive officers other than the Chief Executive Officer, were:

1. John Quisel, J.D., Ph.D., Chief Executive Officer
2. William Savage, MD, Ph.D., Chief Medical Officer

3. Joanne Bryce, CPA, Chief Financial Officer
4. Jonathan Yu, (who departed from her role as Chief Business Financial Officer effective February 7, 2024)

2022 2023 Summary Compensation Table

The following table provides information regarding the total compensation awarded to, earned by, and paid to our named executive officers for services rendered to us in all capacities for the fiscal years ended December 31, 2022 December 31, 2023 and 2021, 2022, as applicable.

Name and Principal Position	Year	Salary ($)(1)	Bonus ($)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation ($)(3)	All Other Compensation ($)	Total ($)	Year	Salary ($)(1)	Bonus ($)	Option Awards ($)(2)	Non-Equity Incentive Plan Compensation ($)(3)	All Other Compensation ($)(4)	Total ($)
John Quisel, J.D., Ph.D.	2022	476,477	—	1,081,150	273,638	—	1,831,265	2023	562,000	—	—	337,200	4,261	903,461
Chief Executive Officer	2021	445,400	—	891,605	250,470	—	1,597,475	2022	476,477	—	1,081,150	273,638	—	1,831,265
William Savage, MD, Ph.D.	2022	378,234	20,000 (5)	318,803	173,719	—	890,756	2023	458,000	—	—	219,840	9,900	687,740
Chief Medical Officer	2021	320,000	—	294,999	105,600	—	720,599	2022	378,234	20,000	318,803	173,719	—	890,756

Joanne Bryce, CPA(3)	2022	355,884	20,000 (5)	277,221	163,438	—	816,543
Joanne Bryce, CPA(5)	2023	419,000	—	1,123,795 (6)	201,120	8,847	1,752,762
Chief Financial Officer	2021	303,818 (6)	24,000 (7)	419,601	88,825	—	836,244
	2022	355,884	20,000	277,221	163,438	—	816,543
Jonathan Yu *Chief Business Officer*	2022	355,884	20,000 (5)	277,221	163,438	—	816,543

(1) The amounts reported reflect salaries earned by each named executive officer during the respective fiscal year.

(2) The amounts reported represent the aggregate grant date fair value of the stock options awarded to our named executive officers during the 2022 2023 and 2021 2022 fiscal years, as applicable, calculated in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718. Such grant date fa values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the stock options reported in this column are set forth Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K. The amounts reported in this column reflect the accounting cost for the stock opti and do not correspond to the actual economic value that may be received by our named executive officers upon the exercise of the stock options or any sale of the common st underlying such stock options.

(3) The amounts represent bonuses earned as of December 31, 2021 and December 31, 2022 December 31, 2023, upon the attainment of one or more pre-established performar goals established by our board of directors on an annual basis. A portion of Ms. Bryce's 2021 bonus was attributable to her service as a consultant.

(4) The amounts represent safe harbor matching contributions under our 401(k) plan to our named executive officers in 2023.

(5) Ms. Bryce was a consultant to us until September 14, 2021 when she transitioned to Chief Financial Officer.

(5) The amounts reported reflect the amount of discretionary bonuses earned in year 2022. Effective February 7, 2024, Ms. Bryce departed from her role as Chief Financial Office and transitioned to an independent contractor advisor.

(6) Includes $210,818 in consulting fees that The amount reported reflects an accounting charge relating to an amendment of the stock options held by Ms. Bryce earned during 2021, prior of as November 27, 2023. In connection with the Bryce Separation Agreement (as defined below), our board of directors approved an extension of the post-termina exercise period relating to becoming Chief Financial Officer.

(7) Ms. Bryce received a signing bonus for her employment in such stock options, such that the position vested and outstanding shares subject to the stock options may be exercis until the earlier of Chief Financial Officer. (i) twelve months following the end of the Advisor Period (as defined below) and (ii) the original expiration date of the stock option.

Narrative to Summary Compensation Table

Base Salaries

Each named executive officer's base salary is a fixed component of annual compensation for performing specific duties and functions, and has been established by our board of directors taking into account each individual's role, responsibilities, skills, and expertise. Base salaries are reviewed annually, typically in connection with our annual performance review process, approved by our board of directors, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and

experience. The annual base salaries for Dr. Quisel, Dr. Savage, and Ms. Bryce and Mr. Yu were increased to $562,000, $419,000 $458,000 and $419,000, respectively effective December 29, 2022 due to updated employment agreements entered into with during the Company. Dr. Savage's fiscal year ended December 31, 2023. There were no annual base salary was increased from $355,300 to $400,000 effective July 1, 2022 increases in connection with his mid-year performance review, and then increased again to $458,000 effective December 29, 2022 due to an updated employment agreement entered into with the Company.2023.

Annual Bonuses

For the fiscal year ended December 31, 2022 December 31, 2023, each named executive officer was eligible to earn an annual cash bonus based on the achievement of certain corporate performance metrics. Corporate objectives were primarily based on development goals for our product candidates financing and business development goals. The target annual bonus for Drs. Dr. Quisel, Dr. Savage, and Savage, Ms. Bryce and Mr. Yu for 2022 2023 was 50%, 40%, 40% and 40%, respectively, of their respective annual base salary as in effect on December 28, 2022 (i.e., prior to the increase provided in the updated employment agreements) December 31, 2023.

Equity Compensation

We believe that equity grants provide executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and stockholders. In addition, we believe that equity grants promote executive retention because they incentivize executive officers to remain employed during the vesting period. During the fiscal year ended December 31, 2022, in connection with our merger with Gemini, we granted stock option awards options to each of our named executive officers. As a result, during the fiscal year ended December 31, 2023, we did not grant any equity awards to our named executive officers. However, in connection with the Bryce Separation Agreement, our board of directors approved an amendment

to the stock options held by Ms. Bryce of as November 27, 2023, pursuant to which the post-termination exercise period relating to such stock options was amended to provide that the vested and outstanding shares subject to the stock options may be exercised until the earlier of (i) twelve months following the end of the Advisor Period and (ii) the original expiration date of the stock option. For additional information regarding equity awards previously granted to our named executive officers, as described in more detail in please see the table under "Outstanding Equity Awards at 2023 Fiscal 2022 Year-End" table.below.

Outstanding Equity Awards at Fiscal 2022 2023 Year-End

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of December 31, 2022 December 31, 2023:

	Option Awards(1)		Option Awards(1)

Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
John Quisel, J.D., Ph.D. *Chief Executive Officer*	12/29/2022	12/29/2022	13,022	2,005	13.50	12/28/2032	12/29/2022 (2)	12/29/2022	33,000	99,002	13.50	12/28/2032
	9/14/2021	9/1/2021	52,611	5,764	9.86	9/13/2031	9/14/2021 (2)	9/1/2021	94,719	73,668	9.86	9/13/2031
	10/23/2020	10/7/2020	33,425	25,000	2.65	10/22/2030	10/23/2020 (3)	10/7/2020	48,810	12,840	2.65	10/22/2030
	3/11/2020	2/25/2020	217,713	13,336	1.01	3/10/2030	3/11/2020 (4)	2/25/2020	231,049	10,162	1.01	3/10/2030
William Savage, MD, Ph.D. *Chief Medical Officer*	12/29/2022	12/29/2022	38,492	92,004	13.50	12/28/2032	12/29/2022 (2)	12/29/2022	9,731	29,193	13.50	12/28/2032
	9/14/2021	7/1/2021	3,673	6,789	9.86	9/13/2031	9/14/2021 (2)	7/1/2021	6,360	4,161	9.86	9/13/2031

	9/1 (4/2 02) 1	9/1/2021	14,125	31,067	9 . 8 6	9/1 3/2 03 1	9/14/2021 (2)	9/1/2021	25,423	19,769	9.86	9/13/2031
	10/ (23/ 5 20) 20	10/7/202 0	5,56 7	4,708	2 . 6 5	10/ 22/ 20 30	10/23/2020 (5)	10/7/2020	8,135	2,140	2.65	10/22/2030
	8/1 (1/2 4 02) 0	8/3/2020	3,38 8	16,93 8	2 . 6 5	8/1 0/2 03 0	8/11/2020 (4)	8/3/2020	10,552	6,774	2.65	8/10/2030
Joanne Bryce, CPA	12/ (29/ 2 20) 22	12/29/2022		33,84 7	1 3 . 5 0	12/ 28/ 20 32	12/29/2022 (2)	12/29/2022	8,461	25,386	13.50	12/28/2032
Chief Financial Officer	9/1 (4/2 02) 1	9/1/2021	24,754	48,700	9 . 8 6	9/1 3/2 03 1	9/14/2021 (2)	9/1/2021	39,077	34,668	9.86	9/13/2031
	10/ (23/ 2 20) 20	10/7/202 0	2,57 5	2,178	2 . 6 5	10/ 22/ 20 30	10/23/2020 (2)	10/7/2020	2,763	990	2.65	10/22/2030
	10/ (23/ 2 20) 20	1/1/2020	3,46 6	1,287	2 . 6 5	10/ 22/ 20 30	10/23/2020 (2)	1/1/2020	2,154	99	2.65	10/22/2030
	11/ (6/2 6 01) 9	5/1/2019	3,77 0	2,258	1 . 0 1	11/ 5/2 02 9	11/6/2019 (6)	5/1/2020	—	752	1.01	11/5/2029
	11/ (6/2 6 01) 9	9/13/201 9	6,83 1	1,575	1 . 0 1	11/ 5/2 02 9						
Jonathan Yu	12/ (29/ 2 20) 22	12/29/2022		33,84 7	1 3 . 5 0	12/ 28/ 20 32						

	9/1 (2)				9.86	9/1/2031
Chief Business Officer	4/2 (2) 02 (1)	7/1/2021	2,138		8.86	3/2/2031
	9/1 (2) 4/2 (2) 02 (1)	9/1/2021	14,138	31,512 (3)	9.86	9/1/2031 3/2/2031
	10/ (2) 23/ (5) 20 (1) 20	10/7/2020	8,135	7,865 (5)	2.43	10/ 22/ 20 30
	8/1 (2) 1/2 (4) 02 (1) 0	7/1/2021	22,900	15,100 (6)	6.05	8/1/2030 0/2031 03 0

(1) All stock options granted in years 2020 and 2021 have been were granted pursuant to the terms of our 2017 Stock Option and Grant Plan, as amended, or our 2017 Plan. All stock options granted in year 2022 have been were granted pursuant to the terms of our Amended and Restated 2021 Stock Option and Incentive Plan, or our 2021 Plan. Pursuant to provisions in our stock plans, the exercise price and number of shares subject to certain of these stock options were adjusted in connection with (i) the 1-for-10 reverse stock split that occurred on December 29, 2022 and (ii) our prior merger with Gemini Therapeutics, Inc., pursuant to which all of our shares of common stock were converted into shares of Gemini's common stock based on an exchange ratio of 0.1096. Accordingly, the exercise prices shown in the table above (and in the corresponding footnotes) reflect our named executive officers' post-reverse stock split holdings and post-conversion holdings.

(2) This stock option vests in 48 equal monthly installments following the Vesting Commencement Date, subject to the named executive officer's continuous service.

(3) 5,138 shares vested on February 25, 2021. The remaining 56,512 shares vest in 44 equal monthly installments following the Vesting Commencement Date, subject to the nam executive officer's continuous service.

(4) 25% of the shares vested on the one-year anniversary of the Vesting Commencement Date. The remaining shares vest in 36 equal monthly installments following the Vesting Commencement Date, subject to the named executive officer's continuous service.

(5) 2,140 shares vested on August 3, 2021. The remaining 8,135 shares vest in 38 equal monthly installments following the Vesting Commencement Date, subject to the named executive officer's continuous service.

(6) This stock option vests in 16 equal quarterly installments commencing on the three-month anniversary of the Vesting Commencement Date, subject to the named executive officer's continuous service.

Employment Arrangements for Named Executive Officers

Dr. John Quisel

On August 9, 2022, we entered into an employment agreement with Dr. Quisel effective as of December 29, 2022, or the Quisel Employment Agreement, who currently serves as our Chief Executive Officer, that supersedes his previous employment agreement. The Quisel Employment Agreement provides for Dr. Quisel's at-will employment, an annual salary of $562,000, subject to our periodic review and increase, but not decrease (except for an across-the-board reduction of no greater than 10% of based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company), an annual bonus with a target amount equal to 50% of his base salary and eligibility to participate in the employee benefit plans generally available to our employees. The Quisel Employment Agreement also provides that upon a termination

without cause (and not due to death or disability) or if Dr. Quisel resigns for good reason, in each case, outside of the period that is within 3 months prior to, or within 12 months after, the occurrence of the first event constituting a change in control, then Dr. Quisel is entitled to receive cash severance equal to continued base salary payments for 12 months, a lump sum payment equal to 100% of the executive's target bonus pro-rated for the year of termination, any earned, but unpaid bonus for the fiscal year prior

to the fiscal year of termination; acceleration of 25% of Dr. Quisel's unvested and outstanding time-based vesting equity awards and payment of COBRA premiums (subject to Dr. Quisel's continued copayment of such premiums at the active employees' rate) for up to 12 months following the termination date. If within 3 months prior to or 12 months following a change of control, Dr. Quisel is terminated by the Company or a successor involuntarily without cause (and not due to death or disability) or Dr. Quisel resigns for good reason, Dr. Quisel shall be entitled to a lump sum cash payment equal to 18 months of his then current base salary, plus 100% of his target bonus for the year of termination, plus any earned, but unpaid bonus for the fiscal year prior to the fiscal year of termination. In addition, upon such a termination, all of Dr. Quisel's outstanding equity awards subject to time-based vesting shall be immediately and fully accelerated and he shall be entitled to the payment of COBRA premiums for up to 18 months (subject to Dr. Quisel's continued copayment of such premiums at the active employees' rate). All severance payments and benefits are conditioned upon Dr. Quisel's execution of a release of claims in our favor. If as a result of a termination of his employment Dr. Quisel becomes subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, Dr. Quisel is subject to a modified cutback of the payments and benefits he would otherwise receive in connection with a change in control, such that he would retain the higher of the net amount he would receive if such payments were reduced to avoid payment of the excise tax and the net amount he would receive if he received such payments in full and paid the excise tax. Dr. Quisel is also subject to our confidentiality, assignment, non-solicitation, and noncompetition policies.

Dr. William Savage

On August 9, 2022, we entered into an employment agreement with Dr. Savage effective as of December 29, 2022, or the Savage Employment Agreement, who currently serves as our Chief Medical Officer, that supersedes his previous offer letter. The Savage Employment Agreement provides for Dr. Savage's at-will employment, an annual salary of $458,000, subject to our periodic review and increase, but not decrease (except for an across-the-board reduction of no greater than 10% of based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company), an annual bonus with a target amount equal to 40% of his base salary and his eligibility to participate in the employee benefit plans generally available to our employees. The Savage Employment Agreement also provides that upon a termination without cause (and not due to death or disability) or if Dr. Savage resigns for good reason, in each case, outside of the period that is within 3 months prior to, or within 12 months after, the occurrence of the first event constituting a change in control, then Dr. Savage is entitled to receive cash severance equal to continued base salary payments for 9 months, any earned, but unpaid bonus for the fiscal year prior to the fiscal year of termination, and payment of COBRA premiums (subject to Dr. Savage's continued copayment of such premiums at the active employees' rate) for up to 9 months. If within 3 months prior to or 12 months following a change of control, Dr. Savage is terminated by the Company or a successor involuntarily without cause (and not due to death or disability) or Dr. Savage resigns for good reason, Dr. Savage shall be entitled to a lump sum cash payment equal to 12 months of this then current base salary, plus 100% of his target bonus for the year of termination, plus any earned, but unpaid bonus for the fiscal year prior to the fiscal year of termination. . In addition, upon such a termination, all of Dr. Savage's outstanding equity awards subject to time-based vesting shall be immediately and fully accelerated and he shall be entitled to the payment of COBRA premiums for up to 12 months (subject to Dr. Savage's continued copayment of such premiums at the active employees' rate). All severance payments and benefits are conditioned upon Dr. Savage's execution of a release of claims in our favor. If as a result of a termination of his employment Dr. Savage becomes subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, Dr. Savage is subject to a modified cutback of the payments and benefits he would otherwise receive in connection with a change in control, such that he would retain the higher of the net amount he would receive if

such payments were reduced to avoid payment of the excise tax and the net amount he would receive if he received such payments in full and paid the excise tax. Dr. Savage is also subject to our confidentiality, assignment, non-solicitation, and noncompetition policies.

Ms. Joanne Bryce

On August 9, 2022, we entered into an employment agreement with Ms. Bryce effective as of December 29, 2022, or the Bryce Employment Agreement, who currently serves as our Chief Financial Officer, that supersedes her previous offer letter. The Bryce Employment Agreement provides for Ms. Bryce's at-will employment, an annual salary of $419,000, subject to our periodic review and increase, but not decrease (except for an across-the-board reduction of no greater than 10% of based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company), an annual bonus with a target amount equal to 40% of her base salary and her eligibility to participate in the employee benefit plans generally available to our employees. The Bryce Employment Agreement also provides that upon a termination without cause (and not due to death or disability) or if Ms. Bryce resigns for good reason, in each case, outside of the period that is within 3 months prior to, or within 12 months after, the occurrence of the first event constituting a change in control, then Ms. Bryce is entitled to receive cash severance equal to continued base salary payments for 9 months, any earned, but unpaid bonus for the fiscal year prior to the fiscal year of termination, and payment of COBRA premiums (subject to Ms. Bryce's continued copayment

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of such premiums at the active employees' rate) for up to 9 months. If within 3 months prior to 12 months following a change of control, Ms. Bryce is terminated by the Company or successor involuntarily without cause (and not due to death or disability) or Ms. Bryce resigns for good reason, Ms. Bryce shall be entitled to cash severance equal to a lump sum cash payment equal to 12 months of her then current base salary, plus 100% of her target bonus for the year of termination, plus any earned, but unpaid bonus for the fiscal year prior to the fiscal year of termination. In addition, upon such a termination, all of Ms. Bryce's

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outstanding equity awards subject to time-based vesting shall be immediately and fully accelerated and she shall be entitled to the payment of COBRA premiums (subject to Ms. Bryce's continued copayment of such premiums at the active employees' rate) for up to 12 months. All severance payments and benefits are conditioned upon Ms. Bryce's execution of a release of claims in our favor. If as a result of a termination of his employment Ms. Bryce becomes subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, Ms. Bryce is subject to a modified cutback of the payments and benefits she would otherwise receive in connection with a change in control, such that she would retain the higher of the net amount she would receive if such payments were reduced to avoid payment of the excise tax and the net amount she would receive if she received such payments in full and paid the excise tax. Ms. Bryce is also subject to our confidentiality, assignment, non-solicitation, and noncompetition policies.

Mr. Jonathan Yu

On August 9, 2022 February 7, 2024, Ms. Bryce departed from her role as Chief Financial Officer. In connection with her departure, we entered into an employment agreement a Transition and Separation Agreement with Mr. Yu effective December 29, 2022, Ms. Bryce, or the Yu Employment Bryce Separation Agreement, who currently serves as our Chief Business Officer, which provides that, supersedes his previous offer letter. The Yu Employment Agreement provides for Mr. Yu's at-will employment, an annual salary of $419,000, subject to our periodic review and increase, but not decrease (except for an across-the-board reduction of no greater than 10% of based on the Company's financial

performance similarly affecting all or substantially all senior management employees Ms. Bryce's execution of the Company), an annual bonus with a target amount equal to 40% of his base salary and his eligibility to participate in the employee benefit plans generally available to our employees. The Yu Employment Bryce Separation Agreement, also provides that upon a termination without cause (and not due to death or disability) or if Mr. Yu resigns for good reason, in each case, outside of the period that is within 3 months prior to, or within 12 months after, the occurrence of the first event constituting a change in control, then Mr. Yu is entitled to receive cash severance equal to continued base salary payments for 9 months, any earned, but unpaid bonus for the fiscal year prior to the fiscal year of termination, and payment of COBRA premiums (subject to Mr. Yu's continued copayment of such premiums at the active employees' rate) for up to 9 months. If within 3 months prior to or 12 months following a change of control, Mr. Yu is terminated by the Company or successor involuntarily without cause (and not due to death or disability) or Mr. Yu resigns for good reason, Mr. Yu shall be entitled to a lump sum cash payment equal to 12 months of his then current base salary, plus 100% of his target bonus for the year of termination, plus any earned, but unpaid bonus for the fiscal year prior to the fiscal year of termination. In addition, upon such a termination, all of Mr. Yu's outstanding equity awards subject to time-based vesting shall be immediately and fully accelerated and he shall be entitled to the payment of COBRA premiums (subject to Mr. Yu's continued copayment of such premiums at the active employees' rate) for up to 12 months. All severance payments and benefits are conditioned upon Mr. Yu's execution of which included a release of claims in our favor. If favor of the Company, Ms. Bryce will receive 100% of her target annual bonus for 2023, despite her not remaining an employee through the date of payment. In addition, subject to Mr. Bryce's execution and nonrevocation of the Bryce Separation Agreement, her continued compliance with her Employee Confidentiality, Assignment, Non-solicitation and Noncompetition Agreement, dated as a result of a September 14, 2021, and her cooperation with us to transition her duties and responsibilities, Ms. Bryce will be entitled to the following: (i) we will engage Ms. Bryce as an advisor between the date of her termination of his employment Mr. Yu becomes (i.e., February 7, 2024) and the date that is nine months after such termination (i.e., November 7, 2024), unless she resigns prior to such date or we terminate her for cause (the "Advisor Period"), and during the Advisor Period we will pay Ms. Bryce $350 per hour of service she provides to the Company, (ii) her base salary for a period of nine months following her termination of employment, (iii) subject to her copayment of premium amounts at the excise tax imposed by Section 4999 of the Internal Revenue Code, Mr. Yu is subject applicable active employees' rate and proper election to a modified cutback of the payments and benefits he would otherwise receive in connection with a change in control, such that he would retain the higher of the net amount he would receive if such payments were reduced to avoid continue COBRA health coverage, payment of the excise tax portion of the premiums equal to the amount that we would have paid to provide health insurance to Ms. Bryce had she remained employed with us for up to nine months following her termination of employment, (iii) the period during which Ms. Bryce may exercise her vested and outstanding stock options following the net amount he would receive if he received such payments cessation of her service relationship with us was extended to the earlier of (A) the date that is twelve months following the end of the Advisor Period and (b) the original expiration date of the stock option, and (iv) a prorated portion of her target annual bonus for 2024, prorated based on the number of days in full and paid 2024 she remained employed by the excise tax. Mr. Yu is also subject to our confidentiality, assignment, non-solicitation, and noncompetition policies.Company.

Health and Welfare Benefits

Our named executive officers, like all full-time employees, are eligible to participate in our health and welfare benefit plans.

Perquisites and Personal Benefits

We generally do not provide perquisites to our executives.

401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax-advantaged basis, or the 401(k) Plan. Participants in the 401(k) Plan are able to defer eligible compensation subject to applicable annual Internal Revenue Code limits. During 2023, we implemented a safe harbor match under our 401(k) program of 50% of a participant's eligible contributions, up to a total of 6% of eligible compensation. We did not provide a matching contribution to the named executive officers or to any employees in 2022. The 401(k) Plan is intended to be qualified under Section 401(a) of the Internal Revenue Code with the 401(k) Plan's

related trust intended to be tax exempt under Section 501(a) of the Internal Revenue Code. As a tax-qualified retirement plan, pre-tax contributions to the 401(k) Plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) Plan, and earnings on Roth contributions are not taxable when distributed from the 401(k) Plan.

DIRECTOR COMPENSATION

Non-Employee Director Compensation Table

The following table presents the total compensation for each person who served as a non-employee member of our board of directors during the fiscal year ended December 31, 2022 December 31, 2023. Dr. Quisel, one of our directors who also serves as our Chief Executive Officer, does not receive any additional compensation for his service as a director. Dr. Quisel is one of our named executive officers and, accordingly, the compensation that we pay to Dr. Quisel is discussed above under ''—2022 2023 Summary Compensation Table'' and ''—Narrative to Summary Compensation Table.''

Other than as described in this paragraph and set forth in the table and described more fully below, we did not pay any compensation or make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2022 2023 for their services as members of the board of directors.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)(2)	Total ($)	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)(4)	Total ($)
Donald Nicholson, Ph.D.	150,000	54,186	204,186	164,000	215,308	379,308
William White, MPP, J.D.	50,000	54,186	104,186	55,000	215,308	270,308
Jay Backstrom, MD, M.P.H.	40,000	54,186	94,186			
Jay Backstrom, MD, M.P.H.(2)				17,692	107,137	124,829
Mona Ashiya, Ph.D.	—	54,186	54,186	49,000	215,308	264,308
Kevin Bitterman, Ph.D.	—	54,186	54,186	53,000	215,308	268,308
Mark Chin, MS, MBA	—	54,186	54,186	47,500	215,308	262,808
Liam Ratcliffe, MD, Ph.D.	—	54,186	54,186	51,500	215,308	266,808

Georges Gemayel, Ph.D(3)	—	54,186	54,186	40,000	215,308	255,308
Eric Snyder, Ph.D(4)	—	—	—			

(1) The amounts reported represent the aggregate grant date fair value of the stock options awarded to the non-employee directors during fiscal year 2022, 2023, calculated in accordance with FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the awards reported in this column are set forth in Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K. The amounts reported in this column reflect the accounting cost for the stock options and does correspond to the actual economic value that may be received upon exercise of the stock option or any sale of any of the underlying shares of common stock.

(2) Dr. Backstrom resigned from our board on June 9, 2023. Upon Dr. Backstrom's resignation, our board approved an amendment to the stock options held by Dr. Backstrom to accelerate the vesting such that any unvested stock options held by Dr. Backstrom became vested and exercisable in full as of June 9, 2023.

(3) Dr. Gemayel joined our board of directors on December 29, 2022.

(4) As of December 31, 2022 December 31, 2023, our non-employee members of our board of directors held the following aggregate number of unexercised options and unvested shares of restricted stock as of such date:

Name	Number of Securities Underlying Unexercised Options	Number of Shares of Unvested Restricted Stock
Donald Nicholson, Ph.D	128,462	1,916
William White, MPP, J.D	44,751	—
Jay Backstrom, MD, M.P.H	21,028	—
Mona Ashiya, Ph.D	7,000	—
Kevin Bitterman, Ph.D	7,000	—
Mark Chin, MS, MBA	7,000	—
Liam Ratcliffe, MD, Ph.D	7,000	—
Georges Gemayel, Ph.D	94,946	—
Eric Snyder, Ph.D.	—	—

(3) Dr. Gemayel joined our board of directors on December 29, 2022.

(4) Dr. Snyder resigned from our board of directors on December 29, 2022, and held no outstanding stock as he was not an independent member of the board of directors.

Name	Number of Securities Underlying Unexercised Options
Donald Nicholson, Ph.D	135,598
William White, MPP, J.D	18,376
Jay Backstrom, MD, M.P.H	30,743
Mona Ashiya, Ph.D	14,136
Kevin Bitterman, Ph.D	14,136
Mark Chin, MS, MBA	14,136
Liam Ratcliffe, MD, Ph.D	14,136
Georges Gemayel, Ph.D	102,082

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Ownership of Our Common Stock

Unless otherwise provided below, the following table sets forth information regarding beneficial ownership of our common stock as of February 28, 2023 February 29, 2024 by:

- each person, or group of affiliated persons, known to us to be the beneficial owner of 5% or more of the outstanding shares of our common stock;
- each of our current directors;

- our principal executive officer and our other executive officers who served during the year ended December 31, 2022 December 31, 20 named in the Summary Compensation table above, whom, collectively, we refer to as our named executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with SEC rules. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include shares of common stock issuable upon the exercise of stock options that are immediately exercisable or exercisable within 60 days after February 28, 2023 February 29, 2024. Except as otherwise indicated, all of the shares reflected in the table are shares of common stock and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

The column entitled “Percentage of Shares Beneficially Owned” is based on a total of 18,988,025 24,681,028 shares of our common stock outstanding as of February 28, 2023 February 29, 2024. Except as otherwise indicated in the footnotes below, the address of the beneficial owner is c/o Disc Medicine, Inc., 321 Arsenal Street, Suite 101, Watertown, MA 02472.

	Number of Shares of Common Stock Beneficially Owned	Percentage of Shares Beneficially Owned	Number of Shares of Common Stock Beneficially Owned	Percentage of Shares Beneficially Owned
5% or Greater Stockholders				
Entities affiliated with Atlas Venture Fund (1)	3,461,784	18.23%		
AI DMI LLC (2)	3,141,759	16.55%		
Novo Holdings A/S (3)	2,340,772	12.33%		
AI DMI LLC(1)			3,345,840	13.45%

Entities affiliated with Paradigm(2)			2,385,857	9.67%
Entities affiliated with Atlas Venture Fund(3)			2,355,172	9.54%
Entities affiliated with FMR LLC (Fidelity)(4)			2,166,819	8.78%
Entities affiliated with OrbiMed (4) (5)	2,269,637	11.95%	1,702,237	6.90%
Bain Capital Life Sciences Opportunities III, LP (5) (6)	1,896,903	9.99%	1,332,545	5.40%
Directors, Named Executive Officers and Other Executive Officers				
John Quisel, J.D., Ph.D.(6) (7)	309,202	1.63%	456,829	1.82%
William Savage, MD, Ph.D.(7) (8)	59,265	*	77,066	*
Joanne Bryce, CPA (8) (9)	55,977	*	65,731	*
Jonathan Yu (9)	59,815	*		
Mona Ashiya, Ph.D.	—	—		
Jay Backstrom, MD, M.P.H.(10)	8,907	*		
Kevin Bitterman, Ph.D.	—	—		
Mark Chin, MS, MBA	—	—		
Mona Ashiya, Ph.D.(10)			7,000	*
Kevin Bitterman, Ph.D.(10)			7,000	*
Mark Chin, MS, MBA(10)			7,000	*
Georges Gemayel(11)	87,946	*	94,946	*
Donald Nicholson, Ph.D.(12)	104,871	*	131,421	*
Liam Ratcliffe, MD, Ph.D.	—	—		
Liam Ratcliffe, MD, Ph.D.(10)			7,000	*
William White, MPP, J.D.(13)	19,632	*	2,560	*
All executive officers and directors as a group (14 persons)	735,353	3.87%	1,004,613	3.92%

* Represents beneficial ownership of less than 1% of our outstanding common stock.

(1) The shares held by AI DMI LLC may be deemed to be beneficially owned by Access Industries Holdings LLC, or AIH, Access Industries Management, LLC, or AIM, and Len Blavatnik because (i) AIH indirectly controls all of the outstanding voting interests in AI DMI LLC, (ii) AIM controls AIH and (iii) Mr. Blavatnik controls AIM and holds a majority o the outstanding voting interests in AIH. Liam Ratcliffe, a member of our board of directors, is Head of Biotechnology at Access Industries, Inc., which is an affiliate of AI DMI LL Each of AIM, AIH, Mr. Blavatnik and Dr. Ratcliffe, and each of their affiliated entities and the officers, partners, members and managers thereof, disclaims beneficial ownership the shares held by AI DMI LLC. The address of AI DMI LLC is c/o Access Industries, Inc., 40 West 57th Street, 28th Floor, New York, NY 10019.

(2) This information is as of December 31, 2023 and based solely on information contained in the Schedule 13G/A filed with the SEC on February 14, 2024 by Paradigm BioCapita Advisors LP, or the Adviser, Paradigm BioCapital Advisors GP LLC, or the Adviser GP, Senai Asefaw, M.D., or Senai Asefaw, and Paradigm BioCapital International Fund Ltd., the Fund. The Fund is a private investment vehicle. The Fund and one or more separately managed accounts managed by the Adviser, or the Account, directly beneficially ow the shares. The Adviser is the investment manager of the Fund and the Account. The Adviser GP is the general partner of the Adviser. Senai Asefaw is the managing member the Adviser GP. The Adviser, the Adviser GP and Senai Asefaw may be deemed to beneficially own the shares directly beneficially owned by the Fund and the Account. Each Reporting Person disclaims beneficial ownership with respect to any shares other than the shares directly beneficially owned by such Reporting Person. The principal business office address is 767 Third Avenue, 17th Floor, New York, NY 10017.

(3) Consists of (i) 2,237,303 1,402,186 shares held by Atlas Venture Fund X, L.P., or Atlas Fund X, 955,155 703,660 shares held by Atlas Venture Opportunity Fund I, L.P., or AVO 218,326 198,326 shares held by Atlas Venture Opportunity Fund II, L.P., or AVOF II, and 51,000 shares held by Atlas Venture Fund XII, L.P., or Atlas Fund XII. Atlas Venture Associates X, L.P. is the general partner of Atlas Fund X, and Atlas Venture Associates X, LLC is the general partner of Atlas Venture Associates X, L.P. Each of Atlas Fund X, Atlas Venture Associates X, L.P., and Atlas Venture Associates X, LLC may be deemed to beneficially own the shares held by Atlas Fund X. Each of Atlas Venture Associates L.P. and Atlas Venture Associates X, LLC disclaim Section 16 beneficial ownership of the securities owned by Atlas Fund X, except to the extent of its pecuniary interest therei

any. The general partner of AVOF I is Atlas Venture Associates Opportunity I, L.P., or AVAO I LP, and the general partner of AVAO I LP is Atlas Venture Associates Opportunity LLC, or AVAO I LLC. The members of AVAO I LLC collectively make investment decisions on behalf of AVAO I LLC. Kevin Bitterman, Ph.D., is a member of AVAO I

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LLC and a member of the Company's Board. Each of AVOF I, AVAO I LP, AVAO I LLC and Dr. Bitterman may be deemed to beneficially own the shares held by AVOF I. Each AVAO I LP, AVAO I LLC and Dr. Bitterman expressly disclaim beneficial ownership of the securities owned by AVOF I, except to the extent of its pecuniary interest therein, if an The general partner of AVOF II is Atlas Venture Associates Opportunity II, L.P., or AVAO II LP, and the general partner of AVAO II LP is Atlas Venture Associates Opportunity II LLC, or AVAO II LLC. The members of AVAO II LLC collectively make investment decisions on behalf of AVAO II LLC. Dr. Bitterman is a member of AVAO II LLC and a membe the Company's Board. Each of AVAO II LP, AVAO II LLC and Dr. Bitterman may be deemed to beneficially own the shares held by AVOF II. Each of AVOF II, AVAO II LP, AVAC LLC and Dr. Bitterman expressly disclaim beneficial ownership of the securities owned by AVOF II, except to the extent of its pecuniary interest therein, if any. The general part of Atlas Fund XII is Atlas Venture Associates XII, L.P., or AVA XII LP. Atlas Venture Associates XII, LLC, or AVA XII LLC, is the general partner of AVA XII LP. The members of A XII LLC collectively make investment decisions on behalf of AVA XII LLC. Dr. Bitterman is a member of AVA XII LLC and a member of the Company's Board. Each of Atlas Fun XII, AVA XII LP, AVA XII LLC and Dr. Bitterman may be deemed to beneficially own the shares held by Atlas Fund XII. Each of AVA XII LP, AVA XII LLC and Dr. Bitterman expressly disclaim Section 16 beneficial ownership of the securities owned by Atlas Fund XII, except to the extent of its pecuniary interest therein, if any. The address for Atlas Ventures is 300 Technology Sq., 8th Floor, Cambridge, MA 02139.

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(2) (4) The 2,166,819 shares held by AI DMI LLC are beneficially owned, or that may be deemed to be beneficially owned, by Access Industries Holdings FMR LLC, or AIH, Access Industries Management, LLC, or AIM, certain of its subsidiaries and Len Blavatnik because (i) AIH indirectly controls all affiliates, and other companies. Abigail P. Johnson is a Director, the Chairman and the Chief Executive Officer of FMR LLC. Members of the outstanding Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting interests in AI ETI common shares of FMR LLC, (ii) AIM controls AIH and (iii) Mr. Blavatnik controls AIM and holds a majority representing 49% of the outstanding voting interests power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholde voting agreement under which all Series B voting common shares will be voted in AIH. Liam Ratcliffe, a member accordance with the majority vote of our board Series B voting common shares. Accordingly, through their ownership of directors, is Head of Biotechnology at Access Industries, Inc., which is an affiliate of AI DMI LLC. Each of AIM, AIH, M Blavatnik and Dr. Ratcliffe, and each of their affiliated entities voting common shares and the officers, partners, members and managers thereof, disclaims beneficial ownership execution of the shares held by AI DMI shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 194 to form a controlling group with respect to FMR LLC. The address of AI DMI FMR LLC is c/o Access Industries, Inc., 40 West 57th 245 Summer Street, 28th Floor, New York, N 10019. Boston, MA 02210.

(3) Novo Holdings A/S has the sole power to vote and dispose of the shares, and no individual or other entity is deemed to hold any beneficial ownership in the shares. Eric Snyde Ph.D. is employed as a Partner at Novo Ventures (US), Inc., which provides certain consultancy services to Novo Holdings A/S, and is a former member of the Company's Boa Dr. Snyder is not deemed to hold any beneficiary ownership or reportable pecuniary interest in the shares held by Novo Holdings A/S. The business address of Novo Holdings is Tuborg Havnevej 19, 2900 Hellerup, Denmark.

(4) (5) OrbiMed Advisors LLC exercises voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild. The busin address is 601 Lexington Avenue, 54th Floor, New York, NY 10022.

(5) (6) Bain Capital Life Sciences Investors, LLC, a Delaware limited liability company, or BCLSI, is the manager of Bain Capital Life Sciences III General Partner, LLC, a Delaware limited liability company, or BCLS Fund III GP, which is the general partner of Bain Capital Life Sciences Fund III, L.P., a Delaware limited partnership, or BCLS Fund III, which the sole member of Bain Capital Life Sciences Opportunities III GP, a Delaware limited liability company, or BCLS III Opportunities GP, and, together with BCLSI, BCLS Fund I GP and BCLS Fund III, the Bain Capital Life Sciences Entities, which is the general partner of BCLSI. As a result, BCLSI may be deemed to share voting and dispositive powe with respect to the securities held by BCLSI. As of February 24, 2022, BCLS III Opportunities GP holds 944,687 shares of Common Stock and pre-funded warrants to purchas 1,229,224 shares of Common Stock. As a result of a beneficial ownership blocker, beneficial ownership of Bain Capital Life Sciences Opportunities III, LP is capped at 9.99% o the outstanding shares of Common Stock, representing 1,896,903 shares of Common Stock calculated as described herein as of February 28, 2023.The The business address these entities is 200 Clarendon Street, Boston, Massachusetts 02116. The principal business address for each of the Bain Capital Life Sciences Entities is 200 Clarendon Stre Boston, Massachusetts 02116.

(6) (7) Consists of 2,700 shares of common stock and options to purchase 309,202 454,129 shares of our common stock that are exercisable within 60 days of February 28, 2023 February 29, 2024.

(7) (8) Consists of 20,325 3,000 shares of common stock and options to purchase 38,940 74,066 shares of our common stock that are exercisable within 60 days of February 28, 2023 February 29, 2024.

(8) (9) Consists of 3,452 5,996 shares of common stock and options to purchase 52,525 59,735 shares of our common stock that are exercisable within 60 days of February 28, 2023 February 29, 2024.

(9) (10) Consists of options to purchase 59,815 7,000 shares of our common stock that are exercisable within 60 days of February 28, 2023 February 29, 2024.

(10) (11) Consists of options to purchase 8,907 94,946 shares of our common stock that are exercisable within 60 days of February 28, 2023.

(11) Consists of options to purchase 87,946 shares of our common stock that are exercisable within 60 days of February 28, 2023 February 29, 2024.

(12) Consists of 15,332 shares of common stock and options to purchase 89,539 116,089 shares of our common stock that are exercisable within 60 days of February 28, 2023 February 29, 2024.

(13) Consists of options to purchase 19,632 2,560 shares of our common stock that are exercisable within 60 days of February 28, 2023 February 29, 2024.

Equity Compensation Plan Information

The following table contains information about our equity compensation plans as of December 31, 2022 December 31, 2023.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)(3)	(c)
Equity compensation plans approved by security holders			
2021 Stock Option and Incentive Plan(1)	833,812	$ 25.98	1,031,615
2021 Employee Stock Purchase Plan(2)	—	$ —	179,898
2017 Stock Option and Grant Plan of Disc	1,670,839	$ 7.20	—
2017 Stock Option and Grant Plan of Gemini	90,189	$ 36.44	—
Equity compensation plans not approved by security holders			
2021 Inducement Plan	45,750	$ 125.90	115,939
Total	2,640,590		1,327,452

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))

	(a)		(b)(3)	(c)
Equity compensation plans approved by security holders				
2021 Stock Option and Incentive Plan(1)	959,469	$	23.15	1,561,926
2021 Employee Stock Purchase Plan(2)	—	$	—	222,953
2017 Stock Option and Grant Plan of Disc	1,491,591	$	7.22	—
2017 Stock Option and Grant Plan of Gemini	—	$	—	—
Equity compensation plans not approved by security holders				
2021 Inducement Plan	7,977	$	125.90	153,712
Total	2,459,037			1,938,591

(1) The number of shares of common stock reserved for issuance under the 2021 Stock Option and Incentive Plan automatically increases on January 1 of each calendar year, starting on January 1, 2022 and continuing through January 1, 2031, in an amount equal to 4% of the total number of shares of the Company's capital stock outstanding on t last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the Board. Subject to this provision, we added 696,224 974,409 shares to the 2021 Stock Option and Incentive Plan effective January 1, 2023 January 1, 2024.

(2) The number of shares of common stock reserved for issuance under the 2021 Employee Stock Purchase Plan automatically increases on January 1 of each calendar year, starting on January 1, 2023 and continuing through January 1, 2031, in an amount equal to the least of (a) 1% of the total number of shares of the Company's capital stock outstanding on the last day of the calendar month before the date of each automatic increase, (b) 43,055 shares of common

stock, or (c) such number of shares determined by the Board. Subject to this provision, we added 43,055 shares to the 2021 Employee Stock Purchase Plan effective Janua 2023 January 1, 2024.

(3) The weighted-average exercise price is calculated based solely on outstanding stock options and does not include outstanding restricted stock awards, which do not have ar exercise price.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The following is a description of transactions or series of transactions since January 1, 2022 January 1, 2023, to which we were or will be a party, in which:

- the amount involved in the transaction exceeds, or will exceed, the lesser of $120,000 or one percent of the average of our total assets the last two completed fiscal years; and
- in which any of our executive officers, directors or holders of five percent or more of any class of our capital stock, including their immediate family members or affiliated entities, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and directors are described in Item 11 – Executive Compensation.

Private Placements of Securities Common Stock Financing

2022 Registration Rights Agreement

We are party to a registration rights agreement, or the 2022 Registration Rights Agreement, with certain holders In June 2023, we completed an underwritten public offering and sale of our capital stock, or the 2022 Investors, pursuant to which we (i) agreed to register for resale 3,015,919 shares of our common stock, issued par value $0.0001, at a purchase price of $49.00 per share and pre-funded warrants to the 2022 Investors, or the Registrable Securities, and (ii) granted certain other registration rights to the 2022 Investors.

In particular, the 2022 Registration Rights Agreement provides for the following registration rights:

- *Shelf registration rights*. No later than 45 calendar days following the completion of the merger, we were required to file with the SEC, a shelf registration statement registering the resale of the Registrable Securities, and use our commercially reasonable efforts to have such registration statement declared effective by the SEC as promptly as possible.
- *Expenses and indemnification*. The fees, costs and expenses of registrations pursuant to the registration rights granted to the 2022 Investors under the 2022 Registration Rights Agreement will be borne by us. The 2022 Registration Rights Agreement contains

customary cross-indemnification provisions, under which we are obligated to indemnify holders of Registrable Securities in the event of material misstatements or omissions in the registration statement attributable to us, and holders of Registrable Securities are obligated to indemnify us for material misstatements or omissions attributable to them.

Common Stock Financing

In August 2022, in connection with our merger with Gemini, we entered into a Subscription Agreement with certain investors. Pursuant to the Subscription Agreement, we sold purchase an aggregate of 21,341,737 204,081 shares of our common stock at a purchase price of $2.51 $48.9999 per share, pre-funded warrant, for an aggregate gross total proceeds of $53.5 million. At the closing of the merger, shares of our common stock held $157.8 million before the merger were exchanged for deducting underwriting discounts, commissions and other offering expenses. The shares of common stock sold included 420,000 shares sold pursuant to an option granted to the underwriters, which was exercised in the combined publicly-traded company based on an exchange ratio of 0.1096. Four full. The purchaser of the investors or their affiliates are pre-funded warrants was a beneficial holders holder of more than 5% of our capital stock, and the table below sets forth the number of shares of our common stock purchased by such holders: stock.

Participant	Shares of our Common Stock	Total Purchase Price ($)
Atlas Venture Opportunity Fund I, L.P.(1)	1,992,031	5,000,000
Novo Holdings A/S(2)	1,195,219	3,000,000
AI DMI LLC(3)	9,960,159	25,000,000
Entities affiliated with OrbiMed Advisors LLC(4)	3,984,063	9,999,998

Participant	Shares of our Common Stock Underlying Pre-Funded Warrants	Total Purchase Price ($)
AI DMI LLC(1)	204,081	9,999,949

(1) Entities affiliated with Atlas Venture Opportunity Fund I, L.P. beneficially own more than five percent of our outstanding capital stock. Dr. Bitterman is a Partner at Atlas Venture and a member of our board of directors.

(2) Novo Holdings A/S is an affiliate of Novo Ventures (US), Inc., and beneficially owns more than five percent of our outstanding capital stock.

(3) AI DMI LLC is an affiliate of Access Industries Management, and beneficially owns more than five percent of our outstanding capital stock. Dr. Ratcliffe is Head of Biotechnolog Access Industries Management and a member of our board of directors.

(4) Entities affiliated with OrbiMed Advisors LLC beneficially own more than five percent of our outstanding capital stock. Dr. Ashiya is a Partner at OrbiMed Advisors LLC and a member of our board of directors.

Registered Direct Offering

In February 2023, we entered into a securities purchase agreement, or the Purchase Agreement, with certain investors. Pursuant to the Purchase Agreement, we sold (i) an aggregate of 1,488,166 shares of our common stock, at a purchase price of $23.00 per share, and (ii) with respect to certain investors, in lieu of shares of our common stock, pre-funded warrants to purchase an aggregate of 1,229,224 shares of our common stock, at a purchase price of $22.9999 per pre-funded warrant, for aggregate gross proceeds of approximately $62.5 million. During the twelve months ended December 31, 2023, all of the pre-funded warrants were exercised in a cashless transaction which resulted in 1,229,221 shares of common stock being issued to the investor. The investors or their affiliates are beneficial holders of more than 5% of our capital stock, and the table below sets forth the number of shares of our common stock and pre-funded warrants to purchase shares of our common stock purchased by such holders:

Participant	Shares of our Common Stock	Shares of our Common Stock Underlying Pre-Funded Warrants	Total Purchase Price ($)
Bain Capital Life Sciences Opportunities III, L.P.(1)	944,687	1,229,224	49,999,830
Entities affiliated with OrbiMed Advisors LLC(2)	108,696	—	2,500,008
AI DMI LLC(3)	434,783	—	10,000,009

(1) Bain Capital Life Sciences Opportunities III, L.P. beneficially owns more than five percent of our outstanding capital stock.

(2) Entities affiliated with OrbiMed Advisors LLC beneficially own more than five percent of our outstanding capital stock. Dr. Ashiya is a Partner at OrbiMed Advisors LLC and a member of our board of directors.

(3) AI DMI LLC is an affiliate of Access Industries Management, and beneficially owns more than five percent of our outstanding capital stock. Dr. Ratcliffe is Head of Biotechnolog Access Industries Management and a member of our board of directors.

License Agreements

In connection with and as partial consideration under the Roche Agreement with Roche executed in 2021, we issue to Roche 482,313 shares of our common stock equal to 2.85% of our issued and outstanding capitalization immediately following the closing of the merger and the pre-closing financing, no additional consideration concurrent with the completion of the merger. The issuance of such shares were not registered under the Securities Act.

In connection with and as partial consideration under the AbbVie Agreement with AbbVie executed in 2019, we issued 4,336,841 shares of our common stock to AbbVie for no additional consideration. Pursuant to this agreement, 2,295,174 shares vested immediately in September 2019, with the remaining 2,041,667 shares subject to a performance condition, which was met during 2020. At the closing of the merger, shares of our common stock held before the merger were exchanged for shares of common stock in the combined publicly-traded company based on an exchange ratio of 0.1096.

Indemnification Agreements

We have entered into agreements to indemnify our directors and executive officers. These agreements require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on our behalf or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

Policies for Approval of Related Party Transactions

Our board of directors reviews and approves transactions with our directors, officers and holders of five percent or more of our voting securities and their affiliates, each a related party. Prior to such transaction, the material facts as to the related party's relationship or interest in the transaction are disclosed to our board of directors prior to their consideration of such transaction, and the transaction is not considered approved by the board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction are disclosed to the stockholders, who must approve the transaction in good faith.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Ernst & Young LLP, or EY, has served as our independent registered public accounting firm since 2020 and has audited our financial statements for the fiscal years ended December 31, 2022 December 31, 2023 and 2021. 2022. The following table sets forth fees billed and unbilled for professional audit services and other services rendered to us by EY for the fiscal years ended December 31, 2022 December 31, 2023 and 2021. 2022.

	Fiscal 2022	Fiscal 2021	Fiscal 2023	Fiscal 2022
Audit Fees	$ 1,145,000	$ 1,085,000	$ 759,000	$ 1,145,000
Audit-Related Fees	—	—	—	—
Tax Fees	35,000	—	89,063	35,000
All Other Fees	—	—	—	—
Total	$ 1,180,000	$ 1,085,000	$ 848,063	$ 1,180,000

Audit Fees

Audit fees consist of fees billed and unbilled for professional services performed by EY for the audit of our annual consolidated financial statements, the review of interim consolidated financial statements, and services that are normally provided in connection with registration statements. The 2023 audit fees included $284,000 of fees in connection with the filing of our Registration Statement on Form S-3 and prospectus supplements. The 2022 audit fees included $565,000 of fees in connection with the filing of our Registration Statement on Form S-4 and $200,000 of fees in connection with the filing of our Registration Statement on Form S-3. The 2021 audit fees included $685,000 of fees in connection with a planned equity financing which did not occur.

Tax Fees

Tax fees consist of tax compliance, tax advice and tax planning services.

Pre-Approval of Audit and Non-Audit Services

It is the policy of our Audit Committee that all services to be provided by our independent registered public accounting firm, including audit services and permitted audit-related and non-audit services, must be approved in advance by our Audit Committee, except that pre-approval is not required for the provision of non-audit services if the "de minimis" provisions of Section 10A(i)(1)(B) of the Exchange Act are satisfied. The Audit Committee may delegate authority to pre-approve non-audit services to one or more members of the Audit Committee, who shall present all decisions made to pre-approve an activity to the full Audit Committee at its first meeting following such decision. All services provided by EY during fiscal years 2022 2023 and 2021 2022 were pre-approved by the Audit Committee in accordance with the pre-approval policy described above.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page 108 107 of this Annual Report on Form 10-K, incorporated into this Item by reference.

2. Financial Statement Schedules

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

3. Exhibits

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index immediately preceding the signature page of this Annual Report on Form 10-K. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Exhibit Index

Exhibit Number	Description
2.1†	Agreement and Plan of Merger and reorganization, dated as of August 9, 2022, by and among Gemini Therapeutics, Inc. Gemstone Merger Sub, Inc. and Disc Medicine, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Proxy Statement/Prospectus on Form S-4 filed on September 2, 2022).

3.1	Amended and Restated Certificate of Incorporation of Disc Medicine, Inc. (incorporated by reference to Annex B to Gemini Therapeutics, Inc.'s Proxy Statement/Prospectus on Form S-4/A (Registration No. 333-249785)).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Disc Medicine, Inc., dated December 28, 2022 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on December 29, 2022).
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Disc Medicine, Inc., dated December 29, 2022 (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on December 29, 2022).
3.4	Amended and Restated By-laws of Disc Medicine, Inc. (incorporated by reference to Annex C to Gemini Therapeutics, Inc.'s Proxy Statement/Prospectus on Form S-4/A (Registration No. 333-249785)).
4.1	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Exchange Act (incorporated by reference to Exhibit 4.4 to Gemini Therapeutics, Inc.'s Annual Report on Form 10-K filed on March 10, 2022).
4.2	Registration Rights Agreement, among Disc Medicine, Inc. and certain of its stockholders, dated December 28, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 29, 2022).
4.3	Registration Rights Agreement, dated February 5, 2021, by and among Gemini Therapeutics, Inc. and the stockholder parties thereto (incorporated by reference to Exhibit 10.1 on Form 8-A12B/A filed on February 5, 2021).
4.4	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-39438) filed February 14, 2023).
10.1††	License Agreement by and among Disc Medicine, Inc., F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated May 7, 2021 (incorporated by reference to Exhibit 10.2 to the Registrant's Proxy Statement/Prospectus on Form S-4 filed on September 2, 2022).
10.2††	License Agreement by and between Disc Medicine, Inc. and AbbVie Deutschland GmbH & Co, KG, dated September 13, 2019 (incorporated by reference to Exhibit 10.3 to the Registrant's Proxy Statement/Prospectus on Form S-4 filed on November 23, 2022).
10.3††	Exclusive License Agreement, dated January 19, 2023, by and between Disc Medicine, Inc. and Mabwell Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39438) filed on May 15, 2023)
10.3	Lease by and between Disc Medicine, Inc. and ARE-MA Region No. 75, LLC, dated October 29, 2021 (incorporated by reference to Exhibit 10.4 to the Registrant's Proxy Statement/Prospectus on Form S-4 filed on September 2, 2022).
10.4	Addendum to License Agreement by and among Disc Medicine, Inc., F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated December 7, 2021 (incorporated by reference to Exhibit 10.5 to the Registrant's Proxy Statement/Prospectus on Form S-4 filed on September 2, 2022).

10.5	Amendment to Addendum to License Agreement by and among Disc Medicine, Inc., F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated February 28, 2022 (incorporated by reference to Exhibit 10.6 to the Registrant's Proxy Statement/Prospectus on Form S-4 filed on September 2, 2022).

Exhibit Number	Description
10.6	Second Amendment to Addendum to License Agreement by and among Disc Medicine, Inc., F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated May 31, 2022 (incorporated by reference to Exhibit 10.7 to the Registrant's Proxy Statement/Prospectus on Form S-4 filed on September 2, 2022).

10.7

Exhibit Number	Description
10.7	Third Amendment to Addendum to License Agreement by and among Disc Medicine, Inc., F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc., dated October 19, 2022 (incorporated by reference to Exhibit 10.21 to the Registrant's Proxy Statement/Prospectus on Form S-4 filed on November 3, 2022).
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	8, 2023 (Registration No. 333-269271)).
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10.12#	Disc Medicine, Inc.

Amended and Restated 2021 Employee Stock Pu

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(incorporated by reference to Ex

hibit 99.3 of Disc Medicine, Inc.'s Form S-8

filed on January 18, 2023 (Registration No.

	333-269271)).
10.13#	2017 Stock Option and Grant P

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rapeutics, Inc.'s Form S-8 filed on April 13

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10.16#	Form of Indemnification Agreement for

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Entitlement Transition and Separation Agreement, dated

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10.19*# 10.19# Employment Agreement, dated as of D

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	Inc. and Jonathan Yu
10.21#	Notice of Termination, Separation Agreement and Release, dated as of December 29, 2022, by and between Gemini Therapeutics, Inc. and Brian Piekos (incorporated by reference to Exhibit 10.10 10.20 to the Registrant's Current Annual Report on Form 8-K 10-K (File No. 001-39438) filed on December 29, 2022 March 31, 2023).
10.21#	Employment Agreement

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Exhibit Number	Description
10.22	Open Market Sale Agreement, dated October 10, 2023, by and between Disc Medicine, Inc. and Jefferies LLC. (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K (File No. 001-39438) filed on October 10, 2023).
10.23	Amendment No. 1 to Open Market Sale Agreement, dated December 5, 2023, by and between Disc Medicine, Inc. and Jefferies LLC. (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K (001-39438) filed on December 5, 2023).
14.1	Code of Business Conduct and Ethics of Disc Medicine, Inc. (incorporated by reference to Exhibit 14.1 to the Registrant's Current Report on Form 8-K filed on December 29, 2022).
21.1*	List of Subsidiaries of Disc Medicine, Inc.
23.1*	Consent of Ernst & Young LLP, independent registered accounting firm.
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

Exhibit Number	Description
31.2*	

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32.1**	Certification pursuant to 18 U.S.C. Sec

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101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Schema With Embedded Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document Documents
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# Indicates a management contract or compensatory plan.

† The annexes, schedules, and certain exhibits to the Merger Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Gemini hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the Commission upon request.

†† Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the Securities and Exchange Commission.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

DISC MEDICINE, INC.

Date: March 31, 2023 March 21, 2024

By: /s/ Joanne Bryce Jean Franchi

Joanne Bryce, CPA Jean Franchi

Chief Financial Officer

(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints each of John Quisel, J.D., Ph.D., Joanne Bryce, CPA Jean Franchi and Rahul Khara, Pharm.D., J.D., acting alone or together with another attorney-in-fact, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any or all further amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ John Quisel John Quisel, J.D., Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 31, 2023 21, 2024
/s/ Joanne Bryce Jean Franchi Joanne Bryce, CPA Jean Franchi	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2023 21, 2024
/s/ Donald Nicholson Donald Nicholson, Ph.D.	Director	March 31, 2023 21, 2024
/s/ Kevin Bitterman Kevin Bitterman, Ph.D.	Director	March 31, 2023 21, 2024
/s/ Liam Ratcliffe Liam Ratcliffe, M.D., Ph.D.	Director	March 31, 2023 21, 2024

/s/ William White William White MPP, J.D.	Director	March 31, 2023 21, 2024
/s/ Mona Ashiya Mona Ashiya, Ph.D.	Director	March 31, 2023 21, 2024
/s/ Mark Chin Mark Chin, MS, MBA	Director	March 31, 2023 21, 2024
/s/ Georges Gemayel Georges Gemayel, Ph.D.	Director	March 31, 2023 21, 2024
/s/ Jay Backstrom Jay Backstrom, M.D., M.P.H.	Director	March 31, 2023

Exhibit 10.18

DISC MEDICINE, INC. November 27, 2023

EMPLOYMENT AGREEMENT Joanne Bryce

Re: Transition and Separation Agreement

Dear Joanne:

This Employment Agreement ("Agreement") is made between letter confirms that your employment with Disc Medicine, Inc. (formerly Gemini Therapeutics, Inc.), (the "Company" "Company"), will be ending. The Company sincerely appreciates your contributions to the Company and Joanne Bryce, CPA (the "You") would like to make this transition as seamless as possible. Consistent with that, the Company will be providing you with the opportunity to serve as an advisor to the Company and is to receive the severance benefits provided under your Employment Agreement with the Company effective as of upon the closing of the proposed business combination among the Company, Disc Medicine Opco, Inc. (formerly Disc Medicine, Inc.) and Gemstone Merger Sub, Inc. pursuant to that certain Agreement and Plan of Merger, dated as of August 9, 2022 (the "Effective Date" "Employment Agreement"). Except This is the Separation Agreement and Release referred to in the Employment Agreement and capitalized, but undefined terms are defined in the Employment Agreement.

Regardless of whether you enter into the Agreement, the following terms will apply with respect to the Restrictive Covenants Agreement and the Equity Documents (each as defined below), this Agreement supersedes in all respects all prior agreements between you and Disc Medicine, Inc., predecessor in interest to the Company, regarding the subject matter herein, including without limitation the offer letter between you and Disc Medicine, Inc. dated September 14, 2021 (the "Prior Agreement").

WHEREAS, the Company desires to continue to employ you and you desire to continue to be employed by the Company on the new terms and conditions contained herein.

NOW, THEREFORE,in consideration ending of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows: your employment:

1. •Employment.

(a) Term. The Company shall employ you and you shall be employed by On the Company pursuant to this Agreement commencing as Date of the Effective Date and continuing until such employment is terminated in accordance with the provisions hereof (the "Term"). Your employment with Termination (defined below), the Company will continue to be "at will," meaning that your employment may be terminated by pay you the Company or you at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties ". You shall serve as the Chief Financial Officer of the Company and shall report directly to the Chief Executive Officer ("CEO"). You shall have such powers and duties as may from time to time be prescribed by the CEO or other duly authorized executive which are consistent with your position as Chief Financial Officer. You shall devote your full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, you may serve on other boards of directors, with the approval of the Board of Directors of the Company (including any committee thereof, the "Board"), which approval shall not unreasonably be withheld by the Board, or engage in religious, charitable or other community activities as long as such services and activities are disclosed to the Board and do not interfere with your performance of your duties to the Company. To the extent applicable, you shall be deemed to have resigned from all officer and, if applicable, board member positions that you hold with the Company or any of its respective subsidiaries and affiliates upon the termination of your employment for any reason. You shall execute any documents in reasonable form as may be requested to confirm or effectuate any such resignations.

2. Compensation and Related Matters Accrued Obligations.

(a) Base Salary. Your initial base salary shall be paid at the rate of $419,000 per year. Your base salary shall be subject to periodic review and increase (but not decrease, except for an across-the-board reduction of no greater than 10% based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company) bythe Board or the Compensation Committee of the Board (the "Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for executive officers.

(b) Incentive Compensation. You shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time. Your target annual incentive

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compensation shall be forty percent (40%) of your Base Salary. The target annual incentive compensation in effect at any given time is referred to herein as "Target Bonus." The actual amount of your annual incentive compensation, if any, shall be determined in the sole discretion of the Board or the Compensation Committee, subject to the terms of any applicable incentive compensation plan that may be in effect from time to time (the "Bonus"). Except as otherwise provided herein, to earn incentive compensation, you must be employed by the Company on the day such incentive compensation is paid. The incentive compensation for each fiscal year will be paid no later than two and a half months following such fiscal year.

(c) Expenses. You shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by you during the Term in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company for its executive officers.

(d) Other Benefits. You shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(e) Paid Time Off. You shall be entitled to take paid time off in accordance with the Company's applicable paid time off policy for executives, as may be in effect from time to time. You shall also be entitled to all paid holidays given by the Company to its employees.

(f) Equity. The equity awards held by you shall continue to be governed by the terms and conditions of the Company's applicable equity incentive plan(s) and the applicable award agreement(s) governing the terms of such equity awards held by you (collectively, the "Equity Documents"); provided, however, and notwithstanding anything to the contrary in the Equity Documents, Section 6(a)(ii) of this Employment Agreement, shall apply in the event of a termination by the Company without Cause or by you for Good Reason in either event within the Change in Control Period (as such terms are defined below).

3. Termination. Your employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. Your employment hereunder shall terminate upon your death.

(b) Disability. The Company may terminate your employment due to your "Disability" if you are unable to perform the essential functions of your then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any question shall arise as to whether during any period you are disabled so as to be unable to perform the essential functions of your then existing position or positions with or without reasonable accommodation, you may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company who is board certified in the specialty relevant to your medical condition to whom you or your guardian has no reasonable objection as to whether you are disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. You shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and you shall fail to submit such certification, the Company's reasonable determination of such issue shall be binding on you. Nothing in this Section 3(b) shall be construed to waive your rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 *et seq*. and the Americans with Disabilities Act, 42 U.S.C. §12101 *et seq.*

(c) Termination by Company for Cause. The Company may terminate your employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean any of the following:

(i) conduct by you constituting a material act of intentional misconduct in connection with the performance of your duties, including, without limitation, (A) willful failure or willful refusal to perform material responsibilities that have been lawfully requested by the CEO; (B) intentional dishonesty to the CEO with respect to any material matter; or (C) intentional misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and *de minimis* use of Company property for personal purposes;

(ii) the commission by you of (A) any felony or (B) a misdemeanor involving moral turpitude, deceit, dishonesty or fraud;

(iii) any intentional misconduct by you, regardless of whether or not in the course of your employment, that results in material injury or material reputational harm to the Company or any of its subsidiaries or affiliates if you were to continue to be employed in the same position;

(iv) your continued willful non-performance by you of your duties hereunder (other than by reason of your physical or mental illness, incapacity or Disability) which has continued for more than 30 days following written notice of such non-performance from the CEO;

(v) a material breach by you of any of the provisions contained in Section 8 of this Agreement or the Restrictive Covenants Agreement and, if such breach is curable, has continued for more than 30 days following written notice of such material breach (as defined below); or

(vi) your willful failure to reasonably cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being reasonably instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the willful inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.

(d) Termination by the Company without Cause. The Company may terminate your employment hereunder at any time without Cause. Any termination by the Company of your employment under this Agreement which does not constitute a termination for Cause

under Section 3(c) and does not result from the death or Disability of you under Section 3(a) or (b) shall be deemed a termination without Cause.

(e) Termination by You. You may terminate employment hereunder at any time for any reason, including but not limited to, Good Reason. For purposes of this Agreement, "Good Reason" shall mean that you have completed all steps of the Good Reason Process (hereinafter defined) following the occurrence of any of the following events without your written consent (each, a "Good Reason Condition") i.e.:

(i) a material diminution in your responsibilities, authority or duties

(ii) a material diminution in your Base Salary except for across-the-board salary reductions of no greater than 10% based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company;

(iii) a material change of at least thirty (30) miles of the location of the physical Company office to which you report (which to avoid doubt does not include any home office you may have); or

(iv) a breach by the Company of the material terms of this Agreement or any other written agreement between the Company and you.

The "Good Reason Process" consists of the following steps:

(v) you reasonably determine in good faith that a Good Reason Condition has occurred;

(vi) you notify the Company in writing of the first occurrence of the Good Reason Condition within 60 days of the first occurrence of such condition;

(vii) you cooperate in good faith with the Company's efforts, for a period of not less than 30 days following such notice (the "Cure Period"), to remedy the Good Reason Condition;

(viii) notwithstanding such Cure Period, the Good Reason Condition continues to exist; and

(ix) you terminate employment within 60 days after the end of the Cure Period.

If the Company cures the Good Reason Condition during the Cure Period, Good Reason shall be deemed not to have occurred.

If your employment with the Company is terminated for any reason, the Company shall pay or provide to you (or your authorized representative or estate) (i) any Base Salary earned through the Employment Date of Termination; (ii) any unpaid expense reimbursements (subject to, and in accordance with, Section 2(c) of this the Employment Agreement); (iii) your accrued but unused vacation days or PTO; and (iv) any vested benefits you may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans; and (v) if your employment is terminated by plans.

- Your eligibility to participate in the Company because of your death or Disability, a lump sum payment of any earned, but unpaid Bonus for the fiscal year prior to the fiscal year your employment is terminated because of your death or Disability (collectively, the "Accrued Obligations"). The earned but unpaid Bonus in subsection (v) will be paid at the same time as the Company pays bonuses to similarly situated executives, but in no event later than the end of the taxable year in which Company's group health plans ceases on the Date of Termination occurs.

4. Notice in accordance with the terms and Date conditions of Termination.

(a) Notice of Termination. Except for termination as specified those plans. You may elect to continue your existing benefits under such plans in Section 3(a), any termination of your employment by the Company or any such termination by

you shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(b) Date of Termination. "Date of Termination" shall mean: (i) if your employment is terminated by death, the date of death; (ii) if your employment is terminated on account of Disability under Section 3(b) or by the Company for Cause under Section 3(c), the date on which Notice of Termination is given; (iii) if your employment is terminated by the Company without Cause under Section 3(d), the date on which a Notice of Termination is given or the date otherwise specified by the Company in the Notice of Termination; (iv) if your employment is terminated by you under Section 3(e) other than for Good Reason, 14 days after the date on which a Notice of Termination is given, and (v) if your employment is terminated by you under Section 3(e) for Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that you give a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement. However, the Company will continue paying you your Base Salary until the original Date of Termination.

5. Severance Pay and Benefits Upon Termination by the Company without Cause or by You for Good Reason Outside the Change in Control Period. If your employment is terminated by the Company without Cause as provided in Section 3(d), or you terminate employment for Good Reason as provided in Section 3(e), each outside of the Change in Control Period (as defined below), then, in addition to theAccrued Obligations, accordance with and subject to (i) your signing a separation agreement and release in a form and manner reasonably satisfactory to the Company, which shall include, without limitation, a general release of claims against the Company and all related persons and entities, a reaffirmation of all of your Continuing Obligations (as defined below**)**, and shall provide that if you materially breach any of the Continuing Obligations, and if such breach is curable, which has continued for more than 30 days following written notice of such breach, all payments of the Severance Amount shall immediately cease (the "Separation Agreement and Release"), and (ii) the Separation Agreement and Release becoming irrevocable, all within 60 days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release), which shall include a seven (7) business day revocation period:

(a) the Company shall pay you an amount equal tonine (9) months of your Base Salary (the "Severance Amount"); provided in the event you are entitled to any payments pursuant to the Restrictive Covenants Agreement, as a condition of such receipt of the Severance Amount, you shall acknowledge and agree in the Separation Agreement and Release that such Severance Amount will be in lieu of any garden leave pay under the Restrictive Covenants Agreement;

(b) a lump sum payment of any earned, but unpaid Bonus for the fiscal year prior to the fiscal year of your Date of Termination, to be paid at the same time as the Company pays bonuses to similarly situated executives, but in no event later than the end of the taxable year in which the Date of Termination occurs; and

(c) subject to your copayment of premium amounts at the applicable active employees' rate and your proper election to receive benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"COBRA").

- You are subject to the Continuing Obligations, including under your Employee Confidentiality, Assignment, Nonsolicitation and Noncompetition Agreement executed by you on September 14, 2021 (the "Restrictive Covenants Agreement").
- If you do not enter into the Agreement below, you will cease vesting in your stock options on the Date of Termination consister with the terms of the Equity Documents, and the unvested portion of your stock options will terminate and become null and voi on the Date of Termination.

The remainder of this letter proposes an agreement between you and the Company (the "Agreement"). With those understandings, you and the Company agree as follows:

1. Date of Termination.

Your employment will terminate on a date mutually agreed between you and the Company (the "Anticipated Termination Date"), unless you and the Company are unable to so agree (in which event the Company will determine the Anticipated Termination Date in good faith), you resign or are terminated by the Company for "Cause" (as defined in your Employment Agreement) prior to the

Anticipated Termination Date. Your actual last day of employment with the Company, whether it is the Anticipated Termination Date or an earlier date, is the "Date of Termination."

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2. 2023 Bonus

The Company will pay you 100% of your target cash bonus for 2023, at the same time 2023 annual bonuses are paid to other executives.

3. Advisor Period

If you (i) enter into, do not revoke and comply with this Agreement (including, without limitation, the Continuing Obligations, as defined below), and (ii) act cooperatively with the Company to transition your duties and responsibilities (the "Conditions"), the Company shall pay will engage you as an independent contractor advisor between the Date of Termination and the date that is nine (9) months after the Date of Termination, unless you resign prior to the group health plan provider, the COBRA provider such date or you a monthly payment equal to the monthly employer contribution that the Company would have made to provide health insurance to you if you had remained employed terminates your engagement for cause as reasonably determined by the Company until (the "Advisor Period").

During the earliest Advisor Period, the Company will pay you $350 for each hour of (A) services you provide the nine (9) month anniversary Company. You agree to track and record your hours in good faith. During the Advisor Period, you will be expected to be reasonably available on an as-needed basis to answer questions from the Chief Executive Officer ("CEO") or other executives or employees, relating to transitioning your duties, but otherwise you are free to use your time as you please, including to search for another job. You will not need to come into the office during the Advisor Period, as any questions can be answered remotely. You agree that you will use your Company email to communicate to third parties outside of the Company only to transition your duties during the Advisor Period, and you acknowledge and agree that you are not authorized to bind the Company. During the Advisor Period, you will not be paid any base salary or other cash compensation (other than the Severance Amount and Benefits described below, subject to the terms of this Agreement), you will not be eligible to participate in the Company's group employee benefit plans, other than as described below and you will not accrue vacation. However, you will continue vesting in your stock options during the Advisor Period.

For the avoidance of doubt, if you fail to satisfy any of the Conditions, the Advisor Period will end and you will cease vesting as of the last day of the Advisor Period and, if the Advisor Period ends as a result of your breach of the Continuing Obligations, you shall have no right to the Severance Benefits or to any other post-employment compensation or benefits from the Company.

4. Severance Pay and Benefits

If you enter into and do not revoke this Agreement, and do not resign and are not terminated by the Company for Cause prior to the Anticipated Termination Date, and sign and return the Certificate attached as Exhibit A within the 7-day period following the Date of

Termination; (B) your eligibility for group medical plan benefits under any other employer's group medical plan; or (C) Termination, the cessation Company will provide you with the following "Severance Amount and Benefits":

(a) Severance Amount. The Company shall pay you a Severance Amount equal to nine (9) months of your continuation rights under COBRA; provided, however, if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Base Salary. The Company shall convert such payments to payroll payments directly to pay you for the time period specified above. Such payments shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

The amounts payable under Sections 5(a) and (c), to the extent taxable, shall be paid out Severance Amount in substantially equal installments in accordance with the Company's payroll practice over nine (9) months commencing within 60days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount, to the extent it qualifies as "non-qualified deferred compensation" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

6. (b)Severance Pay and Health Benefits Upon Termination by the Company without Cause or by You for Good Reason within the Change in Control Period. The provisions of this Section 6 shall apply in lieu of, and expressly supersede, the provisions of Section 5 if (i) your employment is terminated either (a) by the Company without Cause as provided in Section 3(d), or (b) by you for Good Reason as provided in Section 3(e), and (ii) the Date of Termination is within 3 months prior to, or within 12 months after, the occurrence of the first event constituting a Change in Control (as defined below) (such period, the "Change in Control Period"). These provisions of Section 6 shall terminate and be of no further force or effect after a Change in Control Period.

(a) If your employment is terminated by the Company without Cause as provided in Section 3(d) or you terminate employment for Good Reason as provided in Section 3(e) and in each case the Date of Termination occurs during the Change in Control Period, then, in addition to the Accrued Obligations, and subject to the signing of the Separation Agreement and Release by you and the Separation Agreement and Release becoming fully effective, all within the time frame set forth in the Separation Agreement and Release but in no event more than 60 days after the Date of Termination:

(i) the Company shall pay you a lump sum in cash in an amount equal to the sum of(A) twelve (12) months of your then current Base Salary (or your Base Salary in effect immediately prior to the Change in Control, if higher), (B) your Target Bonus for the then-current fiscal year; and (C) any earned, but unpaid Bonus for the fiscal year prior to the fiscal year of your Date of Termination, (the "Change in Control Payment") provided that, if applicable and as a condition of such receipt of the Change in Control Payment, you shall acknowledge and agree in the Separation Agreement and Release that such Change in Control Payment will be in lieu of any garden leave pay under the Restrictive Covenants Agreement; and

(ii) notwithstanding anything to the contrary in any applicable option agreement or other stock-based award agreement, all time-based stock options and other stock-based awards subject to time-based vesting held by you (the "Time-Based Equity Awards") shall immediately accelerate and become fully exercisable or nonforfeitable as of the later of (i) the Date of Termination or (ii) the effective date of the Separation Agreement and Release (the "Accelerated Vesting Date"); *provided* that any termination or forfeiture of the unvested portion of such Time-Based Equity Awards that would otherwise occur on the

Date of Termination in the absence of this Agreement will be delayed until the effective date of the Separation Agreement and Release and will only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation Agreement and Release becoming fully effective within the time period set forth therein. Notwithstanding the foregoing, no additional vesting of the Time-Based Equity Awards shall occur during the period between your Date of Termination and the Accelerated Vesting Date; and

(iii) subject Subject to your copayment of premium amounts at the applicable active employees' rate and your proper election to receive benefits under COBRA, the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended

("COBRA"), the Company shall pay to the group health plan provider, the COBRA provider or you a monthly payment equal to the monthly employer contribution that the Company would have made to provide health insurance to you if you had remained employed by the Company until the earliest of (A) the 12-month nine

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(9) month anniversary of the Date of Termination; (B) your eligibility for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of your continuation rights under COBRA; provided, however, if COBRA.

(c) Exercise Period Extension. If you enter into and comply with this Agreement, and subject to approval by the Company determines that it cannot pay such amounts to Company's Board of Directors, the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to period during which you for the time period specified above. Such payments may exercise your vested stock options (the "Exercise Period") shall be subject to tax-related deductions and withholdings and paid on extended until the Company's regular payroll dates.

The amounts payable under this Section 6(a) (other than 6(a)(i)(C)), to the extent taxable, shall be paid or commence to be paid within 60 days date that is twelve (12) months after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period. The amount payable under Section 6(a)(i)(C) shall be paid at the same time as the Company pays bonuses to similarly situated executives, but in no event later than the end of the taxable year in which Advisor Period (the "Exercise Period Extension"). You acknowledge that as a result of this extension of the Exercise Period, to the extent your vested stock options were incentive stock options, they will convert to nonqualified stock options, subject to applicable law. If you sign this Agreement, you are advised to seek tax guidance from your personal tax advisors with regard to the tax consequences to you of the Exercise Period Extension.

(d) 2024 Prorated Bonus. If the Date of Termination occurs.

(b) Additional Limitation.

(i) Anything in this Agreement occurs between January 1, 2024 and March 31, 2024, the Company will pay you an annual target bonus for 2024 equal to your 2023 salary multiplied by your target bonus percentage of forty percent (40%), prorated based on when the contrary notwithstanding, Date of Termination occurs during 2024 by multiplying the target bonus amount by x/365, where x is the day in the event that year when the amount Date of any compensation, payment or distribution by the Company to or for the benefit of you, whether paid or Termination occurs, and payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code, and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which you became the subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in you receiving a higher After Tax Amount (as defined below) than you would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-

cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 6(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on you as a result of your receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, you shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 6(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and you within 15 business sixty (60) days of the Date of Termination. If the Date of Termination if applicable, occurs on or after April 1, 2024, the Company will pay you an annual target bonus for 2024 equal to your 2023 salary multiplied by your target bonus percentage of forty percent (40%) and adjusted based on the achievement of corporate goals for 2024 as determined by the Board of Directors of the Company, prorated based on when the Date of Termination occurs during 2024 by multiplying the target bonus amount by x/365, where x is the day in the year when the Date of Termination occurs, and payable at the time the Company pays 2024 bonuses to employees.

5. Release of Your Claims

In consideration for, among other terms, the Advisor Period and the opportunity to receive continued vesting during such time, and the Severance Amount and Benefit, to which you acknowledge you would otherwise not be entitled, you voluntarily release and forever discharge the Company, its affiliated and related entities, its and their respective predecessors, successors and assigns, its and their respective employee benefit plans and fiduciaries of such plans, and the current and former officers, directors, shareholders, employees, attorneys, accountants and agents of each of the foregoing in their official and personal capacities (collectively referred to as the "Releasees") generally from all claims, demands, debts, damages and liabilities of every name and nature, known or unknown ("Claims") that, as of the date when you sign this Agreement, you have, ever had, now claim to have or ever claimed to have had against any or all of the Releasees. This release includes, without limitation, all Claims:

- relating to your employment by and termination of employment with the Company;
- of wrongful discharge or violation of public policy;
- of breach of contract;
- of defamation or other torts;
- of retaliation or discrimination under federal, state or local law (including, without limitation, Claims of discrimination or retaliati under the Americans with Disabilities Act, Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act and the Massachusetts Fair Employment Practices Act, M.G.L. c. 151B);
- under any other federal or state statute (including, without limitation, Claims under the Worker Adjustment and Retraining Notification Act or the Fair Labor Standards Act);
- for wages, bonuses, incentive compensation, commissions, stock, stock options, vacation pay or any other compensation or benefits, either under the Massachusetts Wage Act, M.G.L. c. 149, §§148-150C, or otherwise; and

- for damages or other remedies of any sort, including, without limitation, compensatory damages, punitive damages, injunctive relief and attorney's fees;

provided, however, that this release shall not affect your rights under this Agreement or release claims that cannot be released as a matter of law.

You agree not to accept damages of any nature, other equitable or legal remedies for your own benefit or attorney's fees or costs from any of the Releasees with respect to any Claim released by this Agreement. As a material inducement to the Company to enter into this Agreement, you represent that you have not assigned any Claim to any third party.

6. Return of Property

You acknowledge and agree that you are required to return all Proprietary Information (as defined in the Restrictive Covenants Agreement) to the Company upon the termination of the Advisor Period pursuant to the Restrictive Covenants Agreement. This Section 4 is in addition to, and not in lieu of, your obligations to the Company pursuant to the Restrictive Covenants Agreement. By signing below, you acknowledge and agree that upon the termination of the Advisor Period, you will return to the Company, without altering, deleting or purging any files or documents that may contain Company information, all "Company Property," which shall include, without limitation, all Company property and equipment in your possession, custody or control, including, without limitation, all files, notes, memoranda, reports, records, data, sketches, drawings, notebooks, layouts, charts, quotations and proposals, specification sheets, blueprints, models, prototypes, or other written, photographic or other tangible material containing Proprietary Information, and other materials of any nature pertaining to the Proprietary Information of the Company and to your work, including, without limitation, keys and access cards and credit cards. Notwithstanding the foregoing, as discussed above, you may continue to use your Company laptop during the Advisor Period, provided that you comply with this Agreement, do not download or transfer any Proprietary Information to a personal device and promptly return the Company laptop to the Company following the end of the Advisor Period or at the Company's request without wiping or deleting any information. After returning all such earlier time as Company Property to the Company, you must delete and finally purge any duplicates of files or documents that may contain Company information from any non-Company computer or other device that remains your property. In the event that you discover that you continue to retain any such property, you must return it to the Company immediately.

7. Continuing Obligations

As provided in the Employment Agreement, in consideration for your eligibility for the Severance Amount and Benefits, and notwithstanding anything to the contrary in your Restrictive Covenants Agreement, you agree that: (i) you are not eligible for any Garden Leave Pay (as defined in the Restrictive Covenant Agreement) under the Restrictive Covenants Agreement, (ii) your post-employment noncompetition obligations to the Company under the Restrictive Covenants Agreement nevertheless remain in full effect and are fully enforceable, regardless of the circumstances of your termination and regardless of the lack of Garden Leave Pay; and (iii) your eligibility for Severance Amount and Benefits constitutes mutually agreed-upon, sufficient, fair and reasonable consideration for such noncompetition obligations that is reasonably requested independent of your employment with the Company. Your other Continuing Obligations remain in full effect. The Continuing Obligations (as modified by this Agreement) shall remain in effect throughout the Advisor Period; all references to "employ," "employee," 'employment" and derivations thereof in the Continuing Obligations and therefrom shall be read to include the Advisor Period; and any post-employment restrictions under the Continuing Obligations shall not begin to run until the end of the Advisor Period.

8. **Non-disparagement**

Subject to Section 9, you agree not to make any disparaging statements (whether written, oral, through social or electronic media or otherwise) concerning the Company or you. Any determination by any of its affiliates; its or their products or services; or any of its or their current or former officers, directors, shareholders, employees or agents. You further agree not to take any actions or conduct yourself in any way that would reasonably be expected to affect adversely the Accounting Firm shall be binding upon the Company and you. reputation

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(iv)

Definitions. For the purposes of this Section 6, a "Change in Control" shall be deemed to have occurred upon the occurrence of any one of the following events: (a) the sale or transfer of all or substantially all of the assets of the Company (i.e., >50% of the value) on a consolidated basis to one or more unrelated persons or entities, (b) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power and outstanding stock immediately prior to such transaction do not own a majority of the outstanding voting power or fair market value of the stock or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction, (c) the sale of all or substantially all of the stock of the Company to an unrelated person, entity or group thereof acting in concert, (d) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power goodwill of the Company or its affiliates; its or their products or services; or any successor entity immediately upon completion of its or their current or former officers, directors, shareholders, employees or agents.

9. **Communications Regarding Your Departure**

The Company has issued an announcement about your transition and departure (the "Company Announcement"). You agree to limit any communications regarding your transition and departure to statements consistent with the Company Announcement.

10. **Cooperation**

During and after your employment, you agree to cooperate fully with the Company in connection with events or occurrences that transpired while you were employed by the Company. Your full cooperation shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the transaction other than as a result of the acquisition of securities directly from Company at mutually convenient times. During and after your employment, you also shall cooperate fully with the Company in connection with any transaction or (e) any investigation, whether internal or external, or any review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while you were employed by the date Company. During any such period of cooperation: (i) the Company shall reimburse you for any reasonable out-of-pocket expenses incurred in connection with your performance of obligations pursuant to this Section 8; (ii) the Company will pay you $350 for each hour of services you provide the Company; and (iii) you agree to track and record your hours in good faith.

11. **Protected Disclosures and Other Protected Actions**

Nothing contained in this Agreement limits your ability to file a majority charge or complaint with any federal, state or local governmental agency or commission (a "Government Agency"). In addition, nothing contained in this Agreement limits your ability to communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, nor does anything contained in this Agreement apply to truthful testimony in litigation. If you file any charge or complaint with any Government Agency and if the Government Agency pursues any claim on your behalf, or if any other third party pursues any claim on your behalf, you waive any right to monetary or other individualized relief (either individually or as part of the members of the Board is replaced during any 12-month period by directors whose appointment collective or election is not endorsed by a majority of the members of the Board before the date of the appointment or election provided that class action).

12. Tax Treatment; Section 409A

(a) The Company shall undertake to make deductions, withholdings and tax reports with respect to any of the clauses (a) through (e) any capital raising transaction of the Company (including the Company's IPO) shall not be treated as a "Change in Control." Notwithstanding any other provision of this Agreement (other than the foregoing proviso), "Change in Control" shall be interpreted, administered payments and applied in a manner consistent and in compliance with a "change in control event" as set forth in Treasury Regulation Section 1.409A-3(i)(5) ("Change in Control Event").

7. Section 409A.

(a) Anything in benefits under this Agreement to the contrary notwithstanding, if at the time of your separation from service within the meaning of Section 409A of the Code, the Company extent that it reasonably and in good faith determines that you are a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then it is required to the extent any payment or benefit that you become entitled to under this Agreement or otherwise on account of your separation from service would be considered deferred compensation otherwise subject to the 20 percent additional make such deductions, withholdings and tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after your separation from service, or (B) your death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable reports. Nothing in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by construed to require the Company or incurred by to make any payments to compensate you during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime adverse tax effect associated with any payments or other aggregate limitation applicable to medical expenses). Such right to reimbursement benefits or in-kind benefits is not subject to liquidation for any deduction or exchange for another benefit.

(c) To the extent that withholding from any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon your termination of employment, then such payments or benefits shall be payable only upon your "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h). benefit.

(d) (b)The parties intend that payments under this Agreement will be administered in accordance exempt from or comply with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its exemption from or compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder are exempt from or comply with Section 409A of the Code. Each payment pursuant to this Agreement or the Restrictive Covenants Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A

of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to you or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A 2(b)(2).

8. 13. Continuing Obligations.**Other Provisions**

(a)Restrictive Covenants Agreement Termination of Payments. The Disc Medicine, Inc. Employee Confidentiality, Assignment, Nonsolicitation and Noncompetition Agreement effective as If you breach any of September 14, 2021 (the "Restrictive Covenants Agreement"), between Disc Medicine, Inc. and you, attached hereto as Exhibit A, continue to be in full force and effect. For purposes of your obligations under this Agreement (including, without limitation, the obligations Continuing Obligations), then in addition to any other legal or equitable remedies it may have

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for such breach, the Company shall have the right to end the Advisor Period, terminate its payments of the Severance Amount and Benefits to you under this Section 8 and those that arise Agreement and/or to seek repayment of such payments. Any such actions in the Restrictive Covenants Agreement shall collectively be referred event of your breach will not affect your Continuing Obligations to as the "Continuing Obligations." Company.

(b)Third-Party Agreements and Rights Absence of Reliance. You hereby confirm that In signing this Agreement, you are not bound relying upon any promises or representations made by the terms of any agreement with any previous employer or other party which restricts in any way your use or disclosure of information, other than confidentiality restrictions (if any), or your engagement in any business. You represent to the Company that your execution of this Agreement, your employment with the Company and the performance of your proposed duties for the Company will not violate any obligations you may have to any such previous employer or other party. In your work for the Company, you will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and you will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(c) Litigation and Regulatory Cooperation. During and after your employment, you shall reasonably cooperate fully with the Company in (i) the defense or prosecution of any claims or actions now in existence or which may be brought in the future against anyone at or on behalf of the Company which relate to events or occurrences that transpired while you were employed by the Company, and (ii) the investigation, whether internal or external, of any matters about which the Company believes you may have knowledge or information. Your full reasonable cooperation in connection with such claims, actions or investigations shall include, but not be limited to, being available to meet with counsel to answer questions or to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after your employment, you also shall reasonably cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while you were employed by the Company. The Company shall reimburse you for any reasonable out-of-pocket expenses incurred in connection with your performance of obligations pursuant to this Section 8(c). The Company agrees that if you have provided fifteen (15) hours of cooperation to the Company after your Date of Termination, the Company shall pay you an hourly rate of $400 for any additional hours of cooperation, over the initial fifteen (15) hours, except for your testimony pursuant to a lawfully issued summons or subpoena. The Company further agrees that it will pay/reimburse your reasonable out-of-pocket expenses and fees within thirty (30) days of your submission of receipts and invoices to the Company.

(d) Relief. You agree that it may be difficult to measure any damages caused to the Company which might result from any breach by you of the Continuing Obligations, and that in any event money damages may be an inadequate remedy for any such breach. Accordingly, you agree that if you breach, or propose to breach, any portion of the Continuing Obligations, the Company shall be entitled, in addition to all other remedies that it may have, to seek an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company.

(e) Protected Disclosures and Other Protected Action. Nothing in this Agreement shall be interpreted or applied to prohibit you from making any good faith report to any governmental agency or other governmental entity (a "Government Agency") concerning any act or omission that you reasonably believe constitutes a possible violation of federal or state law or making other disclosures that are protected under the anti-retaliation or whistleblower provisions of applicable federal or state law or regulation. In addition, nothing contained in this Agreement limits your ability to communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including your ability to provide documents or other information, without notice to the Company. In addition, for the avoidance of doubt, pursuant to the federal Defend Trade Secrets Act of 2016, you shall not be held criminally or civilly liable under any federal or state trade secret law or under this Agreement or the Restrictive Covenants Agreement for the disclosure of a trade secret that (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

9. Arbitration of Disputes.

(a) Arbitration Generally. Any controversy or claim arising out of or relating to this Agreement or the breach thereof or otherwise arising out of your employment or the termination of that employment (including, without limitation, any claims of unlawful employment discrimination or retaliation, whether based on race, religion, national origin, sex, gender, age, disability, sexual orientation, or any other protected class under applicable law, including without limitation Massachusetts General Laws Chapter 151B) shall, to the fullest extent permitted by law, be settled by arbitration in any forum and form agreed upon by the parties or, in the absence of such an agreement, under the auspices of JAMS in Boston, Massachusetts in accordance with the JAMS Employment Arbitration Rules, including, but not limited to, the rules and procedures applicable to the selection of arbitrators. You understand that you may only bring such claims in your individual capacity, and not as a plaintiff or class member in any purported class proceeding or any purported representative proceeding. You further understand that, by signing this Agreement, the Company and you are giving up any right they may have to a jury trial on all claims they may have against each other. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This Section 9 shall be specifically enforceable. Notwithstanding the foregoing, this Section 9 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate, including without limitation relief sought under the Restrictive Covenants Agreement; provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Section 9.

(b) Arbitration Fees and Costs. You shall be required to pay an arbitration fee to initiate any arbitration equal to what you would be charged as a first appearance fee in court. The Company shall pay the remaining fees and costs of the arbitrator. Each party shall pay its own costs and attorneys' fees, if any. If, however, any party prevails on a statutory or contractual claim that entitles the prevailing party to attorneys' fees (including pursuant to this Agreement), the arbitrator will award attorneys' fees to the prevailing party to the extent permitted by law.

10. Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 9 of this Agreement, the parties hereby consent to the jurisdiction of the state and federal courts of theCommonwealthof Massachusetts. Accordingly, with respect to any such court action, you (a) submit to the exclusive personal jurisdiction of such courts; (b) consent to service of process; and (c) waive any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

11. Indemnification. The "Indemnification Agreement" between the Company and you, dated December 29, 2022 (the "Indemnification Agreement") is hereby incorporated by reference.

12. No Mitigation. The Company agrees that if your employment by the Company is terminated during the term of this Agreement, you are not required to seek other employment or to attempt in any way to reduce any

amounts payable to you by the Company pursuant to Sections 5 or 6 hereof. Further, the amount of any payment provided for in this Agreement shall not be reduced by any compensation earned by you.

13. Integration. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter, including the Prior Agreement, provided that the Restrictive Covenants Agreement, the Indemnification Agreement and the Equity Documents remain in full force and effect.

14. Withholding; Tax Effect. All payments made by the Company to you under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law. Nothing in this Agreement shall be construed to require the Company to make any payments to compensate you for any adverse tax effect associated with any payments or benefits or for any deduction or withholding from any payment or benefit.

15. Assignment. Neither you nor the Company may make any assignment of this Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; provided, however, that the Company may assign its rights and obligations under this Agreement (including the Restrictive Covenants Agreement) without your consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization, consolidate with, or merge into or to whom it transfers all or substantially all of its properties or assets, but only on the condition that it assigns both its rights and obligations. This Agreement shall inure to the benefit of and be binding upon you and the Company, and each of yours and the Company's respective successors, executors, administrators, heirs, personal representatives, and permitted assigns. In the event of your death prior to the completion by the Company of any payments due to you under Sections 5 or 6 of this Agreement, the Company shall continue such payments to the beneficiary you designated in writing to the Company prior to your death, or to your estate, heirs, executors or personal representatives if you failed to make such designation.

16. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

17. (d)Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of your employment to the extent necessary to effectuate the terms contained herein.

18. Waiver Waiver; Amendment. No waiver of any provision hereof of this Agreement shall be effective unless made in writing and signed by the waiving party. The failure of any a party to require the performance of any term or obligation of this Agreement, or the waiver by any a party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

19. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to you at the last address you have on file in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

20. Amendment. This Agreement may not be modified or amended or modified only by except in a written instrument writing signed by both you and by a duly authorized representative officer of the Company.

21. Effect on Other Plans and Agreements. An election by you to resign for Good Reason under the provisions of this Agreement shall not be deemed a voluntary termination of employment by you for the purpose of interpreting the provisions of any of the Company's benefit plans, programs or policies. Nothing in this Agreement shall be construed to limit the rights of you under the Company's benefit plans, programs or policies except as otherwise provided in Section 8 hereof, and except that you shall have no rights to any severance benefits under any Company severance pay plan, offer letter or otherwise. In the event that you are a party to an agreement with the Company providing for payments or benefits under such plan or agreement and under this Agreement, the terms of
this Agreement shall govern and you may receive payment under this Agreement only and not both. Further, Section 5 and Section 6 of this Agreement are mutually exclusive and in no event shall you be entitled to payments or benefits pursuant to both Section 5 and

Section 6 of this Agreement.

22. Governing Law. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealthof Massachusetts, without giving effect to the conflict of laws principles thereof. With respect to any disputes concerning federal law, such disputes shall be determined in accordance with the law as it would be interpreted and applied by the United States Court of Appeals for the First Circuit.

23. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the Effective Date.

DISC MEDICINE, INC.

By: /s/ John D. Quisel

Its: President and Chief Executive Officer

EXECUTIVE

/s/ Joanne Bryce

Joanne Bryce, CPA

Exhibit A

Restrictive Covenants Agreement

Exhibit 10.19

DISC MEDICINE, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is made between Disc Medicine, Inc. (formerly Gemini Therapeutics, Inc.), (the "Company"), and William Savage, MD, Ph.D. (the "You") and is effective as of the closing of the proposed business combination among the Company, Disc Medicine Opco, Inc. (formerly Disc Medicine, Inc.) and Gemstone Merger Sub, Inc. pursuant to that certain Agreement and Plan of Merger, dated as of August 9, 2022 (the "Effective Date"). Except with respect to the Restrictive Covenants Agreement and the Equity Documents (each as defined below), this Agreement supersedes in all respects all prior agreements between you and Disc Medicine, Inc., predecessor in interest to the Company, regarding the subject matter herein, including without limitation the offer letter between you and Disc Medicine, Inc. dated June 28, 2020, as amended on July 1, 2021 (the "Prior Agreement").

WHEREAS, the Company desires to continue to employ you and you desire to continue to be employed by the Company on the new terms and conditions contained herein.

NOW, THEREFORE,in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The Company shall employ you and you shall be employed by the Company pursuant to this Agreement commencing as of the Effective Date and continuing until such employment is terminated in accordance with the provisions hereof (the "Term"). Your employment with the Company will continue to be "at will," meaning that your employment may be terminated by the Company or you at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. You shall serve as the Chief Medical Officer of the Company and shall report directly to the Chief Executive Officer ("CEO"). You shall have such powers and duties as may from time to time be prescribed by the CEO or other duly authorized executive which are consistent with your position as Chief Medical Officer. You shall devote your full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, you may serve on other boards of directors, with the approval of the Board of Directors of the Company (including any committee thereof, the "Board"), which approval shall not unreasonably be withheld by the Board, or engage in religious, charitable or other community activities as long as such services and activities are disclosed to the Board and do not interfere with your performance of your duties to the Company. To the extent applicable, you shall be deemed to have resigned from all officer and, if applicable, board member positions that you hold with the Company or any of its respective subsidiaries and affiliates upon the termination of your employment for any reason. You shall execute any documents in reasonable form as may be requested to confirm or effectuate any such resignations.

2. Compensation and Related Matters.

(a) Base Salary. Your initial base salary shall be paid at the rate of $458,000 per year. Your base salary shall be subject to periodic review and increase (but not decrease, except for an across-the-board reduction of no greater than 10% based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company) bythe Board or the Compensation Committee of the Board (the "Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for executive officers.

(b) Incentive Compensation. You shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time. Your target annual incentive compensation shall be forty percent (40%) of your Base Salary. The target annual incentive compensation in effect at any given time is referred to herein as "Target Bonus." The actual amount of your annual incentive compensation, if any, shall be determined in the sole discretion of the Board or the Compensation Committee, subject to the terms of any applicable incentive compensation plan that may be in effect from time to time (the "Bonus"). Except as otherwise provided herein, to earn incentive compensation, you must be employed by the Company on the day such incentive compensation is paid. The incentive compensation for each fiscal year will be paid no later than two and a half months following such fiscal year.

(c) Expenses. You shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by you during the Term in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company for its executive officers.

(d) Other Benefits. You shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(e) Paid Time Off. You shall be entitled to take paid time off in accordance with the Company's applicable paid time off policy for executives, as may be in effect from time to time. You shall also be entitled to all paid holidays given by the Company to its employees.

(f) Equity. The equity awards held by you shall continue to be governed by the terms and conditions of the Company's applicable equity incentive plan(s) and the applicable award agreement(s) governing the terms of such equity awards held by you (collectively, the "Equity Documents"); provided, however, and notwithstanding anything to the contrary in the Equity Documents, Section 6(a)(ii) of this Agreement shall apply in the event of a termination by the Company without Cause or by you for Good Reason in either event within the Change in Control Period (as such terms are defined below).

3. Termination. Your employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. Your employment hereunder shall terminate upon your death.

(b) Disability. The Company may terminate your employment due to your "Disability" if you are unable to perform the essential functions of your then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any

question shall arise as to whether during any period you are disabled so as to be unable to perform the essential functions of your then existing position or positions with or without reasonable accommodation, you may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company who is board certified in the specialty relevant to your medical condition to whom you or your guardian has no reasonable objection as to whether you are disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. You shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and you shall fail to submit such certification, the Company's reasonable determination of such issue shall be binding on you. Nothing in this Section 3(b) shall be construed to waive your rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 *et seq*. and the Americans with Disabilities Act, 42 U.S.C. §12101 *et seq.*

(c) Termination by Company for Cause. The Company may terminate your employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean any of the following:

(i) conduct by you constituting a material act of intentional misconduct in connection with the performance of your duties, including, without limitation, (A) willful failure or willful refusal to perform

material responsibilities that have been lawfully requested by the CEO; (B) intentional dishonesty to the CEO with respect to any material matter; or (C) intentional misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and *de minimis* use of Company property for personal purposes;

(ii) the commission by you of (A) any felony or (B) a misdemeanor involving moral turpitude, deceit, dishonesty or fraud;

(iii) any intentional misconduct by you, regardless of whether or not in the course of your employment, that results in material injury or material reputational harm to the Company or any of its subsidiaries or affiliates if you were to continue to be employed in the same position;

(iv) your continued willful non-performance by you of your duties hereunder (other than by reason of your physical or mental illness, incapacity or Disability) which has continued for more than 30 days following written notice of such non-performance from the CEO;

(v) a material breach by you of any of the provisions contained in Section 8 of this Agreement or the Restrictive Covenants Agreement and, if such breach is curable, has continued for more than 30 days following written notice of such material breach (as defined below); or

(vi) your willful failure to reasonably cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being reasonably instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the willful inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.

(d) Termination by the Company without Cause. The Company may terminate your employment hereunder at any time without Cause. Any termination by the Company of your employment under this Agreement which does not constitute a termination for Cause under Section 3(c) and does not result from the death or Disability of you under Section 3(a) or (b) shall be deemed a termination without Cause.

(e) Termination by You. You may terminate employment hereunder at any time for any reason, including but not limited to, Good Reason. For purposes of this Agreement, "Good Reason" shall mean that you have completed all steps of the Good Reason Process (hereinafter defined) following the occurrence of any of the following events without your written consent (each, a "Good Reason Condition"):

(i) a material diminution in your responsibilities, authority or duties

(ii) a material diminution in your Base Salary except for across-the-board salary reductions of no greater than 10% based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company;

(iii) a material change of at least thirty (30) miles of the location of the physical Company office to which you report (which to avoid doubt does not include any home office you may have); or

(iv) a breach by the Company of the material terms of this Agreement or any other written agreement between the Company and you.

The "Good Reason Process" consists of the following steps:

(v) you reasonably determine in good faith that a Good Reason Condition has occurred;

(vi) you notify the Company in writing of the first occurrence of the Good Reason Condition within 60 days of the first occurrence of such condition;

(vii) you cooperate in good faith with the Company's efforts, for a period of not less than 30 days following such notice (the "Cure Period"), to remedy the Good Reason Condition;

(viii) notwithstanding such Cure Period, the Good Reason Condition continues to exist; and

(ix) you terminate employment within 60 days after the end of the Cure Period.

If the Company cures the Good Reason Condition during the Cure Period, Good Reason shall be deemed not to have occurred.

If your employment with the Company is terminated for any reason, the Company shall pay or provide to you (or your authorized representative or estate) (i) any Base Salary earned through the Date of Termination; (ii) unpaid expense reimbursements (subject to, and in accordance with, Section 2(c) of this Agreement); (iii) your accrued but unused vacation days or PTO; (iv) any vested benefits you may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans; and (v) if your employment is terminated by the Company because of your death or Disability, a lump sum payment of any earned, but unpaid Bonus for the fiscal year prior to the fiscal year your employment is terminated because of your death or Disability (collectively, the "Accrued Obligations"). The earned but unpaid Bonus in subsection (v) will be paid at the same time as the Company pays bonuses to similarly situated executives, but in no event later than the end of the taxable year in which the Date of Termination occurs.

4. Notice and Date of Termination.

(a) Notice of Termination. Except for termination as specified in Section 3(a), any termination of your employment by the Company or any such termination by you shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(b) Date of Termination. "Date of Termination" shall mean: (i) if your employment is terminated by death, the date of death; (ii) if your employment is terminated on account of Disability under Section 3(b) or by the Company for Cause under Section 3(c), the date on which Notice of Termination is given; (iii) if your employment is terminated by the Company without Cause under Section 3(d), the date on which a Notice of Termination is given or the date otherwise specified by the Company in the Notice of Termination; (iv) if your employment is terminated by you under Section 3(e) other than for Good Reason, 14 days after the date on which a Notice of Termination is given, and (v) if your employment is terminated by you under Section 3(e) for Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that you give a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement. However, the Company will continue paying you your Base Salary until the original Date of Termination.

5. Severance Pay and Benefits Upon Termination by the Company without Cause or by You for Good Reason Outside the Change in Control Period. If your employment is terminated by the Company without Cause as provided in Section 3(d), or you terminate employment for Good Reason as provided in Section 3(e), each outside of the Change in Control Period (as defined

below), then, in addition to theAccrued Obligations, and subject to (i) your signing a separation agreement and release in a form and manner reasonably satisfactory to the Company, which shall include, without limitation, a general release of claims against the Company and all related persons and entities, a reaffirmation of all of your Continuing Obligations (as defined below**)**, and shall provide that if you materially breach any of the Continuing Obligations, and if such breach is curable, which has continued for more than 30 days following written notice of such breach, all payments of the Severance Amount shall immediately cease (the "Separation Agreement and Release"), and (ii) the Separation Agreement and Release becoming irrevocable, all within 60 days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release), which shall include a seven (7) business day revocation period:

(a) the Company shall pay you an amount equal tonine (9) months of your Base Salary (the "Severance Amount"); provided in the event you are entitled to any payments pursuant to the Restrictive Covenants Agreement, as a condition of such receipt of the Severance Amount, you shall acknowledge and agree in the Separation Agreement and Release that such Severance Amount will be in lieu of any garden leave pay under the Restrictive Covenants Agreement;

(b) a lump sum payment of any earned, but unpaid Bonus for the fiscal year prior to the fiscal year of your Date of Termination, to be paid at the same time as the Company pays bonuses to similarly situated executives, but in no event later than the end of the taxable year in which the Date of Termination occurs; and

(c) subject to your copayment of premium amounts at the applicable active employees' rate and your proper election to receive benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company shall pay to the group health plan provider, the COBRA provider or you a monthly payment equal to the monthly employer contribution that the Company would have made to provide health insurance to you if you had remained employed by the Company until the earliest of (A) the nine (9) month anniversary of the Date of Termination; (B) your eligibility for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of your continuation rights under COBRA; provided, however, if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to you for the time period specified above. Such payments shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

The amounts payable under Sections 5(a) and (c), to the extent taxable, shall be paid out in substantially equal installments in accordance with the Company's payroll practice over nine (9) months commencing within 60days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount, to the extent it qualifies as "non-qualified deferred compensation" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

6. Severance Pay and Benefits Upon Termination by the Company without Cause or by You for Good Reason within the Change in Control Period. The provisions of this Section 6 shall apply in lieu of, and expressly supersede, the provisions of Section 5 if (i) your employment is terminated either (a) by the Company without Cause as provided in Section 3(d), or (b) by you for Good Reason as provided in Section 3(e), and (ii) the Date of Termination is within 3 months prior to, or within 12 months after, the occurrence of the first event constituting a Change in Control (as defined below) (such period, the "Change in Control Period"). These provisions of Section 6 shall terminate and be of no further force or effect after a Change in Control Period.

(a) If your employment is terminated by the Company without Cause as provided in Section 3(d) or you terminate employment for Good Reason as provided in Section 3(e) and in each case the Date of Termination occurs during the Change in Control Period, then, in addition to the Accrued Obligations, and subject to the signing of the Separation Agreement and Release by you and the Separation Agreement and Release becoming fully effective, all within the time frame set forth in the Separation Agreement and Release but in no event more than 60 days after the Date of Termination:

(i) the Company shall pay you a lump sum in cash in an amount equal to the sum of(A) twelve (12) months of your then current Base Salary (or your Base Salary in effect immediately prior to the Change in

Control, if higher), (B) your Target Bonus for the then-current fiscal year; and (C) any earned, but unpaid Bonus for the fiscal year prior to the fiscal year of your Date of Termination, (the "Change in Control Payment") provided that, if applicable and as a condition of such receipt of the Change in Control Payment, you shall acknowledge and agree in the Separation Agreement and Release that such Change in Control Payment will be in lieu of any garden leave pay under the Restrictive Covenants Agreement; and

(ii) notwithstanding anything to the contrary in any applicable option agreement or other stock-based award agreement, all time-based stock options and other stock-based awards subject to time-based vesting held by you (the "Time-Based Equity Awards") shall immediately accelerate and become fully exercisable or nonforfeitable as of the later of (i) the Date of Termination or (ii) the effective date of the Separation Agreement and Release (the "Accelerated Vesting Date"); *provided* that any termination or forfeiture of the unvested portion of such Time-Based Equity Awards that would otherwise occur on the Date of Termination in the absence of this Agreement will be delayed until the effective date of the Separation Agreement and Release and will only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation Agreement and Release becoming fully effective within the time period set forth therein. Notwithstanding the foregoing, no additional vesting of the Time-Based Equity Awards shall occur during the period between your Date of Termination and the Accelerated Vesting Date; and

(iii) subject to your copayment of premium amounts at the applicable active employees' rate and your proper election to receive benefits under COBRA, the Company shall pay to the group health plan provider, the COBRA provider or you a monthly payment equal to the monthly employer contribution that the Company would have made to provide health insurance to you if you had remained employed by the Company until the earliest of (A) the 12-month anniversary of the Date of Termination; (B) your eligibility for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of your continuation rights under COBRA; provided, however, if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to you for the time period specified above. Such payments shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

The amounts payable under this Section 6(a) (other than 6(a)(i)(C)), to the extent taxable, shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period. The amount payable under Section 6(a)(i)(C) shall be paid at the same time as the Company pays bonuses to similarly situated executives, but in no event later than the end of the taxable year in which the Date of Termination occurs.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of you, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code, and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which you became the subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in you receiving a higher After Tax Amount (as defined below) than you would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 6(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on you as a result of your receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, you shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 6(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and you within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or you. Any determination by the Accounting Firm shall be binding upon the Company and you.

(iv) Definitions. For the purposes of this Section 6, a "Change in Control" shall be deemed to have occurred upon the occurrence of any one of the following events: (a) the sale or transfer of all or substantially all of the assets of the Company (i.e., >50% of the value) on a consolidated basis to one or more unrelated persons or entities, (b) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power and outstanding stock immediately prior to such transaction do not own a majority of the outstanding voting power or fair market value of the stock or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction, (c) the sale of all or substantially all of the stock of the Company to an unrelated person, entity or group thereof acting in concert, (d) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the Company or any successor entity immediately upon completion of the transaction other than as a result of the acquisition of securities directly from the Company, or (e) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election provided that with respect to any of the clauses (a) through (e) any capital raising transaction of the Company (including the Company's IPO) shall not be treated as a "Change in Control." Notwithstanding any other provision of this Agreement (other than the foregoing proviso), "Change in Control" shall be interpreted, administered and applied in a manner consistent and in compliance with a "change in control event" as set forth in Treasury Regulation Section 1.409A-3(i)(5) ("Change in Control Event").

7. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of your separation from service within the meaning of Section 409A of the Code, the Company determines that you are a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that you become entitled to under this Agreement or otherwise on account of your separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after your separation from service, or (B) your death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by you during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not

affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon your termination of employment, then such payments or benefits shall be payable only upon your "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement or the Restrictive Covenants Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to you or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

8. Continuing Obligations.

(a) Restrictive Covenants Agreement. The Disc Medicine, Inc. Employee Confidentiality, Assignment, Nonsolicitation and Noncompetition Agreement effective as of June 28, 2020 (the "Restrictive Covenants Agreement"), between Disc Medicine, Inc. and you, attached hereto as Exhibit A, continue to be in full force and effect. For purposes of this Agreement, the obligations in this Section 8 and those that arise in the Restrictive Covenants Agreement shall collectively be referred to as the "Continuing Obligations."

(b) Third-Party Agreements and Rights. You hereby confirm that you are not bound by the terms of any agreement with any previous employer or other party which restricts in any way your use or disclosure of information, other than confidentiality restrictions (if any), or your engagement in any business. You represent to the Company that your execution of this Agreement, your employment with the Company and the performance of your proposed duties for the Company will not violate any obligations you may have to any such previous employer or other party. In your work for the Company, you will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and you will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(c) Litigation and Regulatory Cooperation. During and after your employment, you shall reasonably cooperate fully with the Company in (i) the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while you were employed by the Company, and (ii) the investigation, whether internal or external, of any matters about which the Company believes you may have knowledge or information. Your full reasonable cooperation in connection with such claims, actions or investigations shall include, but not be limited to, being available to meet with counsel to answer questions or to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after your employment, you also shall reasonably cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while you were employed by the Company. The Company shall reimburse you for any reasonable out-of-pocket expenses incurred in connection with your performance of obligations pursuant to this Section 8(c). The Company agrees that if you have provided fifteen (15) hours of cooperation to the Company after your Date of Termination, the Company shall pay you an hourly rate of $400 for any additional hours of cooperation, over the initial fifteen (15) hours, except for your testimony pursuant to a lawfully issued summons or subpoena. The Company further agrees that it

will pay/reimburse your reasonable out-of-pocket expenses and fees within thirty (30) days of your submission of receipts and invoices to the Company.

(d) Relief. You agree that it may would be difficult to measure any damages harm caused to the Company which that might result from any breach by you of any of the Continuing Obligations, and Obligations. You further agree that in any event money damages may would be an inadequate remedy for any such breach. breach of the Continuing Obligations.

Accordingly,, you agree that if you breach, or propose to breach, any portion of the Continuing Obligations, the Company shall be entitled, in addition to all other remedies that it may have, to seek an injunction or other appropriate equitable relief to restrain any such breach, without showing or proving any actual damage to the Company. Company and without the necessity of posting a bond. You further agree that if you violate any of the Continuing Obligations, in addition to all other remedies available to the Company at law, in equity, and under contract, you will be obligated to pay all of the Company's costs of enforcement of the Continuing Obligations, including reasonable attorneys' fees and expenses.

(e) (f)Protected Disclosures and Other Protected Action Interpretation. Nothing in In the event of any dispute, this Agreement shall be interpreted or applied to prohibit you from making any good faith report to any governmental agency or other governmental entity (a "Government Agency") concerning any act or omission that you reasonably believe constitutes a possible violation of federal or state law or making other disclosures that are protected under the anti-retaliation or whistleblower provisions of applicable federal or state law or regulation. In addition, nothing contained in this Agreement limits your ability to communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including your ability to provide documents or other information, without notice to the Company. In addition, for the avoidance of doubt, pursuant to the federal Defend Trade Secrets Act of 2016, you shall not be held criminally or civilly liable under any federal or state trade secret law or under this Agreement or the Restrictive Covenants Agreement for the disclosure of a trade secret that (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

9. Arbitration of Disputes.

(a) Arbitration Generally. Any controversy or claim arising out of or relating to this Agreement or the breach thereof or otherwise arising out of your employment or the termination of that employment (including, without limitation, any claims of unlawful employment discrimination or retaliation, whether based on race, religion, national origin, sex, gender, age, disability, sexual orientation, or any other protected class under applicable law, including without limitation Massachusetts General Laws Chapter 151B) shall, to the fullest extent permitted by law, be settled by arbitration in any forum and form agreed upon intended by the parties or, in the absence of such an agreement, under the auspices of JAMS in Boston, Massachusetts to be construed as a whole, to be interpreted in accordance with its fair meaning, and not to be construed strictly for or against either you or the JAMS Employment Arbitration Rules, including, but not limited Company or the "drafter" of all or any portion of this Agreement.

(g)Governing Law; Jurisdiction. This Agreement will be governed by the laws of the Commonwealth of Massachusetts, without regard to the rules and procedures applicable conflicts of law principles thereof that would require the application of the laws of another jurisdiction. The parties hereby submit to the selection of arbitrators. You understand that you may only bring such claims in your individual capacity, and not as a plaintiff or class member in any purported class proceeding or any purported representative proceeding. You further understand that, by signing this Agreement, the Company and you are giving up any right they may have to a jury trial on all claims they may have against each other. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This Section 9 shall be specifically enforceable. Notwithstanding the foregoing, this Section 9 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate, including without limitation relief sought under the Restrictive Covenants Agreement; provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Section 9.

(b) Arbitration Fees and Costs. You shall be required to pay an arbitration fee to initiate any arbitration equal to what you would be charged as a first appearance fee in court. The Company shall pay the remaining fees and costs of the arbitrator. Each party shall pay its own costs and attorneys' fees, if any. If, however, any party prevails on a statutory or contractual claim that entitles the prevailing party to attorneys' fees (including pursuant to this Agreement), the arbitrator will award attorneys' fees to the prevailing party to the extent permitted by law.

10. Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 9 of this Agreement, the parties hereby consent to the exclusive jurisdiction of the state and federal courts of theCommonwealthof Massachusetts. Accordingly, Massachusetts with respect to any such court action, you (a) submit to the

exclusive personal jurisdiction of such courts; (b) consent to service of process; and (c) waive any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

11. Indemnification. The “Indemnification Agreement” between the Company and you, dated December 29, 2022 (the “Indemnification Agreement”) is hereby incorporated by reference. dispute arising under this Agreement.

12. (h)No Mitigation. The Company agrees that if your employment by the Company is terminated during the term of this Entire Agreement you are not required to seek other employment or to attempt in any way to reduce any amounts payable to you by the Company pursuant to Sections 5 or 6 hereof. Further, the amount of any payment provided for in this Agreement shall not be reduced by any compensation earned by you.

13. Integration. This Agreement, together with the Continuing Obligations (as modified by this Agreement), constitutes the entire agreement between you and the parties with respect to the subject matter hereof Company and supersedes all prior any previous agreements or understandings between you and the parties concerning such subject matter, including the Prior Agreement, provided that the Restrictive Covenants Agreement, Company, except for the Indemnification Agreement and the Equity Documents, which remain in full force and effect.

14. (i)Withholding; Tax Effect Time for Consideration. All payments made by You acknowledge and agree that the Company advises you to consult with an attorney before signing this Agreement. You understand and acknowledge that you under have been given the opportunity to consider this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law. Nothing in this Agreement shall be construed to require the Company to make any payments to compensate you for any adverse tax effect associated with any payments or benefits or for any deduction or withholding twenty-one (21) days from any payment or benefit.

15. Assignment. Neither you nor the Company may make any assignment your receipt of this Agreement before signing it (the “Consideration Period”). To accept this Agreement, you must return a signed, unmodified original or any interest in PDF copy of this Agreement so that it is received by operation of law the undersigned at or otherwise, without before the prior written consent expiration of the other; provided, however, that the Company may assign its rights and obligations under Consideration Period. If you sign this Agreement (including before the Restrictive Covenants Agreement) without your consent end of the Consideration Period, you acknowledge that such decision was entirely voluntary and that you had the opportunity to any affiliate or consider this Agreement for the entire Consideration Period. For the period of seven (7) business days from the date when you sign this Agreement, you have the right to any person or entity with whom revoke this Agreement by written notice to the Company shall hereafter effect a reorganization, consolidate with, or merge into or to whom it transfers all or substantially all of its properties or assets, but only on the condition undersigned, provided that such notice is delivered so that it assigns both its rights and obligations. is

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received at or before the expiration of the seven (7) business day revocation period. This Agreement shall inure to not become effective or enforceable during the benefit revocation period. This Agreement shall become effective on the first business day following the expiration of and be binding upon the revocation period. For the avoidance of doubt, (i) if you and breach any of the Company, and each provisions of yours and the Company’s respective successors, executors, administrators, heirs, personal representatives, and permitted assigns. In Agreement during the event of your death prior to Consideration Period, the completion by the Company of any payments due to you under Sections 5 or 6 offer of this Agreement may be withdrawn and your execution of the Company shall continue such payments to the beneficiary you designated in writing to the Company prior to your death, or to your estate, heirs, executors or personal representatives if you failed to make such designation.

16. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so

declared illegal or unenforceable, shall will not be affected thereby, and each portion and provision of this Agreement shall be valid, and enforceable to the fullest extent permitted by law.

17. Survival. The provisions of (ii) if you do not enter into or revoke this Agreement, shall survive the termination of this Agreement and/or the termination of then your employment to the extent necessary to effectuate the terms contained herein.

18. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

19. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to will end but you at the last address you have on file in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

20. Amendment. This Agreement may be amended or modified only by a written instrument signed by you and by a duly authorized representative of the Company.

21. Effect on Other Plans and Agreements. An election by you to resign for Good Reason under the provisions of this Agreement shall will not be deemed a voluntary termination of employment by you for the purpose of interpreting the provisions of entitled to any of the Company's benefit plans, programs or policies. Nothing benefits set forth in this Agreement shall be construed to limit the rights of you under the Company's benefit plans, programs or policies except as otherwise provided in Section 8 hereof, and except that you shall have no rights to any severance benefits under any Company severance pay plan, offer letter or otherwise. In the event that you are a party to an agreement with the Company providing for payments or benefits under such plan or agreement and under this Agreement, the terms of this Agreement shall govern and you may receive payment under this Agreement only and not both. Further, Section 5 and Section 6 of this Agreement are mutually exclusive and in no event shall you be entitled to payments or benefits pursuant to both Section 5 and Section 6 of this Agreement.

22. Governing Law. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealthof Massachusetts, without giving effect to the conflict of laws principles thereof. With respect to any disputes concerning federal law, such disputes shall be determined in accordance with the law as it would be interpreted and applied by the United States Court of Appeals for the First Circuit.

23. (j) Counterparts. This Agreement may be executed in any number of separate counterparts. When both counterparts each of which when so executed and delivered are signed, they shall be taken to be an original; but such counterparts shall treated together constitute as one and the same document. Electronic and pdf signatures shall be deemed to have the same legal effect as originals.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, Please indicate your agreement to the parties have executed terms of this Agreement effective on by signing and returning the Effective Date. original or a PDF copy of this letter within the time period set forth above.

We wish you the best in your future endeavors.

Very truly yours,

DISC MEDICINE, INC.

DISC MEDICINE, INC. By: _____

Name:

Title: _____ Date

This is a legal document. Your signature will commit you to its terms. By signing below, you acknowledge that you have carefully read and fully understand all of the provisions of this Agreement and that you are knowingly and voluntarily entering into this Agreement.

_____

By: /s/ John D. Quisel

_____

Its: Joanne Bryce President and Chief Executive Officer

Date

EXECUTIVE

_____

EXHIBIT A

CERTIFICATE UPDATING RELEASE OF CLAIMS

(THIS SHOULD NOT BE SIGNED AT THE SAME TIME THE TRANSITIONAL SERVICES AND SEPARATION AGREEMENT IS SIGNED. IT SHOULD BE SIGNED INSTEAD WITHIN THE 7 DAYS FOLLOWING THE DATE OF TERMINATION)

I, hereby acknowledge and certify that I entered into the Transitional Services and Separation Agreement with the Company to which this Agreement is attached. Capitalized but undefined terms in this Certificate are defined in the Agreement. Pursuant to the Agreement, I am required to sign this "Certificate," which updates the release of claims in the Agreement, in order to receive the severance benefits described in the Agreement. ***For this Certificate to become effective and for me to receive such severance benefits, I must sign this Certificate after the Date of Termination but no later than seven days after the Date of Termination. I will not sign this Certificate before the Date of Termination.*** Subject to the foregoing, the date I sign this Certificate is the "Certificate Effective Date." I further agree as follows:

1. A copy of this Certificate was attached as an Exhibit to the Agreement.

2. In consideration of the benefits described in the Agreement, for which I become eligible only if I sign Certificate, I hereby extend the release of claims set forth in the Agreement to any and all claims that arose after the d signed the Agreement through the date I signed this Certificate, subject to all other exclusions and terms set forth in t Agreement.

3. I have carefully read and fully understand all of the provisions of this Certificate, I knowingly and vol agree to all of the terms set forth in this Certificate, and I acknowledge that in entering into this Certificate, I am not re on any representation, promise or inducement made by the Company or its officers, directors, employees, agents or o representatives with the exception of those promises expressly contained in this Certificate and the Agreement.

4. I also represent that I have not been subject to any retaliation or any other form of adverse action by released parties for any action taken by me as an employee or resulting from my exercise of or attempt to exercise an statutory rights recognized under federal, state or local law. I agree that I have been paid all unpaid wages and other compensation owed to me of the Date of Termination. I also agree that and that none of my rights have been violated any statute, common law or Company policy, program or agreement. I represent that I have reported any and all work injuries that I suffered during my employment, if any, to the Company before executing this Certificate.

5. I represent that as of the Company's most recent payroll payment of salary or wages to me, I have b fully paid for all salary or wages then due to me, and I acknowledge that I am not eligible for any other compensation the Company, except as otherwise specified in this Agreement.

6. I agree that this Certificate is part of the Agreement.

Accepted and Agreed:

William Savage, MD, Ph.D.

Exhibit A

Restrictive Covenants Agreement

Exhibit 10.20

DISC MEDICINE, INC.

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is made between Disc Medicine, Inc. (formerly Gemini Therapeutics, Inc.), (the "Company"), and Jonathan Yu (the "You") and is effective as of the closing of the proposed business combination among the Company, Disc Medicine Opco, Inc. (formerly Disc Medicine, Inc.) and Gemstone Merger Sub, Inc. pursuant to that certain Agreement and Plan of Merger, dated as of August 9, 2022 (the "Effective Date"). Except with respect to the Restrictive Covenants Agreement and the Equity Documents (each as defined below), this Agreement supersedes in all respects all prior agreements between you and Disc Medicine, Inc., predecessor in interest to the Company, regarding the subject matter herein, including without limitation the offer letter between you and Disc Medicine, Inc. dated May 4, 2020 (the "Prior Agreement").

WHEREAS, the Company desires to continue to employ you and you desire to continue to be employed by the Company on the new terms and conditions contained herein.

NOW, THEREFORE,in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The Company shall employ you and you shall be employed by the Company pursuant to this Agreement commencing as of the Effective Date and continuing until such employment is terminated in accordance with the provisions hereof (the "Term"). Your employment with the Company will continue to be "at will," meaning that your employment may be terminated by the Company or you at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. You shall serve as the Chief Business Officer of the Company and shall report directly to the Chief Executive Officer ("CEO"). You shall have such powers and duties as may from time to time be prescribed by the CEO or other duly authorized executive which are consistent with your position as Chief Business Officer. You shall devote your full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, you may serve on other boards of directors, with the approval of the Board of Directors of the Company (including any committee thereof, the "Board"), which approval shall not unreasonably be withheld by the Board, or engage in religious, charitable or other community activities as long as such services and activities are disclosed to the Board and do not interfere with your performance of your duties to the Company. To the extent applicable, you shall be deemed to have resigned from all officer and, if applicable, board member positions that you hold with the Company or any of its respective subsidiaries and affiliates upon the termination of your employment for any reason. You shall execute any documents in reasonable form as may be requested to confirm or effectuate any such resignations.

2. Compensation and Related Matters.

(a) Base Salary. Your initial base salary shall be paid at the rate of $400,000 per year. Your base salary shall be subject to periodic review and increase (but not decrease, except for an across-the-board reduction of no greater than 10% based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company) bythe Board or the Compensation Committee of the Board (the "Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for executive officers.

(b) Incentive Compensation. You shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time. Your target annual incentive

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compensation shall be forty percent (40%) of your Base Salary. The target annual incentive compensation in effect at any given time is referred to herein as "Target Bonus." The actual amount of your annual incentive compensation, if any, shall be determined in the sole discretion of the Board or the Compensation Committee, subject to the terms of any applicable incentive compensation plan that may be in effect from time to time (the "Bonus"). Except as otherwise provided herein, to earn incentive compensation, you must be employed by the Company on the day such incentive compensation is paid. The incentive compensation for each fiscal year will be paid no later than two and a half months following such fiscal year.

(c) Expenses. You shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by you during the Term in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company for its executive officers.

(d) Other Benefits. You shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(e) Paid Time Off. You shall be entitled to take paid time off in accordance with the Company's applicable paid time off policy for executives, as may be in effect from time to time. You shall also be entitled to all paid holidays given by the Company to its employees.

(f) Equity. The equity awards held by you shall continue to be governed by the terms and conditions of the Company's applicable equity incentive plan(s) and the applicable award agreement(s) governing the terms of such equity awards held by you (collectively, the "Equity Documents"); provided, however, and notwithstanding anything to the contrary in the Equity Documents, Section 6(a)(ii) of this Agreement shall apply in the event of a termination by the Company without Cause or by you for Good Reason in either event within the Change in Control Period (as such terms are defined below).

3. Termination. Your employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. Your employment hereunder shall terminate upon your death.

(b) Disability. The Company may terminate your employment due to your "Disability" if you are unable to perform the essential functions of your then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any question shall arise as to whether during any period you are disabled so as to be unable to perform the essential functions of your then existing position or positions with or without reasonable accommodation, you may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company who is board certified in the specialty relevant to your medical condition to whom you or your guardian has no reasonable objection as to whether you are disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. You shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and you shall fail to submit such certification, the Company's reasonable determination of such issue shall be binding on you. Nothing in this Section 3(b) shall be construed to waive your rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 *et seq*. and the Americans with Disabilities Act, 42 U.S.C. §12101 *et seq.*

(c) Termination by Company for Cause. The Company may terminate your employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean any of the following:

(i) conduct by you constituting a material act of intentional misconduct in connection with the performance of your duties, including, without limitation, (A) willful failure or willful refusal to perform material responsibilities that have been lawfully requested by the CEO; (B) intentional dishonesty to the CEO with respect to any material matter; or (C) intentional misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and *de minimis* use of Company property for personal purposes;

(ii) the commission by you of (A) any felony or (B) a misdemeanor involving moral turpitude, deceit, dishonesty or fraud;

(iii) any intentional misconduct by you, regardless of whether or not in the course of your employment, that results in material injury or material reputational harm to the Company or any of its subsidiaries or affiliates if you were to continue to be employed in the same position;

(iv) your continued willful non-performance by you of your duties hereunder (other than by reason of your physical or mental illness, incapacity or Disability) which has continued for more than 30 days following written notice of such non-performance from the CEO;

(v) a material breach by you of any of the provisions contained in Section 8 of this Agreement or the Restrictive Covenants Agreement and, if such breach is curable, has continued for more than 30 days following written notice of such material breach (as defined below); or

(vi) your willful failure to reasonably cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being reasonably instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the willful inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.

(d) Termination by the Company without Cause. The Company may terminate your employment hereunder at any time without Cause. Any termination by the Company of your employment under this Agreement which does not constitute a termination for Cause under Section 3(c) and does not result from the death or Disability of you under Section 3(a) or (b) shall be deemed a termination without Cause.

(e) Termination by You. You may terminate employment hereunder at any time for any reason, including but not limited to, Good Reason. For purposes of this Agreement, “Good Reason” shall mean that you have completed all steps of the Good Reason Process (hereinafter defined) following the occurrence of any of the following events without your written consent (each, a “Good Reason Condition”):

(i) a material diminution in your responsibilities, authority or duties

(ii) a material diminution in your Base Salary except for across-the-board salary reductions of no greater than 10% based on the Company’s financial performance similarly affecting all or substantially all senior management employees of the Company;

(iii) a material change of at least thirty (30) miles of the location of the physical Company office to which you report (which to avoid doubt does not include any home office you may have); or

(iv) a breach by the Company of the material terms of this Agreement or any other written agreement between the Company and you.

The “Good Reason Process” consists of the following steps:

(v) you reasonably determine in good faith that a Good Reason Condition has occurred;

(vi) you notify the Company in writing of the first occurrence of the Good Reason Condition within 60 days of the first occurrence of such condition;

(vii) you cooperate in good faith with the Company’s efforts, for a period of not less than 30 days following such notice (the “Cure Period”), to remedy the Good Reason Condition;

(viii) notwithstanding such Cure Period, the Good Reason Condition continues to exist; and

(ix) you terminate employment within 60 days after the end of the Cure Period.

If the Company cures the Good Reason Condition during the Cure Period, Good Reason shall be deemed not to have occurred.

If your employment with the Company is terminated for any reason, the Company shall pay or provide to you (or your authorized representative or estate) (i) any Base Salary earned through the Date of Termination; (ii) unpaid expense reimbursements (subject to, and in accordance with, Section 2(c) of this Agreement); (iii) your accrued but unused vacation days or PTO; (iv) any vested benefits you may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans; and (v) if your employment is terminated by the Company because of your death or Disability, a lump sum payment of any earned, but unpaid Bonus for the fiscal year prior to the fiscal year your employment is terminated because of your death or Disability (collectively, the "Accrued Obligations"). The earned but unpaid Bonus in subsection (v) will be paid at the same time as the Company pays bonuses to similarly situated executives, but in no event later than the end of the taxable year in which the Date of Termination occurs.

4. Notice and Date of Termination.

(a) Notice of Termination. Except for termination as specified in Section 3(a), any termination of your employment by the Company or any such termination by you shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(b) Date of Termination. "Date of Termination" shall mean: (i) if your employment is terminated by death, the date of death; (ii) if your employment is terminated on account of Disability under Section 3(b) or by the Company for Cause under Section 3(c), the date on which Notice of Termination is given; (iii) if your employment is terminated by the Company without Cause under Section 3(d), the date on which a Notice of Termination is given or the date otherwise specified by the Company in the Notice of Termination; (iv) if your employment is terminated by you under Section 3(e) other than for Good Reason, 14 days after the date on which a Notice of Termination is given, and (v) if your employment is terminated by you under Section 3(e) for Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that you give a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement. However, the Company will continue paying you your Base Salary until the original Date of Termination.

5. Severance Pay and Benefits Upon Termination by the Company without Cause or by You for Good Reason Outside the Change in Control Period. If your employment is terminated by the Company without Cause as provided in Section 3(d), or you terminate employment for Good Reason as provided in Section 3(e), each outside of the Change in Control Period (as defined below), then, in addition to theAccrued Obligations, and subject to (i) your signing a separation agreement and release in a form and manner reasonably satisfactory to the Company, which shall include, without limitation, a general release of claims against the Company and all related persons and entities, a reaffirmation of all of your Continuing Obligations (as defined below**)**, and shall provide that if you materially breach any of the Continuing Obligations, and if such breach is curable, which has continued for more than 30 days following written notice of such breach, all payments of the Severance Amount shall immediately cease (the "Separation Agreement and Release"), and (ii) the Separation Agreement and Release becoming irrevocable, all within 60 days after the Date of Termination (or such shorter period as set forth in the Separation Agreement and Release), which shall include a seven (7) business day revocation period:

(a) the Company shall pay you an amount equal tonine (9) months of your Base Salary (the "Severance Amount"); provided in the event you are entitled to any payments pursuant to the Restrictive Covenants Agreement, as a condition of such receipt of the Severance Amount, you shall acknowledge and agree in the Separation Agreement and Release that such Severance Amount will be in lieu of any garden leave pay under the Restrictive Covenants Agreement;

(b) a lump sum payment of any earned, but unpaid Bonus for the fiscal year prior to the fiscal year of your Date of Termination, to be paid at the same time as the Company pays bonuses to similarly situated executives, but in no event later than the end of the taxable year in which the Date of Termination occurs; and

(c) subject to your copayment of premium amounts at the applicable active employees' rate and your proper election to receive benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the

Company shall pay to the group health plan provider, the COBRA provider or you a monthly payment equal to the monthly employer contribution that the Company would have made to provide health insurance to you if you had remained employed by the Company until the earliest of (A) the nine (9) month anniversary of the Date of Termination; (B) your eligibility for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of your continuation rights under COBRA; provided, however, if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to you for the time period specified above. Such payments shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

The amounts payable under Sections 5(a) and (c), to the extent taxable, shall be paid out in substantially equal installments in accordance with the Company's payroll practice over nine (9) months commencing within 60days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount, to the extent it qualifies as "non-qualified deferred compensation" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

6. Severance Pay and Benefits Upon Termination by the Company without Cause or by You for Good Reason within the Change in Control Period. The provisions of this Section 6 shall apply in lieu of, and expressly supersede, the provisions of Section 5 if (i) your employment is terminated either (a) by the Company without Cause as provided in Section 3(d), or (b) by you for Good Reason as provided in Section 3(e), and (ii) the Date of Termination is within 3 months prior to, or within 12 months after, the occurrence of the first event constituting a Change in Control (as defined below) (such period, the "Change in Control Period"). These provisions of Section 6 shall terminate and be of no further force or effect after a Change in Control Period.

(a) If your employment is terminated by the Company without Cause as provided in Section 3(d) or you terminate employment for Good Reason as provided in Section 3(e) and in each case the Date of Termination occurs during the Change in Control Period, then, in addition to the Accrued Obligations, and subject to the signing of the Separation Agreement and Release by you and the Separation Agreement and Release becoming fully effective, all within the time frame set forth in the Separation Agreement and Release but in no event more than 60 days after the Date of Termination:

(i) the Company shall pay you a lump sum in cash in an amount equal to the sum of(A) twelve (12) months of your then current Base Salary (or your Base Salary in effect immediately prior to the Change in Control, if higher), (B) your Target Bonus for the then-current fiscal year; and (C) any earned, but unpaid Bonus for the fiscal year prior to the fiscal year of your Date of Termination, (the "Change in Control Payment") provided that, if applicable and as a condition of such receipt of the Change in Control Payment, you shall acknowledge and agree in the Separation Agreement and Release that such Change in Control Payment will be in lieu of any garden leave pay under the Restrictive Covenants Agreement; and

(ii) notwithstanding anything to the contrary in any applicable option agreement or other stock-based award agreement, all time-based stock options and other stock-based awards subject to time-based vesting held by you (the "Time-Based Equity Awards") shall immediately accelerate and become fully exercisable or nonforfeitable as of the later of (i) the Date of Termination or (ii) the effective date of the Separation Agreement and Release (the "Accelerated Vesting Date"); *provided* that any termination or forfeiture of the unvested portion of such Time-Based Equity Awards that would otherwise occur on the Date of Termination in the absence of this Agreement will be delayed until the effective date of the Separation Agreement and Release and will only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation Agreement and Release becoming fully effective within the time period set forth therein. Notwithstanding the foregoing, no additional vesting of the Time-Based Equity Awards shall occur during the period between your Date of Termination and the Accelerated Vesting Date; and

(iii) subject to your copayment of premium amounts at the applicable active employees' rate and your proper election to receive benefits under COBRA, the Company shall pay to the group health plan provider, the COBRA provider or you a monthly payment equal to the monthly employer contribution that the Company would have made

to provide health insurance to you if you had remained employed by the Company until the earliest of (A) the 12-month anniversary of the Date of Termination; (B) your eligibility for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of your continuation rights under COBRA; provided, however, if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to you for the time period specified above. Such payments shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

The amounts payable under this Section 6(a) (other than 6(a)(i)(C)), to the extent taxable, shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period. The amount payable under Section 6(a)(i)(C) shall be paid at the same time as the Company pays bonuses to similarly situated executives, but in no event later than the end of the taxable year in which the Date of Termination occurs.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of you, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code, and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which you became the subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in you receiving a higher After Tax Amount (as defined below) than you would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 6(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on you as a result of your receipt of the Aggregate Payments. For purposes of determining the After Tax Amount,

you shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 6(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and you within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or you. Any determination by the Accounting Firm shall be binding upon the Company and you.

(iv) Definitions. For the purposes of this Section 6, a "Change in Control" shall be deemed to have occurred upon the occurrence of any one of the following events: (a) the sale or transfer of all or substantially all of the assets of the Company (i.e., >50% of the value) on a consolidated basis to one or more unrelated persons or entities, (b) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power and outstanding stock immediately prior to such transaction do not own a majority of the outstanding voting power or fair market value of the stock or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable)

immediately upon completion of such transaction, (c) the sale of all or substantially all of the stock of the Company to an unrelated person, entity or group thereof acting in concert, (d) any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the Company or any successor entity immediately upon completion of the transaction other than as a result of the acquisition of securities directly from the Company, or (e) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election provided that with respect to any of the clauses (a) through (e) any capital raising transaction of the Company (including the Company's IPO) shall not be treated as a "Change in Control." Notwithstanding any other provision of this Agreement (other than the foregoing proviso), "Change in Control" shall be interpreted, administered and applied in a manner consistent and in compliance with a "change in control event" as set forth in Treasury Regulation Section 1.409A-3(i)(5) ("Change in Control Event").

7. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of your separation from service within the meaning of Section 409A of the Code, the Company determines that you are a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that you become entitled to under this Agreement or otherwise on account of your separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after your separation from service, or (B) your death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by you during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon your termination of employment, then such payments or benefits shall be payable only upon your "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement or the Restrictive Covenants Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to you or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

8. Continuing Obligations.

(a) Restrictive Covenants Agreement. The Disc Medicine, Inc. Employee Confidentiality, Assignment, Nonsolicitation and Noncompetition Agreement effective as of May 4, 2020 (the "Restrictive Covenants Agreement"), between Disc

Medicine, Inc. and you, attached hereto as Exhibit A, continue to be in full force and effect. For purposes of this Agreement, the obligations in this Section 8 and those that arise in the Restrictive Covenants Agreement shall collectively be referred to as the "Continuing Obligations."

(b) Third-Party Agreements and Rights. You hereby confirm that you are not bound by the terms of any agreement with any previous employer or other party which restricts in any way your use or disclosure of information, other than confidentiality restrictions (if any), or your engagement in any business. You represent to the Company that your execution of this Agreement, your employment with the Company and the performance of your proposed duties for the Company will not violate any obligations you may have to any such previous employer or other party. In your work for the Company, you will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and you will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(c) Litigation and Regulatory Cooperation. During and after your employment, you shall reasonably cooperate fully with the Company in (i) the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while you were employed by the Company, and (ii) the investigation, whether internal or external, of any matters about which the Company believes you may have knowledge or information. Your full reasonable cooperation in connection with such claims, actions or investigations shall include, but not be limited to, being available to meet with counsel to answer questions or to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after your employment, you also shall reasonably cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while you were employed by the Company. The Company shall reimburse you for any reasonable out-of-pocket expenses incurred in connection with your performance of obligations pursuant to this Section 8(c). The Company agrees that if you have provided fifteen (15) hours of cooperation to the Company after your Date of Termination, the Company shall pay you an hourly rate of $400 for any additional hours of cooperation, over the initial fifteen (15) hours, except for your testimony pursuant to a lawfully issued summons or subpoena. The Company further agrees that it will pay/reimburse your reasonable out-of-pocket expenses and fees within thirty (30) days of your submission of receipts and invoices to the Company.

(d) Relief. You agree that it may be difficult to measure any damages caused to the Company which might result from any breach by you of the Continuing Obligations, and that in any event money damages may be an inadequate remedy for any such breach. Accordingly**,** you agree that if you breach, or propose to breach, any portion of the Continuing Obligations, the Company shall be entitled, in addition to all other remedies that it may have, to seek an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company.

(e) Protected Disclosures and Other Protected Action. Nothing in this Agreement shall be interpreted or applied to prohibit you from making any good faith report to any governmental agency or other governmental entity (a "Government Agency") concerning any act or omission that you reasonably believe constitutes a possible violation of federal or state law or making other disclosures that are protected under the anti-retaliation or whistleblower provisions of applicable federal or state law or regulation. In addition, nothing contained in this Agreement limits your ability to communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including your ability to provide documents or other information, without notice to the Company. In addition, for the avoidance of doubt, pursuant to the federal Defend Trade Secrets Act of 2016, you shall not be held criminally or civilly liable under any federal or state trade secret law or under this Agreement or the Restrictive Covenants Agreement for the disclosure of a trade secret that (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

9. Arbitration of Disputes.

(a) Arbitration Generally. Any controversy or claim arising out of or relating to this Agreement or the breach thereof or otherwise arising out of your employment or the termination of that employment (including, without limitation, any claims of unlawful employment discrimination or retaliation, whether based on race, religion, national origin, sex, gender, age, disability, sexual orientation, or any other protected class under applicable law, including without limitation Massachusetts General Laws Chapter 151B) shall, to the fullest extent permitted by law, be settled by arbitration in any forum and form agreed upon by the

parties or, in the absence of such an agreement, under the auspices of JAMS in Boston, Massachusetts in accordance with the JAMS Employment Arbitration Rules, including, but not limited to, the rules and procedures applicable to the selection of arbitrators. You understand that you may only bring such claims in your individual capacity, and not as a plaintiff or class member in any purported class proceeding or any purported representative proceeding. You further understand that, by signing this Agreement, the Company and you are giving up any right they may have to a jury trial on all claims they may have against each other. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This Section 9 shall be specifically enforceable. Notwithstanding the foregoing, this Section 9 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate, including without limitation relief sought under the Restrictive Covenants Agreement; provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Section 9.

(b) Arbitration Fees and Costs. You shall be required to pay an arbitration fee to initiate any arbitration equal to what you would be charged as a first appearance fee in court. The Company shall pay the remaining fees and costs of the arbitrator. Each party shall pay its own costs and attorneys' fees, if any. If, however, any party prevails on a statutory or contractual claim that entitles the prevailing party to attorneys' fees (including pursuant to this Agreement), the arbitrator will award attorneys' fees to the prevailing party to the extent permitted by law.

10. Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 9 of this Agreement, the parties hereby consent to the jurisdiction of the state and federal courts of theCommonwealthof Massachusetts. Accordingly, with respect to any such court action, you (a) submit to the exclusive personal jurisdiction of such courts; (b) consent to service of process; and (c) waive any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

11. Indemnification. The "Indemnification Agreement" between the Company and you, dated December 29, 2022 (the "Indemnification Agreement") is hereby incorporated by reference.

12. No Mitigation. The Company agrees that if your employment by the Company is terminated during the term of this Agreement, you are not required to seek other employment or to attempt in any way to reduce any amounts payable to you by the Company pursuant to Sections 5 or 6 hereof. Further, the amount of any payment provided for in this Agreement shall not be reduced by any compensation earned by you.

13. Integration. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter, including the Prior Agreement, provided that the Restrictive Covenants Agreement, the Indemnification Agreement and the Equity Documents remain in full force and effect.

14. Withholding; Tax Effect. All payments made by the Company to you under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law. Nothing in this Agreement shall be construed to require the Company to make any payments to compensate you for any adverse tax effect associated with any payments or benefits or for any deduction or withholding from any payment or benefit.

15. Assignment. Neither you nor the Company may make any assignment of this Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; provided, however, that the Company may assign its rights and obligations under this Agreement (including the Restrictive Covenants Agreement) without your consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization, consolidate with, or merge into or to whom it transfers all or substantially all of its properties or assets, but only on the condition that it assigns both its rights and obligations. This Agreement shall inure to the benefit of and be binding upon you and the Company, and each of yours and the Company's respective successors, executors, administrators, heirs, personal representatives, and permitted assigns. In the event of your death prior to the completion by the Company of any payments due to you under Sections 5 or 6 of this Agreement, the Company shall continue such payments to the beneficiary you designated in writing to the Company prior to your death, or to your estate, heirs, executors or personal representatives if you failed to make such designation.

16. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so

declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

17. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of your employment to the extent necessary to effectuate the terms contained herein.

18. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

19. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to you at the last address you have on file in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

20. Amendment. This Agreement may be amended or modified only by a written instrument signed by you and by a duly authorized representative of the Company.

21. Effect on Other Plans and Agreements. An election by you to resign for Good Reason under the provisions of this Agreement shall not be deemed a voluntary termination of employment by you for the purpose of

interpreting the provisions of any of the Company's benefit plans, programs or policies. Nothing in this Agreement shall be construed to limit the rights of you under the Company's benefit plans, programs or policies except as otherwise provided in Section 8 hereof, and except that you shall have no rights to any severance benefits under any Company severance pay plan, offer letter or otherwise. In the event that you are a party to an agreement with the Company providing for payments or benefits under such plan or agreement and under this Agreement, the terms of this Agreement shall govern and you may receive payment under this Agreement only and not both. Further, Section 5 and Section 6 of this Agreement are mutually exclusive and in no event shall you be entitled to payments or benefits pursuant to both Section 5 and Section 6 of this Agreement.

22. Governing Law. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealthof Massachusetts, without giving effect to the conflict of laws principles thereof. With respect to any disputes concerning federal law, such disputes shall be determined in accordance with the law as it would be interpreted and applied by the United States Court of Appeals for the First Circuit.

23. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the Effective Date.

DISC MEDICINE, INC.

Joan
ne
Bryce

By: John D. Quisel

Its: President and Chief Executive Officer

EXECUTIVE

/s/ Jonathan Yu

Jonathan Yu

Exhibit A

Restrictive Covenants Agreement

1

Exhibit 21.1

Legal Name	State of Organization
Disc Medicine Opco, Inc.	Delaware
Disc Medicine Securities Corp.	Massachusetts
Gemini Therapeutics Sub, Inc..	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-269270) of Disc Medicine, Inc.

(2) Registration Statement (Form S-3 No. 333-269272) of Disc Medicine, Inc.

(3) Registration Statement (Form S-3 No. 333-275652) of Disc Medicine, Inc.

(4) Registration Statement (Form S-8 No. 333-269271) pertaining to the 2017 Stock Option and Grant Plan, Amended and Restated 2021 Stock Option and Incentive Plan, and Amended and Restated 2021 Employee Stock Purchas Plan, of Disc Medicine, Inc.

(4) (5) Registration Statement (Form S-8 No. 333-263410) pertaining to the 2021 Stock Option and Incentive Pl of Gemini Therapeutics, Inc.

(5) (6) Registration Statement (Form S-8 No. 333-255194) pertaining to the 2021 Stock Option and Incentive Pl and the 2021 Inducement Plan of Gemini Therapeutics, Inc., and

(6) (7) Registration Statement (Form S-8 No. 333-260243) pertaining to the 2021 Employee Stock Purchase Pla Gemini Therapeutics, Inc.

of our report dated March 31, 2023 March 21, 2024, with respect to the consolidated financial statements of Disc Medicine, Inc. included in this Annual Report (Form 10-K) of Disc Medicine, Inc. for the year ended December 31, 2022 December 31, 2023.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 31, 2023 21, 2024

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
RULE 13A-14(A) / RULE 15D-14(A) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, John Quisel, J.D., Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Disc Medicine, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2023March 21, 2024

/s/ John Quisel

John Quisel, J.D., Ph.D.

President, Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
RULE 13A-14(A) / RULE 15D-14(A) OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

I, Joanne Bryce, CPA, Jean Franchi, certify that:

1. I have reviewed this Annual Report on Form 10-K of Disc Medicine, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2023 March 21, 2024

/s/ Joanne Bryce Jean Franchi

Joanne Bryce, CPA Jean Franchi

Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Annual Report on Form 10-K of Disc Medicine, Inc. (the "Company") for the fiscal year ended December 31, 2022 December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his or her knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition ar results of operations of the Company.

Dated: March 31, 2023 March 21, 2024

/s/ John Quisel

John Quisel, J.D., Ph.D.

President and Chief Executive Officer

(Principal Executive Officer)

/s/ Joanne Bryce Jean Franchi

Joanne Bryce, CPA Jean Franchi

Chief Financial Officer

(Principal Financial and Accounting Officer)