UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 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**
(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)**

(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**

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 10, 2023, there were 19,799,357 shares of Common Stock, $0.0001 par value per share, outstanding.

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RISK FACTOR SUMMARY

The risk factors detailed in Item 1A entitled “Risk Factors” in this Quarterly Report on Form 10-Q 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 future.
- 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 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 trials for any product candidates we develop. Certain of our programs are still in preclinical development and may never advance to clinical development.
- 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.
- Interim, top-line, 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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 and planned Phase 1 clinical trial of MWTX-003 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 might not realize the anticipated benefits of our current collaborations with Mabwell or NIH, or any other collaborations we enter into in the future.
- 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.
- 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.
- 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.
- 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 successful in 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 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.
- 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 under the caption "Forward Looking Statements" of this Quarterly Report on Form 10-Q.

FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, 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 Quarterly Report on Form 10-Q 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 studies 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 trials 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; and
- 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 Quarterly Report on Form 10-Q 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 competitive 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 all; and
- the risk that we experience difficulties in managing our growth and expanding operations.

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 236,422	$ 194,611
Prepaid expenses and other current assets	5,716	3,880
Total current assets	242,138	198,491
Property and equipment, net	180	168
Right-of-use assets, operating leases	1,346	1,430
Other assets	116	116
Total assets	$ 243,780	$ 200,205
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,642	$ 16,162
Accrued expenses	4,025	6,109
Operating lease liabilities, current	313	307
Total current liabilities	9,980	22,578
Operating lease liabilities, non-current	945	1,027
Total liabilities	10,925	23,605
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Common stock, $0.0001 par value; 100,000,000 shares authorized as of March 31, 2023 and December 31, 2022; 19,576,200 and 17,405,231 shares issued March 31, 2023 and December 31, 2022, respectively; and 19,575,242 and 17,403,315 shares outstanding as of March 31, 2023 and December 31, 2022, respectively	2	2
Additional paid-in capital	367,850	288,814
Accumulated deficit	(134,997)	(112,216)
Total stockholders' equity	232,855	176,600
Total liabilities and stockholders' equity	$ 243,780	$ 200,205

The accompanying notes are an integral part of these condensed consolidated financial statements.

DISC MEDICINE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 20,180	$ 7,821
General and administrative	4,945	2,139
Total operating expenses	25,125	9,960
Loss from operations	(25,125)	(9,960)
Other income (expense), net:		
Interest income	2,367	7
Change in fair value of derivative liability	-	100
Total other income (expense), net	2,367	107
Loss before income taxes	(22,758)	(9,853)
Income tax expense	(23)	-
Net loss and comprehensive loss	$ (22,781)	$ (9,853)
Net loss attributable to common stockholders-basic and diluted	$ (22,781)	$ (9,853)
Weighted-average common shares outstanding-basic and diluted	18,954,914	923,750
Net loss per share attributable to common stockholders-basic and diluted	$ (1.20)	$ (10.67)

The accompanying notes are an integral part of these condensed consolidated financial statements.

DISC MEDICINE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share and per share amounts)
(Unaudited)

	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	Equity (Deficit)
Balance at December 31, 2021	5,000,000	$ 2,350	41,666,666	$ 2	37,499,999	$ 44	909,418	$ 1	$ 1,185	$ (65,389)	$ (64,203)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	31,725	—	55	—	55
Vesting of restricted common stock	—	—	—	—	—	—	2,285	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	332	—	332
Net loss	—	—	—	—	—	—	—	—	—	(9,853)	(9,853)
Balance at March 31, 2022	5,000,000	$ 2,350	41,666,666	$ 2	37,499,999	$ 44	943,428	$ 1	$ 1,572	$ (75,242)	$ (73,669)

	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	Equity
Balance at December 31, 2022	—	$ —	—	$ —	—	$ —	17,403,315	$ 2	$ 288,814	$ (112,216)	$ 176,600
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	74,753	—	1,067	—	1,067
Vesting of restricted common stock	—	—	—	—	—	—	958	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,024	—	1,024
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 $408	—	—	—	—	—	—	608,050	—	14,591	—	14,591
Net loss	—	—	—	—	—	—	—	—	—	(22,781)	(22,781)
Balance at March 31, 2023	—	$ —	—	$ —	—	$ —	19,575,242	$ 2	$ 367,850	$ (134,997)	$ 232,855

The accompanying notes are an integral part of these condensed consolidated financial statements.

DISC MEDICINE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (22,781)	$ (9,853)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation and amortization	25	18
Stock-based compensation	1,024	332
Change in fair value of derivative liability	—	(100)
Noncash lease expense	84	74
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(908)	(3,195)
Other assets	—	64
Accounts payable	(10,750)	(982)
Accrued expenses	(2,084)	18
Operating lease liabilities	(76)	(77)
Net cash used in operating activities	(35,466)	(13,701)
Cash flow from investing activities		
Purchases of property and equipment	(29)	(100)
Net cash used in investing activities	(29)	(100)
Cash flow from financing activities		
Proceeds from sale of common stock in registered direct offering, net of issuance costs paid	34,217	—
Proceeds from sale of pre-funded warrants in registered direct offering, net of issuance costs paid	28,262	—
Proceeds from sale of common stock in at-the-market offerings, net of issuance costs paid	14,605	—
Proceeds from stock option exercises	222	55
Net cash provided by financing activities	77,306	55
Net increase (decrease) in cash, cash equivalents and restricted cash	41,811	(13,746)
Cash, cash equivalents and restricted cash, beginning of period	194,788	88,213
Cash, cash equivalents and restricted cash, end of period	$ 236,599	$ 74,467
Supplemental cash flow information		
Cash paid for income taxes	$ —	$ —
Supplemental disclosure of non-cash activities		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 8	$ 11
Receivable for proceeds from stock option exercises included in other current assets	$ 845	$ —
Deferred issuance costs on sale of common stock in registered direct offering included in accounts payable and accrued expenses	$ 69	$ —
Deferred issuance costs on sale of pre-funded warrants in registered direct offering included in accounts payable and accrued expenses	$ 56	$ —
Deferred issuance costs on sale of common stock in at-the-market offerings included in accounts payable and accrued expenses	$ 97	$ —
Deferred issuance costs on equity financing included in accounts payable and accrued expenses	$ —	$ 384

The accompanying notes are an integral part of these condensed 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 current pipeline includes, bitopertin for the treatment of erythropoietic porphyrias ("EPs") including erythropoietic protoporphyria ("EPP"), and X-linked protoporphyria ("XLP"), and Diamond-Blackfan Anemia ("DBA"); DISC-0974 for the treatment of anemia of myelofibrosis ("MF"), and anemia of chronic kidney disease ("CKD"); and MWTX-003 for the treatment of polycythemia vera ("PV"), and other hematologic disorders. In addition, the Company's preclinical programs also include DISC-0998, for the treatment of anemia associated with inflammatory diseases. The 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 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 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 preferred stock (see Note 9) and shares of the Company's common stock issued in the Private Disc pre-closing financing defined below) was exchanged for 0.1096 shares of 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 during the period that is one year after the closing of the merger, calculated in accordance with the CVR Agreement. As of March 31, 2023, no such proceeds have been received.

In connection with the Merger Agreement, certain third parties entered into a subscription agreement with Private Disc to purchase shares of Private Disc's common stock for an aggregate purchase price of $53.5 million (the "pre-closing financing").

Shares of Private Disc's common stock issued pursuant to the pre-closing financing were converted into shares of the 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 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), 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 condensed 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 March 31, 2023 of $236.4 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 condensed consolidated financial statements. The Company has incurred recurring losses and negative cash flows from operations since inception. As of March 31, 2023, the Company had an accumulated deficit of $135.0 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.

2. Summary of Significant Accounting Policies

Summary of Significant Accounting Policies

The significant accounting policies used in preparation of the condensed consolidated financial statements are described in the Company's audited consolidated financial statements as of and for the year ended December 31, 2022, and the notes thereto, which are included in the Company's Annual Report on Form 10-K. There have been no material changes to the significant accounting policies previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Basis of Presentation and Principles of Consolidation

The condensed consolidated financial statements include the Company and its wholly-owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

The Company's condensed 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").

Unaudited Interim Condensed Consolidated Financial Information

The accompanying condensed consolidated financial statements as of March 31, 2023 and for the three months ended March 31, 2023 and 2022 are unaudited. The financial data and other information contained in the notes hereto as of March 31, 2023 and for the three months ended March 31, 2023 and 2022 are also unaudited. The condensed consolidated balance sheet data as of December 31, 2022 was derived from the Company's audited consolidated financial statements included in the Company's Annual Report on Form 10-K.

The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements, and in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair presentation of the Company's financial position as of March 31, 2023 and the results of its operations and cash flows for the three months ended March 31, 2023 and 2022. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2022, and the notes thereto, included in the Company's Annual Report on Form 10-K.

The results for the three months ended March 31, 2023 are not necessarily indicative of results to be expected for the year ended December 31, 2023, or any other interim periods, or any future year or period.

Use of Estimates

The preparation of the Company's condensed 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 condensed consolidated financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these condensed 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); the fair value of Gemini's development programs underlying 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.

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 federally insured financial institutions in excess of federally insured limits and limits its exposure to cash risk by placing its cash with high credit quality accredited financial 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.

Restricted Cash

The Company maintained letters of credit for the benefit of its landlords related to its current leased office space in Watertown, Massachusetts and prior leased office space in Cambridge, Massachusetts. The Company was required to maintain separate cash balances to secure its letters of credit.

Recently Adopted Accounting Pronouncements

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. 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 have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on the Company's condensed consolidated financial statements upon adoption.

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 condensed 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 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 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 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 of the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Financial assets and liabilities measured at fair value on a recurring basis are summarized as follows (in thousands):

	March 31, 2023		
	Level 1	Level 2	Level 3
Assets			
Money market funds in cash and cash equivalents	$ 142,534		
Total	$ 142,534	$ —	$ —

	December 31, 2022		
	Level 1	Level 2	Level 3
Assets			
Money market funds in cash and cash equivalents	$ 40,783	$ —	$ —
Total	$ 40,783	$ —	$ —

The fair value of the Company's cash equivalents, consisting of money market funds, is based on quoted market prices in active markets with no valuation adjustment. There have been no impairments of the Company's assets measured and carried at fair value during the three months ended March 31, 2023 and 2022. In addition, there were no changes in valuation techniques or transfers between Level 1, Level 2 and Level 3 financial assets during the three months ended March 31, 2023 and 2022. The Company did not have any non-recurring fair value measurements on any assets or liabilities during the three months ended March 31, 2023 and 2022.

In May 2021, 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 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. 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 common stock to Roche for no additional consideration upon the Company's completion of an initial public offering or certain merger transactions, a "Roche Qualified 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 common stock to Roche immediately following the completion of the merger. 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 condensed consolidated statements of operations and comprehensive loss in the change in fair value of derivative liability. The Company then reclassified the resulting amount of the derivative liability to additional paid-in capital.

The following table provides a summary of changes in fair value of the Level 3 liability related to the Roche Agreement for the three months ended March 31, 2022 (in thousands):

	LEVEL 3 ROLLFORWARD
Balance at December 31, 2021	$ 6,450
Change in fair value of derivative liability	(100)
Balance at March 31, 2022	$ 6,350

5. Cash, Cash Equivalents and Restricted Cash

Cash, cash equivalents and restricted cash consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 236,422	$ 194,611
Restricted cash	177	177
Total cash, cash equivalents and restricted cash as shown on the condensed consolidated statements of cash flows	$ 236,599	$ 194,788

6. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Computer equipment	$ 206	$ 169
Furniture and fixtures	144	144
Less: Accumulated depreciation	(170)	(145)
Property and equipment, net	$ 180	$ 168

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Accrued research and development	$ 2,457	$ 1,817
Accrued employee-related expenses	876	3,623
Accrued professional fees	347	463
Accrued other	345	206
Total accrued expenses	$ 4,025	$ 6,109

8. Development and License Agreements

License Agreement and Master Service Agreement with Aurigene Discoveries Technology Limited ("Aurigene")

In February 2018, the Company entered into a license agreement with Aurigene, pursuant to which Aurigene granted 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 provided a 90-day notice to terminate the master service agreement effective in March 2023.

Pursuant to the license agreement, 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 three months ended March 31, 2023 and 2022, the Company recorded research and development expense of $0.3 million and $0.3 million, respectively, related to its arrangements with Aurigene.

License and Stock Purchase Agreement with AbbVie Deutschland GmbH & Co. KG ("AbbVie")

In September 2019, the Company entered into an agreement with AbbVie, pursuant to which AbbVie granted the Company an exclusive license, with the right to grant sublicenses, to certain AbbVie intellectual property.

Under this agreement, the Company 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 March 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, 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, 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 $205.0 million upon achievement of certain development, regulatory and commercial milestones. 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, the Company was obligated to issue shares 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. The Company had determined that the obligation to issue common stock upon completion of a Roche Qualified Transaction represented a 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 condensed consolidated statement of operations and comprehensive loss at each period while the instrument was outstanding.

During the three months ended March 31, 2022, the Company recorded expense of $0.1 million within other income (expense), net, related to the change in fair value of the derivative liability.

Upon completion of the merger, the Company issued 482,313 shares of common stock 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.

License Agreement 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.

During the three months ended March 31, 2023, the Company paid Mabwell an upfront payment of $10.0 million. 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. 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.

9. Convertible Preferred Stock

As of March 31, 2023, 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 common stock were converted into shares of the Company's common stock based on the Exchange Ratio.

10. Common Stock

At the closing of the merger, the shares of Private Disc's common stock were converted into shares of the Company's common stock based on the Exchange Ratio.

As of March 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 common stock were subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock. Each share of common stock entitles the holder to one vote on all matters submitted to the stockholders for a vote.

As of March 31, 2023, the Company has 2,527,513 shares of common stock reserved for the exercise of stock options and 1,229,224 shares of common stock reserved for 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 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.

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. Under this program, the Company is able to offer and sell, from time to time at its sole discretion, shares of its common stock through SVB Securities LLC as its sales agent. In an ATM offering, exchange-listed companies incrementally sell newly issued shares into the secondary trading market through a designated broker-dealer at prevailing market prices.

As of March 31, 2023, the Company had sold an aggregate of 608,050 shares of common stock in at-the-market offerings under the shelf. Aggregate gross proceeds from the transactions were $15.0 million and the Company received $14.6 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.

11. Stock-Based Compensation

The Company grants stock-based awards under its 2021 Stock Option and Incentive Plan (the "2021 Plan"), which was approved by its stockholders in February 2021 and amended and restated in January 2023. The Company also has outstanding stock option awards under its 2017 Stock Option and Grant Plan (the "Private Disc Plan"), the 2017 Stock Option and Grant Plan (the "Gemini 2017 Plan"), and the 2021 Inducement Plan, but is no longer granting awards under these plans. The Company also has the option to grant awards under the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which was approved by shareholders in July 2021 and amended and restated in January 2023.

The following table summarizes stock option activity for the three months ended March 31, 2023.

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value (In Thousands)
Outstanding at December 31, 2022	2,640,590	$ 16.19	8.08	$ 25,513
Granted	25,756	$ 23.10		
Exercised	(74,753)	$ 15.04		
Forfeited	(64,080)	$ 99.98		
Outstanding at March 31, 2023	2,527,513	$ 14.17	8.22	$ 28,068
Exercisable at March 31, 2023	1,022,728	$ 18.21	7.09	$ 13,318

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 three months ended March 31, 2023 was $0.5 million.

The weighted-average assumptions used to estimate the fair value of stock options granted were as follows:

	Three Months Ended March 31,	
	2023	2022
Risk-free interest rate	3.86%	1.82%
Expected term (in years)	6.05	6.00
Expected volatility	62%	56%
Expected dividend yield	0%	0%
Fair value per share of common stock	$ 23.10	$ 14.69

The weighted-average grant date fair value of options granted during the three months ended March 31, 2023 and 2022 was $14.06 and $7.85 per share, respectively.

The total fair value of options vested during the three months ended March 31, 2023 was $0.8 million.

As of March 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.

A summary of restricted common stock activity is as follows:

	Three Months Ended March 31,	
	2023	2022
Unvested at the beginning of the year	1,916	10,170
Vested	(958)	(2,285)
Unvested at the end of the period	958	7,885

As of March 31, 2023, the unrecognized stock-based compensation expense related to restricted common stock is expected to be recognized over a weighted-average period of 0.01 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):

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 345	$ 133
General and administrative	679	199
Total stock-based compensation expense	$ 1,024	$ 332

As of March 31, 2023, the total unrecognized stock-based compensation expense related to outstanding awards was $9.3 million and is expected to be recognized over a weighted-average period of 3.12 years.

12. Income Taxes

The Company did not record a provision or benefit for federal income taxes during the three months ended March 31, 2023 and 2022. The Company recorded state income tax expense of less than $0.1 million for the three months ended March 31, 2023, due to interest income. There was no state income tax expense for the three months ended March 31, 2022. The Company continues to maintain a full valuation allowance against all of its deferred tax assets.

The Company has evaluated the positive and negative evidence involving its ability to realize its deferred tax assets and has considered its history of cumulative net losses incurred since inception and its lack of any commercially ready products. The Company has concluded that it is more likely than not that it will not realize the benefits of its deferred tax assets. The Company reevaluates the positive and negative evidence at each reporting period.

The Company has never been examined by the Internal Revenue Service or any other jurisdiction for any tax years and, as such, all years within the applicable statutes of limitations are potentially subject to audit.

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 February 2023 registered direct offering as the pre-funded warrants are exercisable for nominal cash consideration. As of March 31, 2023, no pre-funded warrants have been exercised and 1,229,224 pre-funded warrants are outstanding.

The Company has generated a net loss in all periods presented, so the basic and diluted net loss per share are the 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:

	March 31,	
	2023	2022
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	958	7,885
Options to purchase common stock	2,527,513	1,563,671

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 three months ended March 31, 2023 and 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

The Company leases office space in Watertown, Massachusetts under an operating lease. There have been no material changes to the Company's lease during the three months ended March 31, 2023. For additional information, please refer to Note 15, Leases, to the consolidated financial statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

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.

17. Subsequent Events

The Company has completed an evaluation of all subsequent events after the unaudited condensed consolidated balance sheet date of March 31, 2023 through the date these condensed consolidated financial statements were issued to ensure that these condensed consolidated financial statements include appropriate disclosure of events both recognized in the condensed consolidated financial statements as of March 31, 2023, and events which occurred subsequently but were not recognized in the condensed consolidated financial statements. Non-recognizable subsequent events are summarized below.

ATM Program

Subsequent to March 31, 2023 and through the issuance date of these condensed consolidated financial statements, the Company has sold an aggregate of 217,300 shares of common stock in at-the-market offerings under the shelf for gross proceeds of $5.0 million.

ITEM 2. 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 the unaudited condensed consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2022. Please refer to our note regarding forward-looking statements under the caption "Forward Looking Statements" of this Quarterly Report on Form 10-Q, which is incorporated herein by this reference.

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 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 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 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 interim data from BEACON in June of 2023 and topline data from BEACON and AURORA by end of 2023. 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 2023. We are planning additional trials of bitopertin in other indications.

DISC-0974 is the lead product candidate in our iron homeostasis portfolio. 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 interim data from both of these trials by end of 2023. 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, a monoclonal antibody against Transmembrane Serine Protease 6, or TMPRSS6, that we licensed from Mabwell Therapeutics, Inc., or Mabwell. MWTX-003 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 cleared by the FDA, and we plan to initiate a Phase 1 clinical trial in healthy adult volunteers in the second half of 2023. We expect to develop MWTX-003 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 and development functions;
- expenses incurred in connection with our research and development activities, including under agreements with third parties such as consultants, contractors and CROs;
- costs related to contract development and manufacturing organizations, or CDMOs, that are primarily engaged to provide drug substance and product for our preclinical studies, clinical trials and research and development programs, as well as investigative sites and 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 validation 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 condensed 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 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 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 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 the 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 and administrative consulting services; insurance costs, 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 money market fund accounts.

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 unaudited condensed 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 was measured at fair value as of each reporting date and the change in the fair value for the period was recorded in the condensed 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 Three Months Ended March 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 20,180	$ 7,821	$ 12,359
General and administrative	4,945	2,139	2,806
Total operating expenses	25,125	9,960	15,165
Loss from operations	(25,125)	(9,960)	(15,165)
Other income (expense), net:			
Interest income	2,367	7	2,360
Change in fair value of derivative liability	—	100	(100)
Total other income (expense), net	2,367	107	2,260
Loss before income taxes	(22,758)	(9,853)	(12,905)
Income tax expense	(23)	—	(23)
Net loss	$ (22,781)	$ (9,853)	$ (12,928)

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31, 2023	2022	Change
Bitopertin	$ 2,582	$ 2,355	$ 227
DISC-0974	2,515	2,099	416
MWTX-003	10,042	—	10,042
Personnel-related (including equity-based compensation)	3,120	2,187	933
Other research programs and expenses	1,921	1,180	741
Total research and development expenses	$ 20,180	$ 7,821	$ 12,359

Research and development expenses were $20.2 million for the three months ended March 31, 2023, compared to $7.8 million for the three months ended March 31, 2022. The increase of $12.4 million in research and development expenses was primarily due to a $10.0 million upfront payment under the Mabwell license agreement, as well as a $0.9 million increase in personnel-related costs related to higher research and development headcount.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31, 2023	2022	Change
Personnel-related (including equity-based compensation)	$ 2,082	$ 1,195	$ 887
Legal, consulting and professional fees	1,928	789	1,139
Other expenses	935	155	780
Total general and administrative expenses	$ 4,945	$ 2,139	$ 2,806

General and administrative expenses were $4.9 million for the three months ended March 31, 2023, compared to $2.1 million for the three months ended March 31, 2022. The increase of $2.8 million in general and administrative expenses was primarily due to a $1.1 million increase in legal, consulting and professional fees related to increased legal costs and market research consulting, and a $0.9 million increase in personnel-related costs related to higher general and administrative headcount.

Other Income (Expense), Net

Other income was $2.4 million for the three months ended March 31, 2023, compared to $0.1 million for the three months ended March 31, 2022. The change of $2.3 million in other income (expense), net was primarily due to an increase in interest income based on a larger cash and cash equivalents balance and higher interest rates.

Income Tax Expense

Income tax expense was less than $0.1 million for the three months ended March 31, 2023, compared to no expense for the three months ended March 31, 2022. The change in expense is related to state income tax due to 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 in the foreseeable future as we 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, the proceeds from the merger with Gemini, proceeds from at-the-market offerings and proceeds from a registered

direct offering. Through March 31, 2023, we have received net proceeds of $144.5 million from sales of our Series Seed, Series A and Series B convertible preferred stock, $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 pre-funded warrants in a registered direct offering and $14.6 million from at-the-market offerings. As of March 31, 2023, we had cash and cash equivalents of $236.4 million.

We have incurred significant operating losses since inception and, as of March 31, 2023, had an accumulated deficit of $135.0 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 into 2025. We may also pursue additional cash resources through public or private equity, collaborations or debt financings.

Cash Flows

The following table provides information regarding our cash flows for each period presented (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
Net cash provided by (used in):		
Operating activities	$ (35,466)	$ (13,701)
Investing activities	(29)	(100)
Financing activities	77,306	55
Net increase in cash, cash equivalents and restricted cash	$ 41,811	$ (13,746)

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 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 three months ended March 31, 2023, net cash used in operating activities of $35.5 million was primarily due to our net loss of $22.8 million primarily related to the $10.0 million upfront payment under the Mabwell license agreement and an increase in operating assets and liabilities of $13.8 million primarily related to the payment of merger-related costs which were included in accounts payable at December 31, 2022, partially offset by non-cash expenses of $1.1 million.

During the three months ended March 31, 2022, net cash used in operating activities of $13.7 million was primarily due to our net loss of $9.9 million and change in operating assets and liabilities of $4.1 million primarily related to prepayments on external research and development contracts, partially offset by changes in non-cash expenses of $0.3 million.

Investing Activities

During the three months ended March 31, 2023 and 2022, net cash used in investing activities was related to purchases of property and equipment.

Financing Activities

During the three months ended March 31, 2023, net cash provided by financing activities of $77.3 million consisted primarily of aggregate 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 $14.6 million from the at-the-market offerings.

During the three months ended March 31, 2022, net cash provided by financing activities was related to proceeds from stock option exercises.

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 product 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 requirements for approvals;
- the cost and timing of obtaining materials to produce adequate product supply for any preclinical or clinical development of any product 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 such 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 any 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 receive 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 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.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations as of March 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				
	Total	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 Years
Operating lease commitments[(1)]	$ 1,392	$ 375	$ 782	$ 235	$ —
Total	$ 1,392	$ 375	$ 782	$ 235	$ —

(1) Amounts reflect payments due for our leased office space in Watertown, Massachusetts as of March 31, 2023. The lease term began in November 2021 and will 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 condensed consolidated financial statements.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of our condensed 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 condensed 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. See our Annual Report on Form 10-K for the year ended December 31, 2022 for more information about critical accounting policies as well as a description of our other significant accounting policies.

There have been no material changes to our critical accounting estimates from those described in Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2022.

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 condensed 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, (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 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

As of March 31, 2023 and December 31, 2022, we had cash and cash equivalents of $236.4 million and $194.6 million, respectively, which consisted of cash and money market accounts. 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 we do not have a material exposure to foreign currency risk.

Inflation generally affects us by increasing our cost of 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 three months ended March 31, 2023 and 2022.

ITEM 4. 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 March 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 March 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.

Changes in Internal Control Over Financial Reporting

No change 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 months ended March 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1. 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 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 in this Quarterly Report on Form 10-Q.

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 $22.8 million and $9.9 million for the three months ended March 31, 2023 and 2022, respectively. We had an accumulated deficit of $135.0 million as of March 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, or 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 in 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 may change from time to time;
- the cost of manufacturing our product candidates and products, should they receive regulatory approval, which may vary depending on 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 potential 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; 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 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 INDs in order to commence our planned clinical trials 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 product candidates;
- successfully address the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if any;
- timely file New Drug Applications, or NDAs, and Biologic License Applications, or BLAs, and receive regulatory approvals for our product 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 clinical 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 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 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 into 2025. 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 of 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 the 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 ongoing COVID-19 pandemic.

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 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 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 a Phase 1 clinical trial of MWTX-003 in healthy volunteers in the second half of 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 of these 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 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 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 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 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, for which pre-clinical 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, 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 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. 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 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 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 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 or preliminary data we previously published. As a result, interim, top-line and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim, top-line 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 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 may receive feedback from regulatory authorities that requires us to modify the design or implementation of our preclinical studies or clinical trials or to delay or terminate a clinical trial;
- regulators or IRBs or ethics committees may delay or may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective clinical research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among 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 or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, or we may 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 across indications;
- the number of patients required for clinical trials of our product candidates may be larger than anticipated, enrollment in these clinical trials 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 higher rate than anticipated;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, be unable to provide us with sufficient product supply to conduct or complete preclinical studies or clinical trials, fail to meet their contractual obligations to us in 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 clinical trial sites or investigators;
- we may elect to, or regulators or IRBs or ethics committees may require us or our investigators to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our clinical trials 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 be 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 ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other hematologic disease 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, that may limit patients, 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 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 in pre-clinical models, 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 they 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 product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, 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 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 candidate is 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 regulatory 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 trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA, BLA or other 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 facilities 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 clinical 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.

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. We are initially focused on developing MWTX-003 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, including potential limitations or warnings for our current product candidates and any future product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our current product candidates and any future product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign 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 as 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 be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our current product candidates and any future product candidates or to which we agree as part of a Risk Evaluation and Mitigation Strategy, or REMS, or 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 competitive 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. 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 product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety 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 revocation of 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 and planned Phase 1 clinical trial of MWTX-003 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, 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 clinical trial of bitopertin in DBA, which will be 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 Phase 1b/2 clinical trials of DISC-0974 and ongoing Phase 2 clinical trials of bitopertin 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, and 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 candidates 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 not to continue or renew research, development and/or commercialization programs based on preclinical studies and/or clinical trial results, changes in their strategic focus, availability of funding or other factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators might delay, provide insufficient resources to, or modify or stop research or clinical development for collaboration product 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 to 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 in a 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, which 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 the 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 litigation 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/or 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, 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. 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 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. We may incur added costs and delays in identifying and qualifying any such replacement.

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 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 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, 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 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 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 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.

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 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 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.

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 to 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 product candidate or technology at issue infringes, misappropriates or violates the third party's rights, and, if the court finds that the infringement 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, DISC-0974 and MWTX-003, or future product candidates, or from using our proprietary technologies, unless the third-party licenses 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 cross-licenses to intellectual property rights for our products, or the license to us may be non-exclusive, which would permit third parties to use 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 intellectual 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 securities 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 prospects.

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 cannot be certain that others have not filed patent applications covering our current or future 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 of 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 our 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 licensors 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 in 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 our current or future product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of 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 application 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 particular invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may 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 from 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 patent 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. 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 Commission, upon the recommendation of the EMA's Committee for Orphan Medicinal Products, grants orphan drug designation to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not 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). Additionally, designation is granted for drugs 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 in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers.

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 exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or 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 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 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 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, 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, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access 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. 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 U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which will 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.
- On January 2, 2013, 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 recover 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 and 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 Right to Try Act, was signed into law. The law, among other things, 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.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

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, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to: (i) support legislative reforms that would lower the prices of 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. 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, includes provisions that reduce the 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 new manufacturer financial liability on certain drugs under Medicare Part D, allows the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; requires companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delays 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 designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. 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, 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, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment of up to ten years, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. The HHS, Office of Inspector General, or OIG, heavily scrutinizes relationships between pharmaceutical companies and persons in a position to generate referrals for or the purchase of their products, such as physicians, other healthcare providers, and pharmacy benefit managers, among others. However, there are a number of statutory 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 imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims 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 executing a scheme to defraud any healthcare benefit program (e.g. public or private), or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific 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 require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to HHS information related to transfers of value made to physicians, nurse practitioners, certified nurse anesthetists, physician assistants, clinical nurse specialists, and certified nurse midwives as well as teaching hospitals. Manufacturers are 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 harm consumers; and
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where 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' 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 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 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 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. Other federal and state laws that restrict the use and protect the privacy and security of personally identifiable information, 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 the California Consumer Privacy Act, or CCPA, as amended by the California Privacy Rights Act, or CPRA, which amendments went into effect on January 1, 2023, The CCPA creates specific obligations with respect to processing and storing personal information, and the CPRA amendments created a new state agency that is vested with authority to implement and enforce the CCPA. Additionally, a similar law went into effect 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. 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 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. 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. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the EEA, including personal health data, is subject to the EU General Data Protection Regulation 2016/679, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, 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, 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 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 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, 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), we will be required to incorporate a GDPR transfer mechanism (such as the European Commission approved standard contractual clauses, or SCCs) into our agreements with third parties to govern transfers of personal data outside the EEA. The new SCCs may also impact our business as companies based in the EEA may be reluctant to utilize the new clauses to legitimize transfers 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 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 UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but currently still aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU's GDPR, the European Commission has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EU 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.

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.

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 from cyberattacks, 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 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, such as names, mailing addresses, email addresses, phone numbers and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, 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 security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security 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 or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification 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 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 our sensitive information. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, 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 mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business. 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 is expected to increase 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 in other states.

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 April 30, 2023, we had 51 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 Risks

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.

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 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. Subsequent to these events, additional financial institutions have experienced similar failures and have been placed into receivership. It is possible that other banks will face similar difficulty in the future.

Although we assess our banking 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.

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.

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. 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, we had federal and state net operating loss carryforwards of $69.3 million and $67.7 million, respectively, which begin to expire in various amounts in 2037. As of December 31, 2022, we also had federal and state research and development tax credit carryforwards of $2.7 million and $1.1 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 pandemic, epidemic, or outbreak of an infectious 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, 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 collaborators;
- 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 and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection 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 opinions 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, commercial 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 Quarterly Report on Form 10-Q 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 elected 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 special 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 Officer 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 addition to 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 vote 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 action 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 approval 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, 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 our Annual Report on Form 10-K for the year ended December 31, 2022 lapse, the trading price of our common stock could decline. As of March 31, 2023, we had 19,575,242 shares of common stock outstanding. Of the shares of common stock, 11,632,972 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% 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. 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 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) Recent Sales of Unregistered Securities

None.

(b) Use of Proceeds from Initial Public Offering

Not applicable.

(c) Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS.

The exhibits filed as part of this Quarterly Report are set forth on the Exhibit Index, which is incorporated herein by reference.

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	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on February 14, 2023).
10.1*††	Exclusive License Agreement between Disc Medicine, Inc. and Mabwell Therapeutics, Inc., dated January 19, 2023.
10.2	Securities Purchase Agreement, dated as of February 13, 2023, by and between Disc Medicine, Inc. and the investors identified therein (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on February 14, 2023).
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification 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.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation 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
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

† The annexes, schedules, and certain exhibits to the Merger Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Registrant 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 pursuant to Item 601(b)(10) of Regulation S-K.

SIGNATURES

Pursuant to the requirements 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: May 15, 2023

By: /s/ John Quisel

John Quisel, J.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2023

By: /s/ Joanne Bryce

Joanne Bryce, CPA
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

Certain identified information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential. Information that was omitted has been noted in this document with a placeholder identified by the mark "[***]".

EXCLUSIVE LICENSE AGREEMENT

between

DISC MEDICINE, INC.

and

MABWELL THERAPEUTICS, INC.

Entered into as of January 19, 2023

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Schedule Listing

EXCLUSIVE LICENSE AGREEMENT

This Exclusive License Agreement (this "**Agreement**") is made and entered into as of January 19, 2023 (the "**Execution Date**") by and between Disc Medicine, Inc., a Delaware corporation having its registered address at 321 Arsenal Street, Suite 101, Watertown, MA 02472 ("Disc"), and Mabwell Therapeutics, Inc., a California corporation having its registered address at 505 Coast Boulevard South, Suite 301, La Jolla, CA 92037 ("**Mabwell**"). Disc and Mabwell are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties.**"

Recitals

WHEREAS, Mabwell Controls (as defined below) certain intellectual property rights with respect to Licensed Antibodies (as defined herein) and Licensed Products (as defined herein); and

WHEREAS, Mabwell wishes to grant to Disc, and Disc wishes to take, an exclusive license under such intellectual property rights to Exploit (as defined below) Licensed Antibodies and Licensed Products in the Licensed Territory (as defined below) in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions set forth herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

1. DEFINITIONS

1.1 "**Acquired Affiliate**" has the meaning set forth in Section 5.9(c)(i).

1.2 "**Acquiring Party**" has the meaning set forth in Section 5.9(c)(i).

1.3 "**Affiliate**" means, with respect to a Party, any Person that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, "control" means: (i) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (ii) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.4 "**Agreement"** has the meaning set forth in the preamble hereto.

1.5 "**Alliance Manager**" has the meaning set forth in Section 2.6.

1.6 "**Antibody**" means, with respect to a relevant target, any monoclonal antibody or antigen-binding fragment, modification, or derivative thereof that binds to such target, and includes an immunoglobulin, such as IgA, IgD, IgE, IgG and IgM, in each case, whether multiple or single chain, recombinant or naturally occurring, or a combination of the foregoing, in any species, whole or antigen-binding fragment, including any monospecific antibody, Multispecific Antibody, multimeric antibody, and any analogs, constructs, conjugates, fusions or chemical or other modifications or attachments thereof or thereto. An antigen binding portion of an antibody includes an antigen binding heavy chain, light chain, heavy chain dimer, diabody, Fab fragment, F(ab')2 fragment, single domain, or any FV fragment, including a single chain FV (SCFV), a disulfide stabilized FV fragment (DSFV), or a bispecific DSFV, or a conjugate containing the immunoglobulin or an antigen-binding fragment thereof. For clarity, an antibody that differs in amino acid sequence with respect to the antigen-binding portion thereof will be treated as a separate antibody.

1.7 "**Anti-Corruption Laws**" means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering, or terrorism.

1.8 "**Applicable Law**" means applicable laws, rules, ordinances and regulations, national, supranational, federal, state, local, or foreign law, statute, ordinance, or any rule, regulation, standard, judgment, order, writ, injunction, decree, arbitration award, agency requirement, license, promulgated by a governmental authority including applicable Anti-Corruption Laws, and any applicable rules, regulations, guidelines, policies, procedures or other requirements of the Regulatory Authorities that may be in effect from time to time, including the FFDCA and the PHSA, and having jurisdiction over or related to the relevant subject item.

1.9 "**Arbitration Notice**" has the meaning set forth in Section 13.5(a).

1.10"**Arbitrator**" has the meaning set forth in Section 13.5(a).

1.11"**Arising IP**" means Arising Know-How and Arising Patents.

1.12"**Arising Know-How**" has the meaning set forth in Section 7.1(b).

1.13"**Arising Patents**" has the meaning set forth in Section 7.1(b).

1.14"**Audit Dispute Auditor**" has the meaning set forth in Section 6.10.

1.15"**Biosimilar**" means, with respect to a Licensed Product in a country in the Licensed Territory, any other prescription pharmaceutical product, (a) that is introduced in the Licensed Territory by a Person other than Disc or its Sublicensees who did not purchase such product in a chain of distribution that included any of Disc or its Sublicensees, (b) that is "biosimilar" (as defined in Section 351(i)(2) of the PHSA) or "interchangeable" (as defined in Section 351(i)(3) of the PHSA) to such Licensed Product (or otherwise bioequivalent, biosimilar, interchangeable, or the like, in each case, to such Licensed Product under analogous laws for Antibody products), and (c) that has been licensed or approved as a similar biological medicinal product by FDA pursuant to Section 351(k) of the PHSA, or by EMA pursuant to Directive 2001/83/EC, as may be amended, or any subsequent or superseding law, statute or regulation, or has otherwise obtained Regulatory Approval in such country as a generic, biosimilar, bioequivalent, or interchangeable product from applicable Regulatory Authority by an abbreviated BLA or other abbreviated pathway not requiring the filing of a complete BLA or comparable registration application under the Applicable Law of the FDA or any other applicable Regulatory Authority, including, an application filed under 42 U.S.C. § 262(k) or any similar provisions in a country outside the United States, based in reliance, at least in part, on data generated for a Regulatory Approval of such Licensed Product.

1.16"**BLA**" means a Biologics License Application as defined in the FFDCA, or any corresponding foreign application, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure.

1.17"**Breaching Party**" has the meaning set forth in Section 11.2(a)(i).

1.18"**Business Day**" means a day other than a Saturday or Sunday or a day on which banking institutions in New York, New York or San Diego, California are permitted or required to be closed.

1.19"**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.20"**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs, and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.21"**CDR**" means the complementarity-determining region of an antigen binding region of an Antibody as defined by the Kabat numbering scheme (Kabat et al., Sequences of Proteins of Immunological Interest (1991)).

1.22"**Chairperson**" has the meaning set forth in Section 2.5(a).

1.23"**Change of Control**" means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing at least fifty percent (50%) of the total voting power of all of the then outstanding voting securities of such Party; (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of such Party immediately prior to such transaction, owning at least fifty percent (50%) of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (c) there is a sale, assignment, exclusive license, conveyance, lease or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole that related to this Agreement, through one or more related transactions; provided, however, that any (i) public offering or any other transaction or series of transactions for bona fide capital raising purposes, or (ii) transaction undertaken solely for tax planning purposes or solely to change a Party's domicile, in each case ((i)-(ii)), will not constitute a "Change of Control."

1.24"**Chief Executive Officer**" means, with respect to each Party, the then-current chief executive officer of such Party. As of the Execution Date, the Chief Executive Officer of Disc is John Quisel, and the Chief Executive Officer of Mabwell is Xin Du.

1.25"**Clinical Development Plan**" has the meaning set forth in Section 2.2(b).

1.26"**Clinical Trial Data**" means all data, results, and other information generated by any clinical study or other testing involving the administration of a Licensed Antibody or Licensed Product to a human subject that is conducted by or on behalf of a Party, its Affiliates, or its Sublicensee.

1.27"**Closing Condition**" and "**Closing Conditions**" each have the meaning set forth in Section 12.2.

1.28"**Combination Product**" means a Licensed Product that contains a Licensed Antibody as an active ingredient together with one (1) or more other active ingredients (but excluding any active ingredient that is proprietary to Mabwell and that is not a Licensed Antibody) and is sold for a single price either as a fixed dose/unit or as separate doses/units in a single package.

1.29"**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of, or sale of a product, including activities related to marketing, promoting, distributing, and importing such product, maintaining Regulatory Approval of a product, interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, "**Commercialize**" means to engage in Commercialization.

1.30"**Commercialization Plan**" has the meaning set forth in Section 2.2(c).

1.31"**Commercial Milestone Event**" has the meaning set forth in Section 6.2(b).

1.32"**Commercial Milestone Payment**" has the meaning set forth in Section 6.2(b).

1.33"**Commercially Reasonable Efforts**" means, with respect to the performance of Exploitation activities with respect to a Licensed Product, the carrying out of such activities using efforts and resources comparable to the efforts and resources commonly used by research-based bio pharmaceutical companies of comparable size and resources as Disc for compounds or products of similar market potential at a similar stage in development or product life, taking into account issues of intellectual property scope, subject matter and coverage, safety and efficacy, approved labeling, manufacturing challenges, supply chain disruptions, Regulatory Authority feedback, the likelihood of Regulatory Approval given the Regulatory Authority involved, product profile, competitiveness with respect to Third Party products in the marketplace, and profitability (including pricing and reimbursement status achieved or likely to be achieved) [***]. Commercially Reasonable Efforts will be determined on a country-by-country basis for

a particular Licensed Product, and it is anticipated that the level of effort will be different for different markets and will change over time, reflecting changes in the status of Licensed Product and the market(s) involved.

1.34"**Competing Product**" means [***].

1.35"**Confidential Information**" has the meaning set forth in Section 8.1.

1.36"**Control**" means, with respect to any materials, item of Know-How, Regulatory Documentation and Results, Patent or other intellectual property right, possession of the right by a Party, whether directly or indirectly and whether by ownership, license or otherwise (other than by operation of the license and other grants in Article 5), to grant a license, sublicense, or other right (including the right to reference Regulatory Documentation and Results) to or under such materials, Know-How, Regulatory Documentation and Results, Patent or other intellectual property right to the other Party, as provided for herein, without violating the terms of any agreement with any Third Party. Notwithstanding the foregoing, in the event any materials, item of Know-How, Regulatory Documentation and Results, Patent or other intellectual property right is obtained by or licensed to a grantor, to the extent grantor is permitted to grant the foregoing rights to grantee, after the Execution Date, the practice of which by the grantee pursuant to the license(s) granted to it under this Agreement would require payment to any Third Party (by the grantor), then the grantor shall give prompt notice to the grantee, in sufficient detail to permit the other Party to evaluate such materials, item of Know-How, Regulatory Documentation and Results, Patent or other intellectual property right, and payment and other obligations and conditions applicable to the grantee as a sublicense, and such materials, item of Know-How, Regulatory Documentation and Results, Patent or other intellectual property right will be deemed Controlled only if the grantee has accepted such payment and other obligations and conditions in writing. In addition, notwithstanding anything in this Agreement to the contrary, a Party and its Affiliates will be deemed to not Control any materials, item of Know-How, Regulatory Documentation and Results, Patent or other intellectual property right that is owned or controlled by an Acquired Affiliate, except to the extent that any such materials, item of Know-How, Regulatory Documentation and Results, Patent or other intellectual property right (a) was developed in the course of such Party's or such Acquired Affiliate's performance of activities under this Agreement or (b) through the exploitation of such Party's Know-How, Regulatory Documentation and Results, Patent or other intellectual property right, was actually used in the course of such Party's or such Acquired Affiliate's performance of activities under this Agreement, or (c) was already licensed by such Acquired Affiliate to such Party under this Agreement prior to the applicable Change of Control.

1.37"**Core Licensed Patents**" has the meaning set forth in Section 7.2(a).

1.38"**Cover**" means, with respect to a Patent and any product, process, method, or composition, that, in the absence of ownership of or a license granted under such Patent, the manufacture, use, sale, offering for sale, importation, practice, or other Exploitation of such product, process, method, or composition would infringe a Valid Claim of such Patent.

1.39"**Derivatives**" means [***].

1.40"**Development**" means all activities related to research, pre-clinical testing, other non-clinical testing, test method development, stability testing, toxicology, clinical studies, statistical analysis and report writing, the preparation and submission of BLAs, regulatory affairs with respect to the foregoing, and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. When used as a verb, "Develop" means to engage in Development.

1.41"**Development and Regulatory Milestone Event**" has the meaning set forth in Section 6.2(a).

1.42"**Development and Regulatory Milestone Payment**" has the meaning set forth in Section 6.2(a).

1.43"**Development Plan**" has the meaning set forth in Section 2.2(b).

1.44"**Directed Against**" means, with respect to an Antibody and its relevant target, that such Antibody is engineered or selected to modulate such target or ligand thereof for therapeutic benefit.

1.45"**Disc**" has the meaning set forth in the preamble hereto.

1.46"**Disc Background IP**" has the meaning set forth in Section 7.1(a).

1.47"**Disc Indemnitees**" has the meaning set forth in Section 10.2.

1.48"**Disc Regulatory Documentation and Results**" means any Regulatory Documentation and Results that are Controlled by Disc or any of its Affiliates or Sublicensees during the Term.

1.49"**Disc Regulatory Results**" means any Regulatory Results that are Controlled by Disc or any of its Affiliates or Sublicensees during the Term.

1.50"**Dispute**" has the meaning set forth in Section 13.5(a).

1.51"**Divestiture**" has the meaning set forth in Section 5.9(c)(i).

1.52"**Dollars**" or "**$**" means United States Dollars.

1.53"**Effective Date**" has the meaning set forth in Section 12.1.

1.54"**EMA**" means the European Medicines Agency and any successor agency thereto.

1.55"**Enforcement or Defense Action**" has the meaning set forth in Section 7.3(a).

1.56"**Enforcing Party**" means the party prosecuting an Enforcement or Defense Action pursuant to Section 7.3(b).

1.57"**European Union**" or "**EU**" means the economic, scientific and political organization of member states as it may be constituted from time to time, which as of the Execution Date consists of Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

1.58"**Execution Date**" has the meaning set forth in the preamble hereto.

1.59"**Exploit**" means to make, have made, import, use, have used, sell, have sold, offer for sale, practice, research, Develop, Commercialize, register, Manufacture, have Manufactured, hold, keep (whether for disposal or otherwise), export, transport, distribute, promote, market, dispose of, and otherwise exploit. "**Exploitation**" means any activities that Exploit a compound, product, or process.

1.60"**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.61"**FFDCA**" means the United States Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.62"**Field**" means all fields of use.

1.63"**Firewalls**" means, with respect to a Party, effective walls and screens established between such Party, on the one hand, and on the other hand an Acquired Affiliate or any Person that becomes an Affiliate of such Party after the Execution Date as a result of a Change of Control of such Party, in each case that has a Competing Product, to ensure that no non-public information, materials (such as lab notebooks, document management systems or other documented or memorialized Know-How) or non-personnel resources directly relating to Licensed Antibody

or Licensed Product are accessible by personnel of the Acquired Affiliate or such Person working on the Competing Product. For clarity, where senior management personnel review and evaluate plans and information regarding the activities under this Agreement solely in connection with making portfolio decisions among product opportunities, including such other product or product candidates, such senior management personnel shall not be deemed to be working on the Competing Product under this Agreement so long as they do not pass information from one program to another.

1.64"**First Commercial Sale**" means, with respect to a Licensed Product and a country, the first sale for monetary value for use or consumption by the end user of such Licensed Product in such country after the first Regulatory Approval for such Licensed Product has been obtained in such country. Sales prior to receipt of Regulatory Approval for such Licensed Product, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale.

1.65"**First Indication**" has the meaning set forth in Section 6.2(a).

1.66"**Force Majeure Event**" has the meaning set forth in Section 13.1.

1.67"**Force Majeure Notice**" has the meaning set forth in Section 13.1.

1.68"**GAAP**" means, with respect to Disc or its Sublicensees, United States generally accepted accounting principles or International Financial Reporting Standards, in each case, consistently applied.

1.69"**GMP**" means the then-current good manufacturing practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time.

1.70"**Gross Sales**" has the meaning set forth in the definition of "Net Sales."

1.71"**Identifying Party**" has the meaning set forth in Section 8.3(a).

1.72"**IND**" means (a) an investigational new drug application filed with the FDA for authorization to commence clinical studies and its equivalent in other countries or regulatory jurisdictions (including any investigational medicinal product dossier in the European Union); and (b) all supplements and amendments that may be filed with respect to the foregoing.

1.73"**IND Approval**" means (a) with respect to an IND filed with the FDA in the United States, the earlier of (i) notification by the FDA that the clinical investigations in the IND may begin in accordance with 21 CFR § 312.40, and (ii) thirty (30) days after the FDA receives the IND, unless the FDA provides notice that the investigations described in the IND are subject to a clinical hold under 21 CFR § 312.42; and (b) with respect to an IND filed in countries or regulatory jurisdictions outside of the United States, (i) equivalent notification received by the applicable Regulatory Authority that clinical investigations in the IND may begin, or (ii) passage of the equivalent time period (if applicable) without the applicable Regulatory Authority providing notice that clinical investigations in the IND may not begin.

1.74"**Indemnification Claim Notice**" has the meaning set forth in Section 10.3(a).

1.75"**Indemnified Party**" has the meaning set forth in Section 10.3(a).

1.76"**Indication**" means a separate and distinct disease or medical condition in humans (a) for which a compound or product that is in clinical studies is intended to treat in such clinical studies, or (b) for which a compound or product has received a separate and distinct marketing authorization approval with an approved label claim to treat such disease or condition, as applicable. For clarity, (i) moving from one line of therapy to another within an Indication will not be considered a new Indication, a non-limiting example of which is moving from second line therapy to first line therapy, (ii) a single Indication would include a separate and distinct disease or medical condition in humans, regardless of prophylactic or therapeutic use, pediatric or adult use and irrespective of different formulation(s), dosage forms, dosage strengths, or delivery system(s) used, and (iii) obtaining a label expansion for use of a compound or product in combination with another pharmaceutical product will not be considered to be a new Indication.

1.77"**Initiation**" means, with respect to a clinical trial, the first administration of the studied drug product(s) (or, if applicable, the first dose of a comparator product or placebo, whichever comes first) to a patient enrolled in such clinical trial. "**Initiate**" has a correlative meaning to Initiation.

1.78"**Inventory**" has the meaning set forth in Section 4.4(a).

1.79"**Joint Improvement IP**" means Joint Improvement Know-How and Joint Improvement Patents.

1.80"**Joint Improvement Know-How**" has the meaning set forth in Section 7.1(a).

1.81"**Joint Improvement Patents**" has the meaning set forth in Section 7.1(b).

1.82"**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 2.5(a).

1.83"**Know-How**" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, inventions (whether or not patentable), works of authorship, drawings, assembly procedures, computer programs, apparatuses, specifications, cell lines and related media. Know-How specifically excludes Licensed Materials and Regulatory Documentation and Results.

1.84"**Lead Party**" has the meaning set forth in Section 7.5.

1.85"**Licensed Antibody**" means (a) each of MWTX-001, MWTX-002, and MWTX-003 (each, an "**Initial Antibody**"), including any murine forms of each Initial Antibody or (b) any monospecific, monoclonal variant obtained by modifying the structure or sequence of any Initial Antibody [***]

1.86"**Licensed Improvement IP**" means Licensed Improvement Know-How and Licensed Improvement Patents.

1.87"**Licensed Improvement Know-How**" has the meaning set forth in Section 7.1(b).

1.88"**Licensed Improvement Patents**" has the meaning set forth in Section 7.1(b).

1.89"**Licensed IP**" means Licensed Know-How and Licensed Patents.

1.90"**Licensed Know-How**" shall mean all Know-How, which is Controlled by Mabwell or any of its Affiliates as of the Execution Date or during the Term, including the Licensed Improvement Know-How and Mabwell's interest in the Joint Improvement Know-How that is necessary or reasonably useful to Exploit one or more Licensed Antibodies or Licensed Products in the Licensed Territory

1.91"**Licensed Materials**" means Mabwell's Licensed Antibody cell lines, cell banks, related media and other scientific materials, if any, in the type and quantity listed on **Schedule 1.91** attached hereto, and all progeny thereof.

1.92"**Licensed Patents**" means all Patents Controlled by Mabwell or any of its Affiliates as of the Execution Date or during the Term, including the existing Patents set forth in **Schedule 1.92**, the Licensed Improvement Patents and Mabwell's interest in the Joint Improvement Patents, that are necessary or reasonably useful to Exploit one or more Licensed Antibodies or Licensed Products in the Licensed Territory.

1.93"**Licensed Product**" means any pharmaceutical product (including all forms, presentations, doses and formulations) that contains a Licensed Antibody as an active ingredient, alone or as a Combination Product, but excluding [***] proprietary to Mabwell or any of its Affiliates that is not a Licensed Antibody.

1.94"**Licensed Territory"** means all countries of the world, other than Mabwell Territory.

1.95"**Losses**" has the meaning set forth in Section 10.1.

1.96"**Mabwell**" has the meaning set forth in the preamble hereto.

1.97"**Mabwell Background IP**" has the meaning set forth in Section 7.1(a).

1.98"**Mabwell Indemnitees**" has the meaning set forth in Section 10.1.

1.99"**Mabwell Regulatory Documentation and Results**" means any Regulatory Documentation and Results that are Controlled by Mabwell or any of its Affiliates or Sublicensees as of the Execution Date or during the Term.

1.100"**Mabwell Regulatory Results**" means any Regulatory Results that are Controlled by Mabwell or any of its Affiliates or Sublicensees as of the Execution Date or during the Term.

1.101"**Mabwell Shareholder Approval**" has the meaning set forth in Section 12.3.

1.102"**Mabwell Territory**" means Greater China Region (mainland China, Hong Kong, Macau, and Taiwan) and Southeast Asia (Brunei, Burma (Myanmar), Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Singapore, Thailand and Vietnam).

1.103"**Major Market**" means each of the U.S., the United Kingdom and each member country of the European Union.

1.104"**Manufacturing**" means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and holding of a product or any intermediate thereof, including process development, process qualification and validation, formulation, scale-up, product characterization, stability testing, quality assurance, and quality control. When used as a verb, "Manufacture" means to engage in Manufacturing.

1.105"**Manufacturing Technology Transfer**" has the meaning set forth in Section 4.5(b).

1.106"**Material Adverse Event**" means any event, occurrence, condition, change, circumstance, development, effect or state of facts that has had or would reasonably be expected to have, individually or in the aggregate, a material adverse effect with respect to (a) the business, condition (financial or otherwise), operations, assets, liabilities, prospects or results of operations of a Party and its Affiliates taken as a whole or (b) the ability of a Party to timely perform their respective obligations under this Agreement or to consummate the transactions contemplated therein on a timely basis; provided, however, that "material adverse effect" will not include the effect of any event, occurrence, condition, change, circumstance, development, effect or state of facts arising out of or attributable to any of the following, either alone or in combination: (i) general economic or political conditions (including those affecting the securities markets), (ii) any mutually agreed announcement of the execution of this Agreement or of the consummation of the transaction contemplated hereby, (iii) Force Majeure Events occurring after the Execution Date or (iv) any changes in Applicable Law, in each case of clauses (i), (ii) or (iv) only to the extent such event, occurrence, condition, change, circumstance, development, effect or state of facts does not have a

disproportionate effect on a Party or its Affiliates as compared to other participants operating in the biopharmaceutical industry in the same markets in which such Party or its Affiliates conduct their businesses.

1.107"**Materials**" means antibody cell lines, cell banks, related media and other scientific materials, provided by or on behalf of a Party to the other Party or its designee(s) under this Agreement, and all progeny thereof.

1.108"**Multispecific Antibody**" means any Antibody that combines in a single construct two (or more) different antibody variable domain sequences as defined in Section 1.6, each capable of specifically binding a distinct epitope of an antigen, molecule, immunogen, hapten, or target, including any bispecific, multi-specific, or multivalent antibody, and any analogs, constructs, conjugates, fusions or chemical or other modifications or attachments thereof or thereto. For clarity, "Multispecific Antibody" includes any bispecific Antibody.

1.109"**Multispecific Product**" means a Multispecific Antibody product Directed Against one or more biological targets that includes the Target.

1.110"**MWTX-001**" means the Antibody known as "MWTX-001", having the specific sequence as set forth on **Schedule 1.110**.

1.111"**MWTX-002**" means the Antibody known as "MWTX-002", having the specific sequence as set forth on **Schedule 1.111**.

1.112"**MWTX-003**" means the Antibody known as "MWTX-003", having the specific sequence as set forth on **Schedule 1.112**.

1.113"**Net Sales**" means, with respect to any period, the gross amount accrued (in accordance with GAAP, consistently applied) by Disc, its Affiliates or its Sublicensees or third party distributors from or to, Third Parties for the sale of a Licensed Product (the "**Gross Sales**") in the Licensed Territory, less the following deductions actually incurred, allowed, paid, accrued or specifically allocated in its financial statements for such Licensed Product (all in accordance with GAAP, consistently applied) by Disc or a Sublicensee, whichever is the selling party, and attributable to the sale of such Licensed Product, and not otherwise recovered by or reimbursed to Disc, its Affiliates or Sublicensees: [***]

All discounts, allowances, credits, rebates, and other deductions set forth above shall be fairly and equitably allocated to such Licensed Product and other product(s) of Disc, its Affiliates or its Sublicensee(s) such that such Licensed Product does not bear a disproportionate portion of such deductions.

For purposes of determining Net Sales, a "sale" shall not include transfers or dispositions of a Licensed Product for pre-clinical or clinical purposes, compassionate use, humanitarian and charitable donations, indigent programs, or as samples, in each case, without charge. Disc's transfer of any Licensed Product to a Sublicensee or a third party distributor shall not result in any Net Sales, unless such Licensed Product is consumed or sold to a Third Party by such Sublicensee or a third party distributor in the course of its commercial activities.

In the case of pharmacy incentive programs, hospital performance incentive programs, chargebacks, disease management programs, similar programs or discounts on portfolio product offerings, all rebates, discounts, and other forms of reimbursements shall be allocated among Licensed Products on the basis on which such rebates, discounts and other forms of reimbursements were actually granted or, if such basis cannot be determined, in accordance with Disc's or its or their Sublicensees' existing allocation method; provided that any such allocation to a Licensed Product (i) shall be done in accordance with Applicable Law, including any price reporting laws, rules, and regulations and (ii) subject to clause (i), shall be no greater than a pro rata allocation, such that the portion of each of foregoing rebates, discounts, and other forms of reimbursements shall not be included as deductions from Gross Sales hereunder in any amount greater than the proportion of the number of units of such Licensed Product sold by Disc or its Sublicensees to Third Parties hereunder compared to the number of units of all the products sold by Disc or its Sublicensees to Third Parties to which such foregoing rebate, discount, or other form of reimbursement, as applicable, are granted.

In the event that a Licensed Product is sold in any country in the form of a Combination Product, Net Sales of such Combination Product shall be adjusted by multiplying actual Net Sales of such Combination Product in such country calculated pursuant to the foregoing definition of "Net Sales" by the fraction A/(A+B), where A is the average invoice price in such country of any Licensed Product that contains the same Licensed Antibody(ies) as such Combination Product as its sole active ingredient(s), if sold separately in such country, and B is the average invoice price in such country of each product that contains active ingredient(s) other than Licensed Antibody(ies) contained in such Combination Product as its sole active ingredient(s), if sold separately in such country. If either a Licensed Product that contains Licensed Antibody(ies) as its sole active ingredient or a product that contains any active ingredient(s) other than Licensed Antibody(ies) in the Combination Product as its sole active ingredient(s) is not sold separately in a particular country, prior to the date of the first commercial sale of such Combination Product, through the JSC or otherwise, the Parties shall negotiate in good faith and reach mutual agreement on a reasonable adjustment to Net Sales in such country that takes into account the medical contribution to the Combination Product of, and all other factors reasonably relevant to the relative value of, Licensed Antibody(ies), on the one hand, and all of the other active ingredient(s), collectively, on the other hand.

1.114"**Non-Breaching Party**" has the meaning set forth in Section 11.2(a)(i).

1.115"**Notice Period**" shall have the meaning set forth in Section 11.2(a)(i).

1.116"**Party**" and "**Parties**" have the meaning set forth in the preamble hereto.

1.117"**Patent Challenge**" shall have the meaning set forth in Section 11.2(d).

1.118"**Patents**" means: (i) all national, regional, and international patents and patent applications, including provisional patent applications; (ii) all patent applications filed either from such patents or patent applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications; (iii) any and all patents that have issued or in the future issue from the foregoing patent applications ((i) and (ii)), including utility models, petty patents, innovation patents, design patents, and certificates of invention; (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations, and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((i), (ii) and (iii)); and (v) any equivalent rights, including so-called pipeline protection or any importation, revalidation, confirmation, introduction patent, registration patent, or patent of additions to any of such foregoing patent applications and patents ((i), (ii), (iii), and (iv)).

1.119"**Payment**" has the meaning set forth in Section 6.6(a).

1.120"**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture, or other similar entity or organization, including a government or political subdivision, department, or agency of a government.

1.121"**Phase I Clinical Trial**" means a human clinical trial of a product in subjects (whether or not patients) with the endpoint of determining initial tolerance, safety, pharmacokinetic, or pharmacodynamic information in single dose, single ascending dose, multiple dose, or multiple ascending dose regimens, that would satisfy the requirements of 21 C.F.R. §312.21(a), or similar clinical study in a country other than the United States, in each case, whether such clinical trial is referred to as a phase I clinical study.

1.122"**Phase Ib Clinical Trial**" means a human clinical trial, or portion thereof, of a Licensed Product in patients with the endpoint of determining initial tolerance, safety, pharmacokinetic, or pharmacodynamic information in single dose, single ascending dose, multiple dose, or multiple ascending dose regimens, that would satisfy the requirements of 21 C.F.R. §312.21(a), or similar clinical trial in a country other than the United States, in each case, whether such clinical trial is referred to as a phase Ib clinical trial.

1.123"**Phase I Initiation Payment**" has the meaning set forth in Section 6.2(a).

1.124"**Phase II Clinical Trial**" means a human clinical trial, or portion thereof, of a Licensed Product in patients that is designed to support the safety and biological activity of such Licensed Product for its intended use, and to generate information with respect to warnings, precautions, and adverse reactions that are associated with such Licensed Product in the dosage range to be prescribed or that may be used to find or determine such dosage, that would satisfy the requirements of 21 C.F.R. §312.21(b), or similar clinical trial in a country other than the United States, in each case, whether such clinical trial is referred to as a phase II clinical trial.

1.125"**Phase III Clinical Trial**" means a pivotal or registrational human clinical trial, or portion thereof, of a Licensed Product that would satisfy the requirements of 12 C.F.R. §312.21(b) or 21 C.F.R. §312.21(c), which (whether at the time of Initiation or upon any later expansion, if applicable) has the principal purpose of achieving a determination of safety and efficacy and is designed to provide an adequate basis for obtaining Regulatory Approval to market the such Licensed Product for patients with the disease or condition under such trial, or similar clinical trial in a country other than the United States, in each case, whether such clinical trial is referred to as a phase III clinical trial.

1.126"**PHSA**" means the United States Public Health Service Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.127"**Product Specification**" has the meaning set forth in Section 4.4(a).

1.128"**Progress Report**" has the meaning set forth in Section 2.1(c).

1.129"**Prosecution**" of a Patent means the preparation, filing, prosecution, and maintenance of such Patent. "**Prosecute**" means to engage in Prosecution.

1.130"**Qualified Contract Manufacturer**" means any Third Party contract manufacturer approved by Mabwell (such approval not to be unreasonably withheld, delayed or conditioned) that is generally regarded within the biopharmaceutical industry as an entity that does not (a) inappropriately disclose or misuse the confidential information of its customers and licensors or (b) infringe the patent rights or misappropriate the trade secrets of its customers and licensors. For clarity, Qualified Contract Manufacturers approved by Mabwell as of the Execution Date, if any, are set forth on **Schedule 1.130**, and Mabwell shall have the right to change such Qualified Contract Manufacturer upon written notice to Disc.

1.131"**Quality Agreement**" has the meaning set forth in Section 4.4(d).

1.132"**Regulatory Approval**" means any and all approvals, licenses, registrations or authorizations of any Regulatory Authority in a country necessary to commercially distribute, sell, or market a product or compound in such country, including, where applicable, (i) pricing or reimbursement approval in such country; (ii) pre- and post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto); and (iii) labeling approval.

1.133"**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils, or other government entities regulating or otherwise exercising authority with respect to the Exploitation of a product, including the FDA in the United States and the EMA in the European Union.

1.134"**Regulatory Documentation**" has the meaning set forth in the definition of "Regulatory Documentation and Results".

1.135"**Regulatory Documentation and Results**" means with respect to a Licensed Antibody or Licensed Product, all (a) applications (including all INDs and BLAs), registrations, licenses, authorizations, and approvals (including Regulatory Approvals), regulatory materials, drug dossiers, master files (including drug master files, as defined by 21 C.F.R. § 314.20, and any non-United States equivalents), relating to such Licensed Antibody or Licensed Product; and (b) correspondence, records, and reports submitted to or received from Regulatory Authorities (including

minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files, relating to such Licensed Antibody or Licensed Product ((a) and (b) collectively, "**Regulatory Documentation**"); (c) data generated in the course of any pre-clinical studies conducted in support of the applications or registrations in (a); (d) clinical and other data contained or relied upon in any of the foregoing; (e) clinical study reports relating to such Licensed Antibody or Licensed Product; (f) and any information that relates to a Licensed Antibody or Licensed Product and to pharmacology, toxicology, chemistry, manufacturing and controls data, methods, processes, reports, executed batch records, safety, or efficacy; (g) any safety database required to be maintained for Regulatory Authorities relating to such Licensed Antibody or Licensed Product; and (h) all other data and results (including CMC information) generated in the conduct of any pre-clinical or clinical studies in support of Regulatory Approval for such Licensed Antibody or Licensed Product ((c) – (h) collectively, "**Regulatory Results**").

1.136"**Regulatory Exclusivity**" means, with respect to a Licensed Product in a country, any exclusive marketing rights (other than a Patent) granted to Disc or any of its Affiliates or Sublicensees by a Regulatory Authority for such Licensed Product in such country.

1.137"**Regulatory Results"** has the meaning set forth in the definition of "Regulatory Documentation and Results".

1.138"**Representatives**" has the meaning set forth in Section 8.1.

1.139"**Retention Period**" has the meaning set forth in Section 4.4(a).

1.140"**Reversion Technology Transfer**" has the meaning set forth in Section 11.6(b).

1.141"**Royalty Term**" means, with respect to each Licensed Product and each country in the Licensed Territory, the period beginning on the date of the First Commercial Sale of such Licensed Product in such country and ending on the last to occur of: (i) the expiration of the last-to-expire Licensed Patent in such country that Covers such Licensed Product in such country; (ii) loss of any Regulatory Exclusivity for such Licensed Product in such country; or (iii) [***] years from the date of the First Commercial Sale of such Licensed Product in such country.

1.142"**SDEA**" has the meaning set forth in Section 3.5.

1.143"**Second Indication**" has the meaning set forth in Section 6.2(a).

1.144"**Senior Officer**" means with respect to each Party, a c-suite executive employee, other than the Chief Executive Officer, with relevant subject matter expertise with respect to the nature of the dispute between the Parties.

1.145"**Sublicense Revenue**" means all consideration actually received by Disc or any of its Affiliates for the grant of a sublicense, a non-refundable option (including for an initially refundable option, but only for consideration actually received after such option becomes non-refundable) to obtain a sublicense (including both the grant and the exercise of the option) or a covenant not to sue or similar rights with respect to the rights conferred upon Disc in this Agreement, including any upfront or fixed license payments, and all milestone payments triggered by the achievement of development, regulatory or commercial milestone events of Licensed Product, subject to the following exclusions: [***]. Subject to the forgoing clauses [***], to the extent Disc sublicenses or grants a non-refundable option (including for an initially refundable option, but only for consideration actually received after such option becomes non-refundable), a covenant not to sue or similar rights under the Licensed IP, Licensed Materials, or Mabwell Regulatory Documentation and Results together with Patents, Know-How, materials, or other intellectual property (other than Licensed IP, Licensed Materials, and Mabwell Regulatory Documentation) owned or otherwise Controlled by Disc in the same sublicense agreement, Disc and Mabwell shall discuss in good faith the allocation of consideration received under such sublicense agreement into Sublicense Revenue and non-Sublicense Revenue, provided that if the Parties are unable to come to an agreement on the proposed allocation after discussing such proposed allocation in good faith, then the determination of such allocation shall be subject to the dispute resolution process as described in Section 13.5; and provided further that in no event shall the amount allocated to the Licensed

IP, Licensed Materials or Mabwell Regulatory Documentation and Results be less than [***] of all considerations received for the Licensed IP, Licensed Materials, or Mabwell Regulatory Documentation and Results and other rights in the aggregate. Except as set forth under this Section 1.145 and for the avoidance of doubt, Sublicense Revenue shall also expressly exclude any other consideration otherwise due or payable by Disc or any of its Affiliates to Mabwell elsewhere under this Agreement for the grant of a sublicense (including any consideration actually received upon the exercise of an option right) or a covenant not to sue with respect to the rights conferred upon Disc in this Agreement.

1.146"**Sublicensee**" means any Affiliate of a Party or any Third Party that is granted a sublicense, a non-refundable option (including for an initially refundable option, but only for consideration actually received after such option becomes non-refundable) to obtain a sublicense (whether the option has been exercise or not) or a covenant not to sue or similar rights by either Party under the rights licensed to such Party pursuant to Article 5.

1.147"**Target**" means the biological target known in the scientific arts as transmembrane serine protease 6 ("**TMPRSS6**"), including any and all naturally occurring mutations, variants and alternative sequences thereof.

1.148"**Tax**" or means any form of tax or taxation, levy, duty, charge, social security charge, contribution, or withholding of whatever nature in the nature of a tax (including any related fine, penalty, surcharge, or interest) imposed by, or payable to, a Tax Authority.

1.149"**Tax Authority**" means any government, state, municipality, or any local, state, federal, or other fiscal, revenue, customs or excise authority, body, or official anywhere in the world, authorized to levy Tax.

1.150"**Technical Failure**" means [***].

1.151"**Term**" has the meaning set forth in Section 11.1.

1.152"**Terminated Country**" has the meaning set forth in Section 11.4.

1.153"**Terminated Product**" has the meaning set forth in Section 11.4.

1.154"**Termination Notice**" has the meaning set forth in Section 11.2(a)(i).

1.155"**Third Indication**" has the meaning set forth in Section 6.2(a).

1.156"**Third Party**" means any Person other than Mabwell, Disc and their respective Affiliates.

1.157"**Third Party Claims**" has the meaning set forth in Section 10.1.

1.158"**Third Party Infringement Action**" has the meaning set forth in Section 7.4.

1.159"**Third Party IP Right**" has the meaning set forth in Section 7.5.

1.160"**Tolling Period**" has the meaning set forth in Section 11.2(a)(i).

1.161"**United Kingdom**" means the United Kingdom of Great Britain and Northern Ireland, consisting of England, Scotland, Wales, and Northern Ireland.

1.162"**United States**" or "**U.S.**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.163"**Valid Claim**" means (a) a claim of any issued and unexpired Patent that has not been subject to (i) irretrievable lapse, abandonment, revocation, dedication to the public, or disclaimer; or (ii) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court, governmental agency, national or regional patent office, or other appropriate body that has competent jurisdiction, such holding, finding, or decision being final

and unappealable or unappealed as a matter of right within the time allowed for such appeal; or (b) a claim of a pending Patent application that was filed and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application, and excluding any claim of such application that has been pending for more than [***] from the date of filing of the earliest patent application to which such patent application claims priority, unless and until such claim is included in an issued or granted patent.

1.164"**VAT**" has the meaning set forth in Section 6.6(c).

1.165"**Withholding Tax Action**" has the meaning set forth in Section 6.6(a).

2. DEVELOPMENT AND COMMERCIALIZATION

2.1 **Diligence Obligations.**

(a) [***]

(b) Without limiting the foregoing, Disc shall, directly on its behalf, or through one or more of its Affiliates or Sublicensees, Initiate a Phase I Clinical Trial for a Licensed Product in the First Indication in the Licensed Territory by [***]; provided, however, if at any time Disc determines that it is unlikely to meet any such deadline despite using Commercially Reasonable Efforts, Disc shall notify Mabwell in writing and explain in reasonable detail (other than in the case where a delay results from Mabwell's, its Affiliate's or Sublicensee's action or inaction), the technical or manufacturing challenges, safety or efficacy concerns, supply chain disruptions, patient enrollment difficulties, feedback from a Regulatory Authority or other reasons therefore causing the delay, and in such case, so long as Disc is using Commercially Reasonable Efforts to meet such deadline, such deadline shall be tolled or automatically extended for [***], during which time the Parties shall discuss the resolution of such reasons for any delays, if practicable. Without limiting the foregoing, the deadlines shall be automatically extended by the duration of any delay caused by: [***]. Any further extension of the deadlines, due to reasons other than those set forth in clauses [***], shall require Mabwell's written approval, which shall not be unreasonably withheld, conditioned or delayed for up to [***]. Notwithstanding anything to the contrary in this Section 2.1(b), Disc shall be deemed to have Initiated a Phase I Clinical Trial for a Licensed Product in the First Indication in the Licensed Territory if Disc pays Mabwell the Phase I Initiation Payment.

(c) By [***] during the Term, Disc will submit a written progress report to Mabwell covering [***], which report in a mutually agreed format shall include information sufficient to enable Mabwell to ascertain progress by Disc or its Sublicensees toward meeting its diligence obligations hereunder (each, a "**Progress Report**"). Each Progress Report shall describe, where relevant: progress toward Development, obtaining Regulatory Approval for, and Commercialization of at least one Licensed Product, including work completed, key scientific discoveries, summary of work-in-progress, current schedule of anticipated events or milestones, estimated total Development time remaining before a Licensed Product will be Commercialized, market plans for introduction of such Licensed Product, and progress of marketing and selling, including the quantities of Licensed Product in inventory and sales information of the Licensed Product.

2.2 **Development and Commercialization Responsibilities.**

(a) Disc shall be responsible for all Development and Commercialization activities with respect to Licensed Antibodies and Licensed Products in the Licensed Territory. Mabwell shall be responsible for all Development and Commercialization activities with respect to Licensed Antibodies and Licensed Products in the Mabwell Territory. Disc shall have the right to generate, or otherwise make or Exploit any Combination Product in the Licensed Territory solely in accordance with the following: if Disc desires to generate, or otherwise make or Exploit any Combination Product, Disc shall promptly notify Mabwell in writing, including the other active pharmaceutical ingredient being incorporated in such Combination Product and any proposed update to the Development Plan with respect thereto. Disc shall have the right to generate, or otherwise make or Exploit such Combination Product pursuant to the Development Plan, as amended from time to time pursuant to Section 2.2(c).

(b) All Development of each Licensed Antibody and Licensed Product by or on behalf of Disc under this Agreement will be conducted pursuant to a written development plan that sets forth, in reasonable detail, all pre-clinical, clinical and regulatory activities (and the anticipated timelines) to be conducted by or on behalf of Discs to obtain Regulatory Approval of at least one Licensed Product in the Licensed Territory (including but not limited to the Major Markets) (the "**Development Plan**"). As of the Effective Date, the Parties have agreed on the initial Development Plan, which is attached hereto as **Schedule 2.2(b)**. From time to time, but at least [***], Disc will propose updates or amendments to the Development Plan in consultation with the JSC and submit such proposed updated or amended plan to the JSC for its review and approval before adopting such update or amendment. Disc shall also provide to Mabwell, via the JSC, a reasonably detailed clinical development plan, including the protocols and dosing regimen for all clinical trials of the Licensed Products to be conducted by or behalf of Disc and all investigator-sponsored and investigator-initiated trials of the Licensed Products in the Licensed Territory(the "**Clinical Development Plan**"), in each case prior to any patient enrollment, for review and approval by the JSC.

(c) All Commercialization of each Licensed Antibody and Licensed Product by or on behalf of Disc will be conducted, pursuant to a written plan that sets forth in reasonable detail, the commercialization activities for such Licensed Product in the Licensed Territory (the "**Commercialization Plan**"), including commercialization strategy, marketing and sales strategy. On a Licensed Product-by-Licensed Product basis, Disc will prepare and submit to the JSC an initial Commercialization Plan for review and approval no later than [***] before the anticipated date of Regulatory Approval for such Licensed Product in the Field in the Licensed Territory. In addition, Disc shall also provide to Mabwell, via the JSC, a two-year sales forecast for such Licensed Product concurrent with such initial Commercialization Plan (to be updated on an annual rolling basis). From time to time, but at least annually, Disc will prepare updates or amendments to the Commercialization Plan, and will submit such update or amendment to the JSC review and approval before adopting such update or amendment. Specifically and without limiting the foregoing, Disc shall timely carry out all Commercialization activities set forth in and in accordance with the Commercialization Plan. Disc will keep Mabwell reasonably informed of its, its Affiliates' and Sublicensees' Commercialization activities with respect to the Licensed Products in the Licensed Territory. Without limiting the foregoing, Disc will provide Mabwell, through the JSC, with a commercialization report at least [***] regarding the Commercialization activities with respect to all Licensed Products in each Indication in the Licensed Territory, and will make available to Mabwell such additional information about its Commercialization activities as may be reasonably requested by Mabwell from time to time.

(d) On at least [***] basis, through the JSC, Mabwell shall provide to Disc a written copy of Mabwell's high level plans (which shall include, for the avoidance of doubt, development plans, clinical trial plans, planned filings of Regulatory Documentation with a Regulatory Authority and commercialization plans) for the Development and Commercialization of the Licensed Antibodies and Licensed Products in each Indication in the Mabwell Territory.

2.3 **Development and Commercialization Costs**. Subject to the remainder of this Section 2.3, (a) Disc shall be responsible for all Development and Commercialization costs with respect to Licensed Antibodies and Licensed Products in the Licensed Territory during the Term, and (b) Mabwell shall be responsible for all Development and Commercialization costs with respect to Licensed Antibodies and Licensed Products in the Mabwell Territory. Disc shall have the right to reference the Mabwell Regulatory Documentation and Results and to copy, access, use, and have used the Mabwell Regulatory Documentation and Results in accordance with Section 5.5(a) during the Term; provided that Disc's right to reference and right to copy, access, use, and have used any Clinical Trial Data included in Mabwell's Regulatory Documentation and Results and generated on or after the Effective Date, other than Clinical Trial Data exchanged between the Parties pursuant to Section 3.5, shall be subject to Disc's reimbursement of Mabwell for [***]. Mabwell shall have the right to reference the Disc Regulatory Documentation and Results and to copy, access, use and have used the Disc Regulatory Documentation and Results in accordance with Section 5.5(b) during the Term; provided that Mabwell's right to reference and right to copy, access, use, and have used any Clinical Trial Data included in Disc's Regulatory Documentation and Results and generated on or after the Effective Date, other than Clinical Trial Data exchanged between the Parties pursuant to Section 3.5, shall be subject to Mabwell's reimbursement of Disc for [***].

2.4 **Development and Commercialization Records**. Each Party shall, and shall cause its respective Affiliates and Sublicensees to, maintain, in good scientific manner, complete and accurate books and records, including general accounting ledgers, invoice/sale registers, original invoices and shipping documents, tax returns,

inventory and manufacturing records, license, sublicense and distributor agreements and price lists, product catalogs and other marketing materials pertaining to the Development and Commercialization of and the obtainment and maintenance of Regulatory Approvals for each Licensed Product in its respective territory, in sufficient detail to verify compliance with its obligations under this Agreement. Such books and records shall (a) be in compliance with Applicable Law; (b) properly reflect all work done and results achieved in the performance of a Party's, its Affiliates' and its Sublicensees' Development and regulatory activities and Commercialization hereunder; (c) not include or be commingled with records of research or development activities outside the scope of this Agreement; and (d) be retained by each Party for at least [***].

2.5 **Joint Steering Committee.**

(a) **Formation; Composition**. Within [***] of the Effective Date, the Parties will establish a joint steering committee (the "**Joint Steering Committee**" or "**JSC**") comprised of [***] qualified representatives from each Party (or appointed representatives of any Affiliate of such Party) with sufficient seniority within the applicable Party to make decisions arising within the scope of the JSC's responsibilities. The JSC may change its size from time to time by mutual consent of the Parties, provided that the JSC will consist at all times of an equal number of representatives of each of Mabwell and Disc. If a representative from either Party is unable to attend or participate in a JSC meeting, the Party who designated that representative may designate a substitute JSC representative for the meeting in its sole discretion upon prior written notice to the other Party. Representation by proxy shall not be allowed. A quorum of the JSC shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. Each Party may replace its JSC representatives at any time upon written notice to the other Party. The JSC may invite non-members to participate in the discussions and meetings of the JSC, provided that such participants will have no voting authority at the JSC and shall be Representatives of the inviting Party, for clarity all such non-members shall be subject to restrictions regarding the confidentiality and non-use of Confidential Information no less restrictive than the provisions set forth in Section 8. The JSC will be chaired by one of the representatives ("**Chairperson**") and will rotate between and appointed by the Parties every [***] during the Term, provided that the first Chairperson of JSC will be a representative of Disc. The role of the Chairperson will be to convene and preside at meetings of the JSC. The Chairperson will have no additional powers or rights beyond those held by the other JSC representatives. The Alliance Managers will work with the Chairperson to prepare and circulate agendas and to ensure the preparation of minutes.

(b) **Specific Responsibilities**. The JSC will:

(i) review and discuss the Regulatory Documentation and Results exchanged under Section 4.3;

(ii) discuss the Parties' activities under this Agreement over the preceding Calendar Quarters, including the progress of Development, regulatory, Manufacturing and Commercialization activities, Commercialization forecasts, and any adverse events;

(iii) review and discussion of the then-current Development Plan, Clinical Development Plan, and Commercialization Plan, and any Progress Report delivered under this Agreement;

(iv) review and approval of any update or amendment to any Development Plan, Clinical Development Plan, or Commercialization Plan;

(v) review, discuss and approve any update or amendment to any of Mabwell's development, clinical development, or commercialization plans, to the extent any such update or amendment would reasonably be expected to (in Disc's reasonable belief) materially adversely affect the Development or Commercialization of any Licensed Antibody or any Licensed Product by Disc in the Licensed Territory or by Mabwell in the Mabwell Territory pursuant to Section 2.5(e);

(vi) review and discuss Clinical Trial Data generated over the preceding Calendar Quarters; and

(vii)perform such other functions as appropriate, to further the purposes of this Agreement, in each case as agreed in writing by the Parties.

(c) **Meetings**. During the Term, the JSC will meet at least quarterly, unless otherwise agreed to by the JSC. No later than [***] prior to any meeting of the JSC, the Alliance Managers will jointly prepare and circulate an agenda for such meeting; provided, however, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. Either Party (through its Alliance Manager or otherwise) may also call a special meeting of the JSC by providing at least [***] prior written notice to the other Party if such Party reasonably believes that a significant matter must be discussed prior to the next scheduled meeting, in which event such Party will work with the Chairperson of the JSC to provide the members of the JSC no later than [***] prior to the special meeting with an agenda for the meeting and materials reasonably adequate to enable an informed review of the matters to be discussed. The JSC may meet in person, by videoconference, or by teleconference. In-person JSC meetings will be held at locations mutually agreed upon by the Parties. Each Party will bear the expense of its respective JSC members' participation in JSC meetings. The Alliance Managers will be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect the information shared during the meeting. The Alliance Managers will send draft meeting minutes to each member of the JSC for review and approval within [***] after each JSC meeting. Such minutes will be deemed approved unless one or more members of the JSC objects to the accuracy of such minutes within [***] of receipt. Minutes will be officially endorsed by the JSC at the next JSC meeting, and will be signed by the then-presiding Chairperson.

(d) **Reporting**. At least [***] prior to each quarterly meeting of the JSC, each Party will circulate to the JSC members for discussion at such quarterly meeting a high-level summary of the status and activities conducted by or on behalf of such Party, its Affiliates and its Sublicensees with respect to the Exploitation of Licensed Antibodies and Licensed Products in such Party's territory in the period since the last quarterly JSC meeting, together with a high-level summary of such activities proposed to be conducted in the next subsequent quarterly period.

(e) **Decision Making.** All decisions within the JSC will be made by consensus, with each Party's representatives collectively having one vote. If the JSC is unable to reach consensus on a matter for which it has decision making authority within [***] after such matter is referred to the JSC for decision, then either Party may elect by written notice to refer such matter to the Chief Executive Officers of both Parties for resolution, and the Chief Executive Officers of both Parties will use good faith efforts to resolve such dispute within [***]. If the Chief Executive Officers of both Parties cannot reach resolution with respect to such dispute, then (i) Disc will have final decision-making authority for all issues that relate to the Licensed Territory, except that Disc shall not make any final decision that would have a substantial likelihood of materially adversely affecting the Development or Commercialization of any Licensed Antibody or any Licensed Product in the Mabwell Territory; and (ii) Mabwell will have final decision-making authority for all issues that relate to the Mabwell Territory, except that Mabwell shall not make any final decision that would have a substantial likelihood of materially adversely affecting the Development or Commercialization of any Licensed Antibody or any Licensed Product in the Licensed Territory. If a Party reasonably believes in good faith that an action or inaction of the other Party would have a substantial likelihood of materially adversely affecting the Development or Commercialization of any Licensed Antibody or any Licensed Product in its respective Territory, such Party shall provide the JSC with reasonably sufficient details to further assess the circumstances and evaluate whether such material adverse effect exists or would exist. Without limitation to the foregoing, the Parties hereby agree that matters explicitly reserved to the consent, approval or other decision-making authority of one or both Parties, as expressly provided in this Agreement, are outside the jurisdiction and authority of the JSC, including amendment, modification or waiver of compliance with this Agreement (which may only be amended or modified as provided in Section 13.8). Neither Party will have the right to use its final decision-making authority to materially increase the other Party's obligations under this Agreement or to a Third Party (including performance obligations of such other Party, the costs and expenses to be borne by such other Party, or payment or other obligations of such other Party).

2.6 **Alliance Managers**. Within [***] following the Effective Date, each Party shall appoint (and notify the other Party of the identity of) an alliance manager (each, an "**Alliance Manager**"). Each Party may, at any time, replace its Alliance Manager with another suitably qualified individual, on written notice to the other Party. The Alliance Managers shall meet at least [***] and shall be primarily responsible for facilitating communications between the Parties including by and through the JSC. Each Alliance Manager will also be responsible for:

(a) providing a single point of communication and facilitating the flow of information;

(b) ensuring that the governance procedures and the rules set forth herein are complied with;

(c) identifying and raising disputes to the JSC for discussion in a timely manner;

(d) planning and coordinating internal and external communications in accordance with the terms of this Agreement; and

(e) planning and coordinating schedules for JSC meetings.

For the avoidance of doubt, the Alliance Managers will be entitled to attend all JSC meetings.

3. **Regulatory Matters**

3.1 **Notification of Clinical Trial Initiations**. Disc shall notify Mabwell at least [***] prior to commencing any clinical trial (or expansion thereof) relating to Licensed Antibodies or Licensed Products in the Licensed Territory. Mabwell shall notify Disc at least [***] prior to commencing any clinical study (or expansion thereof) relating to Licensed Antibodies or Licensed Products in the Mabwell Territory.

3.2 **Regulatory Documentation and Results.**

(a) **Responsibility to File Regulatory Documentation**. As between the Parties, Disc shall be solely responsible for filing and submitting, and shall have the sole right to file and submit, Regulatory Documentation (including INDs and BLAs) with respect to Licensed Products and Licensed Antibodies in the Licensed Territory during the Term. As between the Parties, Mabwell shall be solely responsible for filing and submitting, and shall have the sole right to file and submit, Regulatory Documentation (including INDs and BLAs) with respect to Licensed Products and Licensed Antibodies in the Mabwell Territory.

(b) **Assignment of Regulatory Filings**. On a Licensed Antibody-by- Licensed Antibody basis, within [***] following Effective Date and concurrently with the payment set forth in Section 6.1 (Upfront Payment) from Disc, Mabwell will transfer and assign to Disc, free of all liens and encumbrances, Mabwell's and its Affiliates' entire right, title, and interest in and to, and copies of, all INDs, regulatory filings, and Regulatory Documentation and Results with respect to such Licensed Antibody in the Licensed Territory that is in the possession and control of Mabwell or its Affiliates, including any drug master files maintained by Mabwell, its Affiliates or a Third Party solely with respect thereto. In furtherance of the foregoing, the Parties will fully cooperate and promptly make the appropriate notifications or filings to the applicable Regulatory Authorities, including IND transfer letters, as may be necessary to effect such transfer.

(c) **Review of Regulatory Documentation Filings**.

(i) **Filings by Disc**. No later than [***] prior to filing or submitting any material Regulatory Documentation (including any INDs and BLAs) with or to any Regulatory Authority in the Licensed Territory, Disc shall provide Mabwell with a copy of such Regulatory Documentation only to the extent that such Regulatory Documentation is necessary or reasonably useful to Mabwell's Development or Commercialization of Licensed Products in the Mabwell Territory. Mabwell shall promptly review and provide any comments through its designated representative and in any event no later than [***], and Disc shall consider in good faith any timely comments received from Mabwell. In addition, Disc will notify Mabwell of any material Regulatory Documentation submitted to or received from any Regulatory Authority in the Licensed Territory and, subject to any payments required by Mabwell pursuant to Section 2.3, will provide Mabwell with copies thereof within [***] after submission or receipt. Disc will also notify Mabwell of any other material communication with any Regulatory Authority in the Licensed Territory within [***] after such communication. Such Regulatory Documentation and material communications shall be subject to the license grant in Section 5.5(b).

(ii) **Filings by Mabwell**. No later than [***] prior to filing or submitting any material Regulatory Documentation (including any INDs and BLAs) with or to any Regulatory Authority in the Mabwell Territory, Mabwell shall provide Disc with a copy of such Regulatory Documentation only to the extent that such Regulatory Documentation is necessary or reasonably useful to Disc's Development or Commercialization of Licensed Products in the Licensed Territory. Disc shall promptly review and provide any comments through its designated representative and in any event no later than [***], and Mabwell shall consider in good faith any timely comments received from Disc. In addition, Mabwell will notify Disc of any material Regulatory Documentation submitted to or received from any Regulatory Authority in the Mabwell Territory and, subject to any payments required by Disc pursuant to Section 2.3, will provide Disc with copies thereof within [***] after submission or receipt. Mabwell will also notify Disc of any other material communication with any Regulatory Authority in the Mabwell Territory within [***] after such communication. Such Regulatory Documentation and material communications shall be subject to the license grant in Section 5.5(a).

(d) **Ownership of Regulatory Documentation and Results**. As between the Parties, and subject to Section 11.4, Disc shall solely own all Regulatory Documentation and Results (including Regulatory Approvals) in the Licensed Territory. As between the Parties, Mabwell shall solely own all Regulatory Documentation and Results (including Regulatory Approvals) in the Mabwell Territory. Each Party shall cause all Persons who perform activities for such Party, its Affiliates, or its Sublicensees, as applicable, under this Agreement to be under an obligation to assign their rights in or to any Regulatory Documentation and Results to such Party. Without limiting the foregoing, if such Party is unable to cause such Person to agree to such assignment obligation despite such Party's using commercially reasonable efforts to negotiate such assignment obligation, then such Party shall cause such Person to grant to such Party an exclusive license (even as to such Person) in or to such Regulatory Documentation and Results, including all rights therein or thereto. In no event shall a Licensed Antibody, Licensed Product, Licensed Patent, Licensed Materials, Licensed Know-How, Licensed Improvement Patent and Licensed Improvement Know-How which are solely owned by Mabwell be construed as Regulatory Documentation and Results.

(e) **Regulatory Audits and Inspection**. Upon reasonable advance notice, each Party or its representatives will have the right to audit the regulatory, safety, quality and compliance systems, Clinical Trial Data, procedures and practices of the other Party, its Affiliates, Sublicensees or subcontractors (including clinical trial sites) relating to the Development, Manufacture and Commercialization of each Licensed Antibody and Licensed Product, to the extent that such audit is necessary for the auditing Party to respond to a specific request or inquiry from a Regulatory Authority. Each Party will promptly notify the other Party of any audit or inspection of such Party, its Affiliates, Sublicensees or subcontractors by any Regulatory Authority relating to the Licensed Products and will provide the other Party with a summary of any material findings in connection therewith. Each Party will also permit the Regulatory Authorities to conduct audits and inspections of other Party, its Affiliates, Sublicensees or subcontractors relating to the Licensed Products where required by Applicable Law, and will ensure that such Affiliates, Sublicensees and subcontractors permit and cooperate with such audits and inspections.

(f) **Regulatory Meetings**. Each Party shall provide the other Party with reasonable advance notice of all material meetings, conferences and discussions with any Regulatory Authority in its territory related to the Licensed Antibody or Licensed Products, and shall promptly provide the other Party with a written summary of such meeting or discussion, including the result, action or decision from such meeting or discussion with Regulatory Authority.

3.3 **Recalls, Suspensions, and Withdrawals.**

(a) **Licensed Territory**. Disc shall notify Mabwell [***] following its determination that any event, incident or circumstance has occurred that may result in the need for a recall, market suspension or market withdrawal of a Licensed Product in the Licensed Territory and shall include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, Disc shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal in the Licensed Territory during the Term; provided that prior to any implementation of such a recall, market suspension or market withdrawal, Disc shall consult with Mabwell and shall consider Mabwell's comments in good faith. If a recall, market suspension or market withdrawal is mandated by a Regulatory Authority in the Licensed Territory, as between the Parties, Disc shall initiate such a recall, market suspension or market withdrawal in compliance with Applicable Law, provided that after the termination of this Agreement Mabwell shall have the right to initiate and control initiate

such a recall, market suspension or market withdrawal. Disc shall be responsible for all costs of any such recall, market suspension, or market withdrawal, except in the event and to the extent that a recall, market suspension or market withdrawal resulted from Mabwell's breach of its obligations hereunder or from such Mabwell's or its Representatives fraud, gross negligence, willful misconduct, or failure to comply with Applicable Law, in which case Mabwell shall bear the expense of such recall, market suspension or market withdrawal.

(b) **Mabwell Territory**. Mabwell shall notify Disc [***] following its determination that any event, incident or circumstance has occurred that may result in the need for a recall, market suspension or market withdrawal of a Licensed Product in the Mabwell Territory and shall include in such notice the reasoning behind such determination and any supporting facts during the Term. As between the Parties, Mabwell shall have the right to make the final determination whether to voluntarily implement any such recall, market suspension or market withdrawal in the Mabwell Territory; provided that prior to any implementation of such a recall, market suspension or market withdrawal, Mabwell shall consult with Disc and shall consider Disc's comments in good faith. If a recall, market suspension or market withdrawal is mandated by a Regulatory Authority in the Mabwell Territory, as between the Parties, Mabwell shall initiate such a recall, market suspension, or market withdrawal in compliance with Applicable Law. Mabwell shall be responsible for all costs of any such recall, market suspension or market withdrawal, except in the event and to the extent that a recall, market suspension or market withdrawal resulted from Disc's breach of its obligations hereunder or from such Disc's or its Representatives fraud, gross negligence, willful misconduct, or failure to comply with Applicable Law, in which case Disc shall bear the expense of such recall, market suspension or market withdrawal.

3.4 **Safety Databases.**

(a) **Global Safety Database; Licensed Territory**. As between the Parties, Disc shall establish, hold and maintain ([***]) a global safety database for Licensed Antibodies and Licensed Products with respect to information on adverse events concerning Licensed Antibodies and Licensed Products, as and to the extent required by Applicable Law. Disc shall collect all information necessary to comply with its pharmacovigilance responsibilities in the Licensed Territory, including, as applicable, any adverse drug experiences taking place within the Licensed Territory (including those events or experiences that are required to be reported to the FDA under 21 C.F.R. sections 312.32 or 314.80 or to foreign Regulatory Authorities under corresponding Applicable Law outside the United States) from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, clinical studies, and commercial experiences with a Licensed Product, and such safety database shall be maintained by Disc for at least [***].

(b) **Mabwell Territory**. Mabwell shall establish, hold and maintain ([***]) a safety database for Licensed Products in the Mabwell Territory. Mabwell shall collect all information necessary to comply with its pharmacovigilance responsibilities in the Mabwell Territory, including, as applicable, any adverse drug experiences taking place within the Mabwell Territory (including those events or experiences that are required to be reported to the FDA under 21 C.F.R. sections 312.32 or 314.80 or to foreign Regulatory Authorities under corresponding Applicable Law outside the United States) from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, clinical studies and commercial experiences with a Licensed Product, and such safety database shall be maintained by Mabwell for at least [***].

3.5 **Adverse Event Reporting**. Within [***] following the Effective Date, Disc and Mabwell shall enter into a Safety Data Exchange Agreement ("**SDEA**"). The SDEA will define the pharmacovigilance responsibilities of the Parties and govern the process and procedures for the exchange of global adverse event safety data between the Parties in a mutually agreed format in order to monitor the safety Licensed Antibodies and Licensed Products and to meet reporting requirements for applicable Regulatory Authority. Subject to Section 11.4, Disc shall be responsible for all such reporting requirements in the Licensed Territory, and Mabwell shall be responsible for all such reporting requirements in the Mabwell Territory.

4. TECHNOLOGY AND REGULATORY TRANSFER, MANUFACTURING, AND SUPPLY

4.1 **Transfer of Licensed Know-How and Licensed Materials.**

(a) **Transfer of Initial Licensed Know-How and Licensed Materials**. Within [***] following the Effective Date and concurrently with the payment set forth in Section 6.1 (Upfront Payment) from Disc, Mabwell shall transfer to Disc: [***].

(b) **Transfer of Licensed Improvement Know-How and Joint Improvement Know-How**. Upon the reasonable written request of Disc and to the extent not previously provided, Mabwell shall transfer to Disc [***]. For clarity, nothing herein obligates Mabwell to generate any Licensed Improvement Know-How.

(c) **Subsequent Transfers of Licensed Know-How**. To the extent not provided pursuant to Section 4.1(a) or 4.1(b), from time to time during the Term, Mabwell shall keep Disc reasonably informed as to any Licensed Know-How that comes into Mabwell's Control, and upon Disc's written request and to the extent not previously provided, Mabwell will provide to Disc [***].

(d) **Translations of Know-How**. Mabwell is only obligated to provide all Know-How under this Section 4.1 in the language in which such Know-How then exists (without translating such Know-How into another language), and if Disc reasonably requests the translation of any Know-How, any such translation will be performed [***].

4.2 **Transfer of Arising Know-How and Joint Improvement Know-How by Disc.**

(a) **Transfer of Arising Know-How and Joint Improvement Know-How**. Upon the reasonable written request of Mabwell and to the extent not previously provided, Disc shall transfer to Mabwell [***].

(b) **Translations of Know-How**. Disc is only obligated to provide all Know-How under this Section 4.2 in the language in which such Know-How then exists (without translating such Know-How into another language), and if Mabwell reasonably requests the translation of any Know-How, any such translation will be performed [***].

4.3 **Transfer of Regulatory Documentation and Results**. To the extent not provided pursuant to Article 3, from time to time during the Term, Mabwell shall keep Disc reasonably informed as to any Regulatory Documentation and Results that comes into Mabwell's Control to the extent necessary or reasonably useful for Disc to Exploit Licensed Products in the Licensed Territory. Subject to any required payments by Disc pursuant to Section 2.3, and upon Disc's request, Mabwell shall transfer to Disc a copy of any such Regulatory Documentation and Results. Additionally, to the extent not provided pursuant to Article 3, from time to time during the Term, Disc shall keep Mabwell reasonably informed as to any Regulatory Documentation and Results that comes into Disc's Control to the extent necessary or reasonably useful for Mabwell to Exploit Licensed Products in the Mabwell Territory. Subject to any required payments by Mabwell pursuant to Section 2.3, and upon Mabwell's request, Disc shall transfer to Mabwell a copy of any such Regulatory Documentation and Results.

4.4 **Supply of Licensed Antibody for Phase I Clinical Trial.**

(a) **Phase I Trial Supply**. Subject to Section 4.4(b), Mabwell shall or cause its Affiliate to supply to Disc [***] in accordance with (i) the applicable product specifications and manufacturing processes for such Licensed Product as set forth in **Schedule 4.4(a)** (the "**Product Specification**") and (ii) FDA Guidance for Industry: cGMP for Phase I Investigational Drugs (July 2008), for Disc to conduct a Phase I Clinical Trial in the relevant jurisdiction(s) in the Licensed Territory (the "**Inventory**"). Mabwell hereby agrees to timely (and in no event later than [***] following the Effective Date unless otherwise agreed to by the Parties) provide to Disc, at no cost to Disc other than any transportation charges, which shall be at the expense of and chargeable to Disc, including any duties

or customs charges, such quantity of Inventory as set forth in this Section 4.4(a). For the avoidance of doubt and notwithstanding the foregoing sentence, Mabwell may retain reference samples of such Inventory.

(b) **Storage and Delivery of Inventory**. Prior to supplying Disc or its designee with the Inventory, Mabwell shall hold such Inventory on Disc's behalf and conduct stability testing of such Inventory on Disc's behalf for up to [***] from the Effective Date of this Agreement without charge to Disc ("**Retention Period**"). Disc may request, and Mabwell may, but is not obligated, to agree, that Mabwell holds such Inventory for an additional [***] after the Retention Period subject to a storage fee to be paid by Disc to Mabwell as mutually agreed by the Parties. In any event, Mabwell shall have no obligation to hold the Inventory for more than [***] following the Effective Date. After the Retention Period, all actual and reasonable Inventory-related costs, storage costs, transportation costs, landing costs and other costs associated with such stability testing shall be borne by Disc. Mabwell shall invoice to Disc for such actual and reasonable costs on a monthly or quarterly basis at Mabwell's sole election, and Disc shall pay such costs within [***] after receiving such invoice.

(c) **Inventory Representations and Warranties**. Mabwell hereby represents and warrants that: (i) the Inventory is Manufactured in accordance with the Product Specification and FDA Guidance for Industry: cGMP for Phase I Investigational Drugs (July 2008), (ii) as of the date on which the Inventory is supplied to Disc or its designee hereunder, such Inventory will have been stored and maintained in accordance with the Product Specification; and (iii) the Inventory is free and clear of any liens, charges and encumbrances. Together with the delivery of the Inventory, Mabwell shall provide Disc with a certificate of compliance stating that the Inventory delivered to Disc was Manufactured in accordance with Product Specification and FDA Guidance for Industry: cGMP for Phase I Investigational Drugs (July 2008).

(d) **Quality**. Within [***] following the Effective Date, Mabwell and Disc will negotiate in good faith and enter into a quality agreement in accordance with the Product Specification ("**Quality Agreement**") on commercially reasonable terms with respect to the Inventory Manufactured by or on behalf of Mabwell pursuant to this Section 4.4. The Quality Agreement will contain provisions necessary for compliance with Product Specification and FDA Guidance for Industry: cGMP for Phase I Investigational Drugs (July 2008), including responding to requests and inquiries from Regulatory Authorities during the Term, including reviews of batch records, analytical tests, quality audits and inspections of Mabwell's manufacturing facilities, in each case to the extent related to the Inventory supplied by Mabwell to Disc hereunder.

(e) **Rejection of Inventory**. In the event that (i) the Inventory does not comply with the Product Specification, (ii) the Inventory has not been stored or maintained in accordance with the Product Specification as of the date on which the Inventory is supplied to Disc or its designee, or (iii) a Regulatory Authority determines that the applicable Inventory does not comply with FDA Guidance for Industry: cGMP for Phase I Investigational Drugs (July 2008), in each case (i)-(iii), without limiting Disc's remedies under this Agreement, Mabwell shall, at no cost to Disc, promptly Manufacture and deliver to Disc (or its designee) replacement quantities of Inventory that comply with Product Specifications and FDA Guidance for Industry: cGMP for Phase I Investigational Drugs (July 2008) and addresses any specific feedback from a Regulatory Authority. To the extent applicable, Mabwell shall also provide Disc with corresponding documentation detailing how the newly Manufactured Inventory overcomes the concerns raised by the applicable Regulatory Authority regarding the original Inventory.

(f) **Additional Manufacture of Licensed Antibodies and Licensed Products**. Subject to Section 4.4(e) and Section 4.5, as between the Parties, for the supply of all further quantities of Licensed Antibodies and Licensed Products beyond that contained in the Inventory, Disc shall have the sole responsibility for procuring, and shall at its own expense Manufacture (or have Manufactured), such Licensed Antibodies and Licensed Products for its Development and Commercialization activities in the Field in the Licensed Territory. Notwithstanding the foregoing, the Parties may choose to enter into a separate supply agreement for Mabwell's supply of further quantities of Licensed Antibodies and Licensed Products beyond that contained in the Inventory.

4.5 **Manufacture and Technology Transfer and Licensed Materials.**

(a) For clarity, pursuant to the license granted to it under Section 5.1, Disc shall have the right to Manufacture Licensed Products in the Licensed Territory or Mabwell Territory for the purpose of Disc's Development, Commercialization and other Exploitation activities hereunder with respect thereto in the Licensed Territory.

(b) Without limiting Section 4.1, and to the extent not previously provided under Section 4.1(a), within [***] after the written request of Disc, Mabwell shall provide Disc (or its Qualified Contract Manufacturer) [***] (clauses (i)-(iii), collectively, the "**Manufacturing Technology Transfer**"). In addition, [***] Mabwell shall provide to Disc (or its Qualified Contract Manufacturer) consulting and technical assistance, using qualified and competent personnel, reasonably required for Disc (or its Qualified Contract Manufacturer) to complete and fully enable the Manufacturing Technology Transfer, up to [***] full-time equivalent ("**FTE**") hours. Any additional assistance for the same, using qualified and competent personnel, shall be at a rate of [***] per hour (or [***] at [***] hours per annum) up to [***] additional FTE hours, with a maximum total of [***] total FTE hours of assistance under this Section 4.5(b).

5. GRANT OF RIGHTS

5.1 **Disc Exclusive License to Licensed IP**. Subject to the terms and conditions of this Agreement, including Section 5.2, Mabwell hereby grants to Disc an exclusive (even as to Mabwell and its Affiliates), royalty bearing (in accordance with Section 6.3), non-transferable (other than as provided in Section 13.3) license, with the right to grant sublicenses (in accordance with Section 5.7), under the Licensed IP to (a) Exploit Licensed Antibodies and Licensed Products in the Field in the Licensed Territory, and (b) conduct (whether directly or on its behalf) pre-clinical research and Manufacturing activities for the Licensed Antibodies or Licensed Products in the Mabwell Territory solely for purposes of Exploiting such Licensed Antibodies and Licensed Products in the Licensed Territory.

5.2 **Mabwell Retained Rights**. Mabwell and each of its Affiliates shall retain the right under the Licensed IP and Licensed Materials to (a) perform Mabwell's obligations under this Agreement, and (b) directly or on its behalf, conduct pre-clinical research and Manufacturing activities for Licensed Antibodies and Licensed Products in the Licensed Territory for purposes of Exploiting such Licensed Antibodies and Licensed Products in the Mabwell Territory. Mabwell and each of its Affiliates shall also retain all rights under the Licensed IP and Licensed Materials that are not expressly licensed to Disc under this Agreement.

5.3 **Mabwell License to Arising IP and Joint Improvement IP**. Subject to the terms and conditions of this Agreement, Disc hereby grants to Mabwell (a) an exclusive (even as to Disc and its Affiliates or Sublicensees, but subject to Disc's rights retained under Section 5.4), royalty-free, fully paid-up, non-transferable (other than as provided in Section 13.3) license, with the right to grant sublicenses (in accordance with Section 5.7), under the Arising IP and Disc's interest in Joint Improvement IP to Exploit Licensed Antibodies and Licensed Products in the Field in the Mabwell Territory, (b) a non-exclusive, royalty-free, fully paid-up, non-transferable (other than as provided in Section 13.3) license, with the right to grant sublicenses (in accordance with Section 5.7) under the Arising IP solely to (i) directly or on its behalf, conduct pre-clinical research and Manufacturing activities during the Term for Licensed Antibodies and Licensed Products in the Licensed Territory, for purposes of Exploiting such Licensed Antibodies and Licensed Products in the Mabwell Territory and (ii) perform Mabwell's obligations under this Agreement.

5.4 **Disc Retained Rights**. Disc and each of its Affiliates shall retain the right under the Arising IP and Disc's interest in Joint Improvement IP to (a) perform Disc's obligations under this Agreement, and (b) directly or on its behalf, conduct pre-clinical research and Manufacturing activities for Licensed Antibodies and Licensed Products in the Mabwell Territory for purposes of Exploiting such Licensed Antibodies and Licensed Products in the Licensed Territory. Disc and each of its Affiliates shall also retain all rights under the Arising IP and Disc's interest in Joint Improvement IP that are not expressly licensed to Mabwell under this Agreement.

5.5 **Rights of Reference and Right to Use Results.**

(a) **Disc Right of Reference and License to Regulatory Documentation and Results**. Subject to any required payments by Disc pursuant to Section 2.3, Mabwell hereby grants to Disc (i) the right to reference Mabwell Regulatory Documentation and Results, with the right to grant further rights of reference in accordance with Section 5.7; and (ii) a non-exclusive, non-transferable (other than as provided in Section 13.3), royalty-free license, with the right to grant sublicenses in accordance with Section 5.7, to copy, access, and otherwise use and have used Mabwell Regulatory Documentation and Results, in each case ((i) and (ii)) solely for purposes of Developing and obtaining Regulatory Approval of Licensed Products in the Licensed Territory during the Term or after the expiration

(but not early termination) of this Agreement, subject to the terms and conditions of, and in accordance with, this Agreement.

(b) **Mabwell Right of Reference and License to Regulatory Documentation and Results**. Subject to any required payments by Mabwell pursuant to Section 2.3, Disc hereby grants to Mabwell (i) the right to reference Disc Regulatory Documentation and Results, with the right to grant further rights of reference in accordance with Section 5.7; and (ii) a non-exclusive, non-transferable (other than as provided in Section 13.3), royalty-free license to copy, access, and otherwise use or have used Disc Regulatory Documentation and Results, in each case ((i) and (ii)) solely for purposes of Developing and obtaining Regulatory Approval of Licensed Products in the Mabwell Territory during the Term or after the expiration (but not early termination) of this Agreement, subject to the terms and conditions of, and in accordance with, this Agreement.

(c) **Cooperation**.

(i) Subject to Disc's required payments pursuant to Section 2.3, Mabwell shall, if requested by Disc, provide a signed statement that Disc may rely on, and the applicable Regulatory Authority may access, any Mabwell Regulatory Documentation and Results in support of Disc's application for Regulatory Approval in the Licensed Territory for a Licensed Product pursuant to Section 5.5(a). Neither Party shall withdraw or inactivate any regulatory filing under its Control that the other Party references pursuant to this Section 5.5 without the other Party's consent (which shall not be unreasonably withheld, delayed, or conditioned).

(ii) Subject to Mabwell's required payments pursuant to Section 2.3, Disc shall, if requested by Mabwell, provide a signed statement that Mabwell may rely on, and the applicable Regulatory Authority may access, any Disc Regulatory Documentation and Results in support of Maxwell's application for Regulatory Approval in the Mabwell Territory for a product that contains a Licensed Antibody as an active ingredient.

5.6 **Disc License to Licensed Materials**. Mabwell hereby grants Disc an exclusive (but subject to rights retained under Section 5.2), non-transferable (other than as provided in Section 13.3), royalty-free license, with the right to grant sublicenses in accordance with Section 5.7, to (a) use or have used the Licensed Materials and (b) Manufacture or have Manufactured Licensed Antibodies or Licensed Product, in each case (a) and (b), for purposes of exercising its rights and carrying out its obligations under this Agreement in the Mabwell Territory (in connection with Disc's rights in the Mabwell Territory under Sections 5.1(b) and 5.4) and the Licensed Territory.

5.7 **Sublicenses Under Rights of Reference**. Each Party shall have the right to grant sublicenses (or further rights of reference), through multiple tiers, under the licenses and rights of reference granted to such Party in this Article 5. Any such sublicenses shall be consistent with this Agreement.

5.8 **Sublicensees Generally**. Each Party shall be liable for all acts and omissions of its Sublicensees, and breach of a Sublicensee shall be deemed a breach of such Party. Mabwell shall notify Disc and provide the name of the sublicensee to Disc after the grant of a sublicense (other than non-exclusive sublicenses granted to research and development or commercialization subcontractors in Mabwell's ordinary course of business) within [***] after the execution thereof. Disc will provide Mabwell a copy of each sublicense (other than non-exclusive sublicenses granted to research and development subcontractors in Disc's ordinary course of business) and any subsequent amendments thereto, within [***] of execution or receipt thereof, as the case may be. Disc will provide Mabwell all copies of Disc's Sublicensees' royalty reports within [***] of receipt thereof. Such sublicense, amendment, and royalty report copies may redact sensitive information not necessary for Mabwell to ascertain such sublicensee's compliance with this Agreement. The terms of each sublicense, including the rights granted to each Sublicensee under the Licensed IP or Arising IP, as applicable, will be consistent with the applicable terms of this Agreement, including the rights granted to Disc under Section 5.1 and to Mabwell under Section 5.3, in each case, applicable to the scope of the sublicense granted to such Sublicensee. Each Party will require language materially similar to that in Section 9.1(e) in every sublicense and subcontract agreement under this Agreement. Each Party may fulfill any of its obligations or responsibilities under this Agreement through any of its Affiliates, Sublicensees or Third Party subcontractors.

5.9 **Exclusivity**.

(a) **Mabwell Exclusivity**. [***].

(b) **Disc Exclusivity**. [***].

(c) **Transactions Involving Competing Products**.

(i) **Acquisition of Existing Competing Product**. If, after the Execution Date, any Third Party becomes an Affiliate of either Party (the "**Acquired Affiliate**") as a result of a merger, acquisition, consolidation, asset sale, or other similar transaction (whether in a single transaction or series of related transactions), other than pursuant to a Change of Control of such Party (the "**Acquiring Party**"), the foregoing restrictions in this Section 5.9 shall not apply to any Competing Product of such Acquired Affiliate existing as of the closing date of such transaction, provided that (1) the Acquiring Party implements (as of the closing of such transaction) and enforces Firewalls, and (2) the Acquiring Party provides the other Party with written notice of such transaction promptly, but no later than [***], following the earlier of the first public announcement of such transaction or the execution of a definitive agreement relating to such transaction and the Acquiring Party shall (or shall cause such Acquired Affiliate to), within [***] after the closing of such transaction, either: (x) complete a Divestiture of the Competing Product; or (y) wind down and terminate the development or commercialization of such Competing Product. "Divestiture" means, with respect to a Party and a Competing Product, that such Party or its Acquired Affiliate sells or transfers all rights to such Competing Product to a Third Party without further contractual obligation for such Party or any of its Affiliates to undertake or support any diligence or performance obligations with respect to such Competing Product, or to perform or support any development, manufacturing or commercial activities with respect to such Competing Product.

(ii) **Competing Products of Acquirers**. The foregoing restrictions in this Section 5.9 shall not apply to Persons that become Affiliates of a Party after the Execution Date as a result of a Change of Control of such Party, provided that such Party implements (as of the closing of such transaction) and enforces Firewalls.

(d) [***].

5.10**No Implied Licenses**. No right or license under any Know-How, Patents or Regulatory Documentation and Results of either Party or its Affiliates is granted or shall be granted by implication. All such rights or licenses are or shall be granted only as expressly provided in this Agreement. Disc will not, and will not permit any of its Affiliates or Sublicensees to, practice any Licensed IP outside the scope of the license granted by Mabwell to Disc under Section 5.1.

5.11**Restrictions on Encumbrances**. Each Party will not, and will not authorize any of its Affiliates, subcontractors, or Sublicensees (or their further Sublicensees or subcontractors) to, assign, transfer, convey or otherwise encumber its right, title and interest in the Licensed Patents or Arising Patents, or any component of the Licensed Know-How or Arising Know-How, in the Licensed Territory or in the Mabwell Territory, in each case in a manner that would conflict with or adversely affect the license and rights granted to the other Party under this Agreement.

6. PAYMENTS AND RECORDS

6.1 **Upfront Payment**. In partial consideration of the rights granted by Mabwell to Disc hereunder, within [***] following the Effective Date, Disc shall pay to Mabwell a one-time non-refundable payment of ten million Dollars ($10,000,000).

6.2 **Milestone Payments.**

(a) **Development and Regulatory Milestones**. In partial consideration of the rights granted by Mabwell to Disc hereunder, Disc shall pay Mabwell the following one-time, non-refundable milestone payments (each, a "**Development and Regulatory Milestone Payment**") for the first Licensed Product to achieve each milestone event below (each, a "**Development and Regulatory Milestone Event**") by Disc, its Affiliates or its Sublicensee in the Licensed Territory. For clarity, each Development and Regulatory Milestone Payment shall be made only once, regardless of the number of times the corresponding Development and Milestone Regulatory Event is achieved (and regardless of whether the corresponding Development and Milestone Regulatory Event is achieved for more than one Licensed Product in the Licensed Territory).

Development and Regulatory Milestone Event	**Development and Regulatory Milestone Payment**
[***]	
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	
[***]	[***]
[***]	[***]
[***]	[***]

Total Development and Regulatory Milestone Payments: $127.5 million.

If a Development and Regulatory Milestone Event with respect to the First Indication, Second Indication or Third Indication is skipped and not been paid but a subsequent Development and Regulatory Milestone Event is achieved with respect to such Indication, then all prior Development and Regulatory Milestone Event for Licensed Product for such Indication shall be deemed achieved and shall become due and payable at the time of achievement of the subsequent Development and Regulatory Milestone Event.

As used herein, "First Indication", "Second Indication" and "Third Indication" refer to the order of Indications for which the milestones are achieved, and do not need to be the same for each milestone. For example, "Second Indication" can be different for "Initiation of a Phase III Clinical Trial in the Second Indication in Licensed Territory" and "Obtaining Regulatory Approval in the United States for the Second Indication".

(b) **Commercial Milestones**. In partial consideration of the rights granted by Mabwell to Disc hereunder, Disc shall pay to Mabwell the following one-time, non-refundable payments (each, a "**Commercial Milestone Payment**") upon the first achievement of the annual Net Sales of Licensed Products in the Licensed Territory as follows in a given Calendar Year (each, a "**Commercial Milestone Event**"). For clarity, each Commercial Milestone Payment shall be made only once, regardless of whether the corresponding Commercial Milestone Event is achieved multiple times.

Commercial Milestone Event	Commercial Milestone Payment
Upon first achieving Net Sales of Licensed Products totaling [***] in a Calendar Year.	[***]
Upon first achieving Net Sales of Licensed Products totaling [***] in a Calendar Year.	[***]
Upon first achieving Net Sales of Licensed Products totaling [***] in a Calendar Year.	[***]
Upon first achieving Net Sales of Licensed Products totaling [***] in a Calendar Year.	[***]
Upon first achieving Net Sales of Licensed Products totaling [***] in a Calendar Year.	[***]
Upon first achieving Net Sales of Licensed Products totaling [***] in a Calendar Year.	[***]

Total Commercial Milestone Payments: $275 million.

(c) **Payment of Development and Regulatory Milestone Payments and Commercial Milestone Payments**. Disc shall notify Mabwell promptly of the achievement of each Development and Regulatory Milestone Event and Commercial Milestone Event. In the event that, notwithstanding the fact that Disc has not provided Mabwell such a notice, Mabwell believes that any such milestone event has been achieved, it shall so notify Disc in writing, and the Parties shall promptly meet and discuss in good faith whether such milestone event has been achieved. Any dispute under this Section 6.2(c) regarding whether or not such a milestone has been achieved shall be subject to resolution in accordance with Section 13.5. All undisputed Development and Regulatory Milestone Payments and Commercial Milestone Payments shall be due within [***] after the achievement of the applicable milestone event. For the avoidance of doubt, all undisputed portions of Development and Regulatory Milestone Payments and Commercial Milestone Payments shall be due and payable within [***] after the achievement of the applicable milestone event as set forth in this Section 6.2(c) pending resolution of any disputed portion of a milestone event.

6.3 **Royalties.**

(a) **Royalty Rates**. In partial consideration of the rights granted by Mabwell to Disc hereunder, and subject to Sections 6.3(b) and 6.3(c), Disc shall pay to Mabwell a royalty on Net Sales of all Licensed Products in the Licensed Territory during each Calendar Year, at the following rates:

Portion of Net Sales in a Calendar Year	Royalty Rate on such Portion of Net Sales in such Calendar Year
Portion of Net Sales greater than [***] and less than [***] in a Calendar Year.	[***]
Portion of Net Sales between greater than or equal to [***] and less than [***] in a Calendar Year.	[***]
Portion of Net Sales greater than or equal to [***] and less than [***] in a Calendar Year.	[***]

Portion of Net Sales greater than or equal to [***] and less than [***] in a Calendar Year.	[***]
Portion of Net Sales greater than or equal to [***] and less than [***] in a Calendar Year.	[***]
Portion of Net Sales greater than or equal to [***] in a Calendar Year.	[***]

(b) **Royalty Term**. Disc shall have no obligation to pay any royalty with respect to Net Sales of a Licensed Product in any country after the Royalty Term for such Licensed Product in such country has expired.

(c) **Royalty Rate Reductions**. The royalties payable under Section 6.3(a) will be subject to the following:

(i) **Third Party License**s. If Disc enters into an agreement with a Third Party in order to obtain a license to a Patent of a Third Party in a country in the Licensed Territory that Covers (A) the composition of matter of a Licensed Antibody (but excluding any modification made by Disc to the Initial Antibody), or (B) a method of use (including method of treatment, administration claims) of a Licensed Antibody in any of the following Indications: [***], in each case (A) and (B), Disc shall be entitled to deduct from royalties payable under Section 6.3(a) in a given Calendar Year, with respect to the Net Sales of Licensed Products containing such Licensed Antibody in such country, [***] of all royalty payments paid to such Third Party on account of the sales of such Licensed Product in such country in such Calendar Year under such agreement to the extent directly attributable to such Third Party Patent;

(ii) **Biosimilar Competition**. If during the Royalty Term for a given Licensed Product in a given country in the Licensed Territory, unit sales of Biosimilars of such Licensed Product in such country in a Calendar Quarter equal or exceed [***] of the total market (*i.e.*, the sum of the total number of units for such Biosimilars and Licensed Product), then, commencing upon January 1 of the following Calendar Year and for so long as the sales of such Biosimilars in such country in a Calendar Quarter continue to equal or exceed [***] of the of the total market, the royalty rates set forth in Section 6.3(a) in such country during such Calendar Quarter each shall be reduced by [***]. Unit volume sales will be identified and calculated based on relevant information published by IQVIA, any successor to IQVIA, or any other similar industry-standard Third Party source used by Disc; and

(iii) **Lack of Patent Protection**. If a Licensed Product is not Covered by any Licensed Patent in a given country in the Licensed Territory during a Calendar Quarter, the applicable royalty rate(s) in Section 6.3(a) shall be reduced by [***] in such country during such Calendar Quarter;

(iv) **Cumulative Reductions Floor**. Notwithstanding Sections 6.3(c)(i)-6.3(c)(iii), the cumulative offset pursuant to this Section 6.3(c) will not decrease the royalties otherwise payable by Disc to Mabwell under Section 6.3(a) (following application of all applicable reductions under this Section 6.3(c)) by more than [***] on a Licensed Product-by-Licensed Product and country-by-country basis in any Calendar Quarter. Disc may carry forward any such reductions permitted in accordance with this Section 6.3(c) that are incurred or accrued in a Calendar Quarter but that are not applied against royalties due to Mabwell for such Licensed Product in such country in such Calendar Quarter as a result of the foregoing floor and apply such amounts against royalties due to Mabwell for such Licensed Product in such country in any subsequent Calendar Quarter (subject to the minimum floor set forth in this Section 6.3(c)(iv)) until the amount of such reduction has been fully applied against royalties due to Mabwell for such Licensed Product in such country.

(d) **Royalty Reports and Payments**. Disc shall calculate all amounts payable to Mabwell pursuant to Section 6.3(a) (subject to Sections 6.3(b) and 6.3(c)) for each Calendar Quarter at the end of such Calendar Quarter. Such amounts shall be converted to Dollars in accordance with Section 6.6. Disc shall pay to Mabwell the royalty amounts due with respect to a given Calendar Quarter within [***] after the end of such Calendar Quarter. Each payment of royalties due to Mabwell shall be accompanied by a statement specifying for the applicable Calendar Quarter, on country-by-country basis, Gross Sales, Net Sales, deductions taken to arrive at Net Sales (including such

amounts expressed in local currency and as converted to Dollars), and a calculation of the royalty payments due on such Net Sales.

6.4 **Sublicense Revenue**. In partial consideration of the rights granted by Mabwell to Disc hereunder, Disc shall pay to Mabwell a percentage of all Sublicense Revenue as follows. Payments of applicable Sublicense Revenue to Mabwell will be due within [***] after receipt of such Sublicense Revenue by Disc from a Sublicensee.

Sublicense Revenue Tier	**Percentage Due**
Sublicense Revenue under a sublicense granted [***].	[***]
Sublicense Revenue under a sublicense granted [***].	[***]
Sublicense Revenue under a sublicense granted [***].	[***]
Sublicense Revenue under a sublicense granted [***].	[***]
Sublicense Revenue under a sublicense granted [***].	[***]
Sublicense Revenue under a sublicense granted [***].	[***]

6.5 **Mode of Payment; Offsets**. All payments to Mabwell under this Agreement shall be made by deposit of Dollars in the requisite amount to the following bank account, or such other bank account as Mabwell may from time to time designate by notice to Disc: [***]

For the purpose of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), Disc shall convert any amount expressed in a foreign currency into Dollar equivalents upon written notice to Mabwell using its or its Sublicensee's, as applicable, standard conversion methodology consistent with GAAP.

6.6 **Taxes.**

(a) **General.** Except as otherwise provided in this Section 6.6, all payments made by Disc to Mabwell pursuant to this Agreement (each, a "**Payment**") shall be paid free and clear of any and all taxes, except for any withholding taxes required by Applicable Law. Any amounts withheld, deducted or paid to any governmental or taxing authority that are not the result of a Withholding Tax Action (as defined below) shall be treated as paid to Mabwell for the purposes of this Agreement. If any Taxes are required to be withheld from a Payment, and such withholding cannot be reduced or eliminated under an applicable tax treaty, Disc shall (i) deduct or withhold from the Payment any taxes that it is required by Applicable Law to deduct or withhold, (ii) pay such taxes to the applicable governmental or taxing authority, (iii) remit the remaining amount of such Payment to Mabwell, and (iv) send to Mabwell proof of such payment within [***] following such payment. Notwithstanding the foregoing, the Parties acknowledge and agree that if Disc (or its assignee pursuant to Section 13.3) is required by Applicable Law to withhold taxes in respect of any Payment, and if such withholding obligation arises or is increased solely as a result of a Withholding Tax Action by Disc after the Effective Date, then, notwithstanding anything to the contrary herein, any such Payment shall be increased to take into account such increased withholding taxes as may be necessary so that, after making all required withholdings, Mabwell (or its assignee pursuant to Section 13.3) receives an amount equal to the sum it would have received had no such Withholding Tax Action occurred. A "**Withholding Tax Action**" means (i) a permitted assignment by Disc pursuant to Section 13.3 to an Affiliate outside of the United States; (ii) the exercise by Disc of its rights under this Agreement through an Affiliate outside of the United States; (iii) a redomiciliation of Disc, or an assignee or a successor to a jurisdiction outside the United States; and (iv) any action by Disc that causes this Agreement to become subject to tax in a jurisdiction outside of the United States or subject any Payments to withholding in any jurisdiction that would not have been required absent such action.

(b) **Cooperation**. The Parties agree to cooperate with one another and use reasonable efforts to avoid or reduce tax withholding or similar obligations in respect of any payments made by a Party to the other Party under this Agreement. Disc shall use commercially reasonable efforts to inform Mabwell of any forms, certificates or other items necessary to reduce or eliminate any such withholding or similar taxes and provide Mabwell a reasonable opportunity to provide such forms, certificate or other items. Without limiting the foregoing, if a Party is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to the other Party or the appropriate governmental authority (with the assistance of the other Party to the extent that this is reasonably required and is requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the other Party of its obligation to withhold such tax, and the other Party shall apply the reduced rate of withholding or dispense with withholding, as the case may be; provided that the other Party has received evidence of the requesting Party's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [***] prior to the time that the applicable payments are due.

(c) **Value Added Tax**. Notwithstanding anything contained in Section 6.5 or in this Section 6.6, this Section 6.6(c) shall apply with respect to any sales, use, transfer, documentary, goods and services, value added or similar tax ("**VAT**"). All Payments are exclusive of VAT. If any VAT is chargeable in respect of any Payments, Disc shall pay VAT at the applicable rate in respect of any such Payments following the receipt of a VAT invoice in the appropriate form issued by Mabwell in respect of those Payments, such VAT to be payable on the later of the due date of the payment of the Payments to which such VAT relates and [***] after the receipt by Disc of the applicable invoice relating to such VAT payment. If Mabwell directly pays any VAT, Disc shall promptly reimburse Mabwell for such VAT, including all reasonable related costs.

(d) **Foreign Derived Intangible Income**. The Parties shall use commercially reasonable efforts to provide, and to cause their respective Affiliates, subcontractors, sublicenses, customers, and applicable Third Parties to provide, at the expense of the requesting Party, any information and documentation reasonably requested by the other Party to obtain the benefits with respect to payments made under this Agreement of (i) Section 250 of the Internal Revenue Code of 1986, as amended and the applicable Treasury Regulations and/or (ii) any new U.S. federal income tax legislation enacted during the term of this agreement that could reasonably be expected to provide a material tax benefit to either Party.

6.7 **Interest on Late Payments**. Without limiting any other rights or remedies available to a Party hereunder, any undisputed late payment or portion thereof by a Party will bear interest, to the extent permitted by Applicable Law, at an annual rate of [***], computed from the date such payment was due until the date the applicable Party makes the payment. Where the late payment is caused by recipient of the payment, including for reasons such as failure to communicate in a timely manner changes to bank details, or failure to respond to communications from payor regarding the interpretation or dispute of the terms of such payment, then no interest will be payable by payor.

6.8 **Financial Records**. Disc shall, and shall cause its Affiliates and Sublicensees to, keep complete and accurate financial books and records pertaining to the Commercialization of Licensed Products hereunder, including royalty reports in accordance with Section 6.3(d), in sufficient detail to calculate and verify all amounts payable hereunder. Disc shall and shall cause its Affiliates and Sublicensees to retain such books and records until [***].

6.9 **Audit**. During the Term of this Agreement and for a period of [***] thereafter, at the request of Mabwell, Disc (a) shall permit Mabwell or an independent auditor designated by Mabwell and reasonably acceptable to Disc, at reasonable times and upon reasonable notice, to audit the books and records maintained by Disc or its Affiliates pursuant to Section 2.4 and Section 6.8, solely to ensure Disc's and its Affiliate's compliance with this Agreement and the accuracy of all reports and payments made hereunder; and (b) shall cause its Sublicensees with active sublicense agreements (and for [***] thereafter) to permit an independent auditor designated by Mabwell and reasonably acceptable to Disc and such Sublicensee, at reasonable times and upon reasonable notice, to audit the books and record maintained by such Sublicensees pursuant to Section 2.4 and Section 6.8, solely to ensure such Sublicensees' compliance with this Agreement and the accuracy of all reports and payments made hereunder. Any such audit shall be conducted during regular business hours in a reasonable manner and shall be limited to books and records up to [***] prior to audit notification, provided that in no event shall such audit extend to books and records relating to any period after the Term. Such audit shall not be performed more frequently than [***] nor more frequently than once with respect to records covering any specific period of time. The auditors shall only state factual findings in the audit reports and shall not interpret this Agreement. The final audit report shall be shared with Disc

(or its Sublicensee, as applicable) at the same time it is shared with Mabwell. As between Mabwell and Disc, the cost of any such audit (and the costs of the Auditor, if any) shall be borne by Mabwell, unless the audit reveals or the Auditor determines, with respect to a period, a variance of more than [***] from the reported amounts for such period, in which case Disc shall bear the cost of the audit and Auditor, if any (including any dispute with respect thereto, pursuant to Section 6.10). If such audit concludes (or, if the Parties dispute the result of such audit, the Audit Dispute Auditor concludes) that (x) additional amounts were owed by Disc, Disc shall pay the additional amounts within [***] after the date on which such final audit report (or the decision of the Audit Dispute Auditor) is received by Disc, with interest from the date originally due as provided in Section 6.7, or (y) excess payments were made by Disc, Disc may credit such excess payment against any future payment due to Mabwell under this Agreement; provided, however, that where no such future payments are due to Mabwell, Mabwell shall promptly reimburse Disc for any such amounts.

6.10**Audit Dispute**. In the event of a good faith dispute with respect to any audit under Section 6.9, Mabwell and Disc shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [***], the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other auditor as the Parties shall mutually agree (the "**Audit Dispute Auditor**"). The Audit Dispute Auditor shall be impartial and independent. The decision of the Audit Dispute Auditor shall be final and binding absent manifest error. The cost of the Audit Dispute Auditor shall be allocated between the Parties as set forth for other auditors in Section 6.9.

7. INTELLECTUAL PROPERTY

7.1 **Ownership of Intellectual Property.**

(a) **Background Technology**. Subject to Section 7.1(c), as between the Parties, and except with respect to any Arising IP, Licensed Improvement IP or Joint Improvement IP, which is addressed in Section 7.1(b), (i) Mabwell will retain all right, title and interest in and to any Patents (including Licensed Patents), Know-How (including Licensed Know-How), and other intellectual property rights Controlled by Mabwell or any of its Affiliates prior to the Effective Date or independently acquired or developed during the Term outside of the scope of this Agreement without any use, reference to or reliance upon Disc Background IP or Disc Confidential Information (collectively, "**Mabwell Background IP**"), and (ii) Disc will retain all right, title and interest in and to any Patents, Know-How, and other intellectual property rights Controlled by Disc or any of its Affiliates prior to the Effective Date or independently acquired or developed during the Term outside of the scope of this Agreement without any use, reference to or reliance upon Mabwell Background IP or Mabwell Confidential Information (collectively, "**Disc Background IP**").

(b) **Arising IP and Improvements**. Subject to Section 7.1(c), as between the Parties, (i) Disc shall solely own and retain all right, title and interest in and to any and all Know-How and inventions that are conceived, discovered, developed, or otherwise made solely by or on behalf of Disc, its Affiliates or its Sublicensees under or in connection with this Agreement, whether or not patented or patentable (the "**Arising Know-How**"), and any and all Patents and other intellectual property rights with respect thereto (each an "**Arising Patent");** (ii) Mabwell shall solely own and retain all right, title and interest in and to any and all Know-How and inventions that are conceived, discovered, developed, or otherwise made solely by or on behalf of Mabwell, its Affiliates or its Sublicensees under or in connection with this Agreement, whether or not patented or patentable (the "**Licensed Improvement Know-How**"), and any and all Patents rights with respect thereto (the "**Licensed Improvement Patents**") and other intellectual property rights with respect thereto; and (iii) the Parties shall jointly own and retain all right, title and interest in and to any and all Know-How and inventions that are conceived, discovered, developed, or otherwise made jointly by or on behalf of (x) Disc, its Affiliates or its Sublicensees, on the one hand, and (y) Mabwell, its Affiliates or its Sublicensees, on the other hand, in each case ((x) and (y)) in connection with this Agreement, whether or not patented or patentable (the "**Joint Improvement Know-How**"), and any and all Patents with respect thereto (the "**Joint Improvement Patents**") and other intellectual property rights with respect thereto. Subject to Sections 5.1 and 5.9, each Party may independently exploit its interest in the Joint Improvement Know-How, Joint Improvement Patents, and other intellectual property rights with respect to the Joint Improvement Know-How without any duty to account to the other Party.

(c) **United States Law**. The determination of whether Know-How and other inventions are conceived, discovered, developed, or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be

made in accordance with Applicable Law in the United States, irrespective of where such conception, discovery, development or making occurs.

(d) **Assignment Obligation**. Each Party shall cause all Persons who perform activities for such Party, its Affiliates, or its Sublicensees or Sublicensees, as applicable, under this Agreement or who conceive, discover, develop, or otherwise make any Know-How or other inventions by or on behalf of such Party or Sublicensees or Sublicensees, as applicable, under or in connection with this Agreement to be under an obligation to assign (or, if such Party is unable to cause such Person to agree to such assignment obligation despite such Party's using commercially reasonable efforts to negotiate such assignment obligation, then to grant an exclusive license under) their rights in any Know-How and inventions resulting therefrom, and all Patents and other intellectual property rights with respect thereto, to such Party, except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case, a suitable license or right to obtain such a license shall be obtained).

(e) **Reporting of Know-How**. Each Party shall keep the other Party reasonably informed as to any Arising Know-How or Licensed Improvement Know-How, respectively, following such Party's conception, discovery, development, or obtaining Control of such Know-How. Each Party shall keep the other Party reasonably informed as to any Joint Improvement Know-How following such Party's conception, discovery, or development of such Know-How. The Parties shall jointly prepare an invention disclosure for such Joint Improvement Know-How.

(f) **Joint Research Agreement**. The Parties agree and acknowledge that this Agreement shall be a "joint research agreement" as defined in 35 U.S.C. 100(h).

(g) **Trademarks**. Disc shall be responsible for the registration, filing, maintenance, and enforcement of all trademarks in the Licensed Territory in connection with the Exploitation of Licensed Antibodies and Licensed Products pursuant to this Agreement, and Disc shall own all such trademarks and all goodwill therein and thereto. Mabwell shall be responsible for the registration, filing, maintenance, and enforcement of all trademarks in the Mabwell Territory in connection with the Exploitation of Licensed Products pursuant to this Agreement, and Mabwell shall own all such trademarks and all goodwill therein and thereto.

7.2 **Maintenance and Prosecution of Patents.**

(a) Disc shall, through counsel of its choice and at its own cost and expense, and subject to this Section 7.2, Prosecute: (i) the Licensed Patents listed on **Schedule 7.2(a)** and any Patents within the Licensed Patents having common priority with any such Licensed Patent, other than divisional patent applications and any issued patents therefrom with claims that are not directed to the Licensed Antibody or Licensed Product; (ii) any Licensed Patents not listed on **Schedule 7.2(a)** that specifically Cover the Licensed Antibody or Licensed Product (for clarity, not including any Licensed Patents that are applicable to products other than Licensed Antibody or Licensed Product, such as formulation or manufacture patents, but in any event, including those Patents that claim the composition of matter, methods of use or methods of administration with respect to a Licensed Antibody or Licensed Product) (clauses (i) and (ii) collectively, the "**Core Licensed Patents**"); and (iii) Arising Patents, including in each case ((i), (ii), or (iii)) any related interference, re-issuance, re-examination, and opposition proceedings with respect thereto, in the Licensed Territory with respect to such Core Licensed Patents and worldwide with respect to the Arising Patents. For clarity, Mabwell shall have the sole right and discretion to Prosecute the Licensed Patents in the Mabwell Territory at its own cost and expense. For purposes of this Section 7.2, all references to Licensed Patents shall include Joint Improvement Patents.

(b) If Disc decides not to Prosecute any Core Licensed Patent in one or more countries in the Licensed Territory pursuant to Section 7.2(a), Disc shall provide reasonable prior written notice to Mabwell of such intention, and Mabwell may, but is not obligated to, assume the control and direction of the Prosecution of such Patent in such country(ies) at its sole cost and expense. If Disc decides not to Prosecute an Arising Patent in one or more countries in the Mabwell Territory pursuant to Section 7.2(a), Disc shall provide reasonable prior written notice to Mabwell of such intention, and, solely to the extent that such Arising Patent is necessary for Mabwell to Exploit a Licensed Antibody or Licensed Product in such country(ies), Mabwell may, but is not obligated to, assume the control and direction of the Prosecution of such Patent in such country(ies) at its sole cost and expense.

(c) Mabwell shall, through counsel of its choice and at its own cost and expense, and subject to this Section 7.2, Prosecute the Licensed Patents other than the Core Licensed Patents, including any related interference, re-issuance, re-examination, and opposition proceedings with respect thereto, in the Licensed Territory and Mabwell Territory.

(d) If Mabwell decides not to Prosecute any Licensed Patent other than a Core Licensed Patent in one or more countries in the Licensed Territory pursuant to Section 7.2(c), Mabwell shall provide reasonable prior written notice to Disc of such intention. Disc may, but is not obligated to, assume the control and direction of the Prosecution of such Patent in such country(ies) at its sole cost and expense.

(e) A Party Prosecuting any Licensed Patents or Arising Patents pursuant to this Section 7.2 shall periodically inform the other Party of all material steps with regard to such Prosecution by the Prosecuting Party of such Licensed Patents and Arising Patents, including by providing the other Party with a copy of material communications to and from any Patent authority regarding such Licensed Patents and by providing the other Party drafts of any material filings or responses to be made to such Patent authorities sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for the other Party to review and comment thereon. The prosecuting Party shall consider in good faith the requests and suggestions of the other Party with respect to such drafts and with respect to strategies for filing and prosecuting such Licensed Patents. The other Party shall, and shall cause its Affiliates to, assist and cooperate with the prosecuting Party, as the prosecuting Party may reasonably request from time to time, in the Prosecution of the Licensed Patents pursuant to this Section 7.2, including providing access to relevant documents and other evidence and making its employees available at reasonable business hours.

(f) Disc shall have the first right, but not the obligation, to make decisions regarding, Patents that Disc is Prosecuting pursuant to Section 7.2(a) or 7.2(c) in the Licensed Territory, including extensions in the United States pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates and any other extensions that are now or become available in the future at its own cost. Disc's decision to apply for patent term extensions or file terminal disclaimers with respect to such Patents shall be made after considering Mabwell's reasonable comments in good faith. Mabwell shall provide prompt and reasonable assistance, as requested by Disc and at Disc's cost, to aid Disc's filing of such extensions and any applicable disclaimers, including providing access to relevant documents and other evidence and making its employees available at reasonable business hours.

(g) Unless Disc has terminated this Agreement with respect to the European Union (within the Licensed Territory) pursuant to Section 11.2(b), in the event that Unified Patent Court Agreement comes into force during the Term of this Agreement, Disc shall be solely responsible for making all decisions regarding Patents, including decisions regarding opting-out or opting-in of existing European Patents into the jurisdiction of the Unified Patent Court or the registration of European Patents with Unitary Effect.

7.3 **Enforcement and Defense of Licensed Patents and Licensed Know-How.**

(a) **Notice**. Each Party shall promptly notify the other Party in writing of (i) any alleged or threatened infringement of the Licensed Patents or Joint Improvement Patents that involves any Licensed Antibody, Licensed Product or Competing Product in the Licensed Territory or Arising Patents worldwide; (ii) any notification under the Biologics Price Competition and Innovation Act of 2009, as amended, or any similar law, from a Biosimilar applicant arising from the filing of an application for the Regulatory Approval of a Biosimilar for which Biosimilar a claim of infringement of any of the Licensed Patents or Joint Improvement Patents in the Licensed Territory or Arising Patents worldwide by the Manufacture or sale of such product could reasonably be asserted; (iii) any unauthorized use or misappropriation of any of the Licensed Know-How or Joint Improvement Know-How that involves any Licensed Antibody, Licensed Product or Competing Product in the Licensed Territory or the Arising Know-How worldwide; and (iv) any alleged or threatened assertion of invalidity or unenforceability by a Third Party of any of the Licensed Patents or Joint Improvement Patents in connection with any Licensed Antibody, Licensed Product or Competing Product in the Licensed Territory or Arising Patents worldwide that Disc is Prosecuting pursuant to Section 7.2; in each case ((i) – (iv)), of which such Party becomes aware, and shall provide the other Party with all available evidence regarding such known or suspected infringement or unauthorized use (clauses (i)-(iv), each an "**Enforcement or Defense Action**"), and the Parties shall confer.

(b) **First Right to Enforce or Defend**.

(i) As between the Parties, Disc shall have the first right, but not the obligation, to enforce or defend (as applicable) any Enforcement or Defense Action in the Licensed Territory, including as a defense or counterclaim in connection with any such Enforcement or Defense Action at Disc's sole cost and expense, using counsel of Disc's choice. At Disc's request, Mabwell shall join any such Enforcement or Defense Action initiated by Disc pursuant to this Section 7.3(b), at Disc's sole cost and expense (unless Mabwell chooses to be represented by its own counsel, in which case Mabwell shall bear such costs and expenses), to the extent necessary for Disc to establish or maintain standing; provided that Disc shall retain control of such Enforcement or Defense Action. If Disc informs Mabwell that Disc has elected not to enforce or defend any such Enforcement or Defense Action or if Disc does not bring such legal action within [***] after the Parties' conference, Mabwell may enforce or defend such action at its sole cost and expense; provided that (i) Disc shall have the right to join as a party to such action at its own cost and expense and (ii) Mabwell shall retain control of such Enforcement or Defense Action.

(ii) As between the Parties, Mabwell shall have the first right, but not the obligation, to enforce or defend (as applicable) any Enforcement or Defense Action for Licensed Patents, Joint Improvement Patents or Arising Patents within the scope of Mabwell's exclusive license under Section 5.3(a), that involves any Licensed Antibody, Licensed Product or Competing Product in the Mabwell Territory, including as a defense or counterclaim in connection with any such Enforcement or Defense Action at Mabwell's sole cost and expense, using counsel of Mabwell's choice. At Mabwell's request, Disc shall join any such Enforcement or Defense Action initiated by Mabwell pursuant to this Section 7.3(b), at Mabwell's sole cost and expense (unless Disc chooses to be represented by its own counsel, in which case Disc shall bear such costs and expenses), to the extent necessary for Mabwell to establish or maintain standing; provided that Mabwell shall retain control of such Enforcement or Defense Action. If Mabwell informs Disc that Mabwell has elected not to enforce or defend any such Enforcement or Defense Action or if Mabwell does not bring such legal action within [***] after the Parties' conference, Disc may enforce or defend such action at its sole cost and expense; provided that (i) Mabwell shall have the right to join as a party to such action at its own cost and expense and (ii) Disc shall retain control of such Enforcement or Defense Action.

(iii) As between the Parties, Mabwell shall have the sole right, but not the obligation, to enforce or defend the Licensed Patents against any infringement or challenge worldwide that does not involve any Licensed Antibody, Licensed Product or Competing Product, at Mabwell's own cost and expense and as Mabwell reasonably determines appropriate, and Mabwell shall have the right to retain all recoveries.

(c) **Cooperation**. The Parties agree to cooperate fully in any Enforcement or Defense Action pursuant to this Section 7.3, including by making the inventors, applicable records, and documents (including laboratory notebooks) with respect to the relevant Patents and Know-How available to the Enforcing Party and furnishing a power of attorney in connection with the Enforcing Party's activities set forth in this Section 7.3, at the Enforcing Party's request. The Enforcing Party shall have the right to settle such claim; provided that neither Party shall have the right to settle any Enforcement or Defense Action under this Section 7.3 in a manner that has a material adverse effect on the rights or interest of the other Party or in a manner that imposes any costs or liability on or involves any admission by, the other Party, without the express written consent of such other Party (which consent shall not be unreasonably withheld, delayed, or conditioned) and provided, further, that any such settlement or consent judgment that grants a sublicense to any Third Party will be consistent with the applicable requirements of Article 5.

(d) **Recovery**. Except as otherwise agreed by the Parties, any recovery realized as a result of such litigation described above in Sections 7.3(b)(i) and 7.3(b)(ii) (whether by way of settlement or otherwise) shall be first allocated to reimburse the each of the Parties for their respective costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be retained by the Enforcing Party, provided that any such amount retained by Disc in any Enforcement or Defense Action for Licensed Patents in the Licensed Territory shall be treated as Net Sales hereunder.

7.4 **Infringement Actions by Third Parties**. If the Exploitation of any Licensed Product in the Licensed Territory pursuant to this Agreement results in, or is reasonably expected to result in, any action by a Third Party alleging infringement or violation of any intellectual property right by Disc, its Affiliates or its Sublicensees, including any defense or counterclaim in connection with an Enforcement or Defense Action initiated pursuant to Section 7.3(b)

(a "**Third Party Infringement Action**"), the Party first becoming aware of such alleged infringement or violation shall promptly notify the other Party thereof in writing. As between the Parties, Disc shall be responsible for defending any such action at its sole cost and expense, using counsel of Disc's choice. Mabwell may participate in any such action at its sole election with counsel of its choice at its sole cost and expense; provided that Disc shall retain the right to control such action. Mabwell shall, and shall cause its Affiliates to, assist and cooperate with Disc, as Disc may reasonably request from time to time, in connection with its activities set forth in this Section 7.4 at Disc's cost and expense, including, where necessary, furnishing a power of attorney solely for such purpose, joining in or being named as a necessary party to such action, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours. Without the other Party's prior written consent, neither Party shall have the right to settle any Third Party Infringement Action under this Section 7.4 in a manner that has a material adverse effect on the rights or interest of the other Party or in a manner that imposes any costs or liability on or involves any admission by the other Party.

7.5 **Third Party IP Rights**. If, in the reasonable opinion of Disc and its counsel, it is necessary or advisable to obtain any licenses or rights under any Patent or Know-How of a Third Party in any country in the Licensed Territory in order for Disc, its Affiliates or its Sublicensees to Exploit a Licensed Antibody or Licensed Product in the Licensed Territory (such right, a "**Third Party IP Right**"), then, the Parties will determine whether or not, and which Party will take the lead to, seek to obtain a license or other similar rights to such Third Party IP Right for the Licensed Antibody or Licensed Product on a worldwide basis (such Party, the "**Lead Party**"); provided that if the Parties cannot agree, then each Party shall have the right to obtain a license, covenant not to sue or other similar rights to such Third Party IP Right for the Licensed Antibody or Licensed Product in its applicable territory (i.e., the Licensed Territory with respect to Disc and the Mabwell Territory with respect to Mabwell). The Lead Party shall keep the other Party reasonably informed of the negotiation with the Third Party and the applicable terms upon which such license or other rights to such Third Party IP Right will be obtained, and the other Party shall receive a sublicense to such Third Party IP Right to Exploit Licensed Antibodies and Licensed Products in such Party's applicable territory if such Party accepts all payment obligations and other obligations and conditions applicable to such sublicense in writing.

8. CONFIDENTIALITY AND NON-DISCLOSURE

8.1 **Confidentiality and Non-Use Obligations**. Each Party shall, and shall cause its Affiliates, actual or prospective Sublicensees, as applicable, and its and their officers, directors, employees, subcontractors, and agents (collectively, "**Representatives**") to, (1) keep confidential and not publish or otherwise disclose to any Third Party, except to the extent such disclosure is expressly permitted by the terms of this Agreement, and (2) not use directly or indirectly for any purpose other than as necessary to exercise its rights and carry out its obligations under this Agreement, any Confidential Information of the other Party. "**Confidential Information**" of a Party means any information of such Party or is Affiliates that is furnished or otherwise made known to the other Party during the Term of this Agreement that is marked as confidential, non-public or proprietary, or otherwise can be reasonably inferred from context to be confidential, non-public or proprietary, including information relating to the scientific, regulatory, business affairs, or other activities of the disclosing Party or its Affiliates or Sublicensees, as applicable. For clarity, failure to mark Confidential Information shall in no event on its own disqualify such information from being considered Confidential Information under the definitions or for purposes of this Agreement. Development plans, Commercialization plans and key initiatives disclosed by Mabwell pursuant to Sections 2.2 and 2.5 and Mabwell Regulatory Documentation and Results shall be the Confidential Information of Mabwell. Disc's development records maintained under Section 2.4, Development Plans, Commercialization Plans and key initiatives disclosed by Disc pursuant to Sections 2.2 and 2.5, Disc's financial records maintained under Section 6.8, and Disc Regulatory Documentation and Results shall be the Confidential Information of Disc. Additionally, Joint Improvement Know-How, Joint Improvement Patents, and the existence and terms of this Agreement and the Parties' respective activities hereunder shall be deemed to be the Confidential Information of both Parties, and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto. Notwithstanding the foregoing, Confidential Information shall not include any information that the receiving Party can demonstrate through competent written or documentary evidence:

(a) is or hereafter becomes part of the public domain by public use, publication, general knowledge, or the like through no breach of this Agreement or other act or omission by the receiving Party or its Representatives;

(b) to have been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information;

(c) is subsequently received by the receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to such information;

(d) has been published by a Third Party or otherwise enters the public domain through no fault of the receiving Party or its Representatives or breach of this Agreement; or

(e) can be demonstrated by contemporaneously maintained written evidence to have been independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information or breach of this Agreement.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

8.2 **Permitted Disclosures**. Each Party may disclose Confidential Information to the extent that such disclosure is made pursuant to Section 8.4 or Section 8.5 or:

(a) is made to such Party's Representatives only on a need-to-know basis and pursuant to written obligations of confidentiality and non-use with respect to such Confidential Information at least as protective as the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 8; provided that each Party shall be liable for all acts and omissions of its Representatives under this Article 8, and any breach by a Representative of a Party shall be deemed a breach by such Party.

(b) solely with respect to Disc's development records maintained under Section 2.4, and Disc's financial records maintained under Section 6.8, is made to an independent auditor in accordance with Section 6.9 or Section 6.10;

(c) is made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial, or local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law, including by reason of filing with securities regulators; provided that (i) the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency; (ii) if disclosed, such Confidential Information is used only for the purposes for which the order was issued; and (iii) the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order. Without limiting the foregoing, with respect to any disclosures of Confidential Information pursuant to the requirements of a stock exchange in the Licensed Territory or the Mabwell Territory (including the Shanghai Stock Exchange), in addition to complying with the foregoing requirements ((i) – (iii)), the Party disclosing such information pursuant to this Section 8.2(c) shall (x) provide to the other Party a copy of any proposed disclosure no later than [***] prior to its submission; and (y) incorporate all reasonable comments and proposed edits made by such other Party with respect to the redaction of information in such disclosure to protect such other Party's Confidential Information;

(d) subject to Section 3.2(c), is made by or on behalf of the receiving Party to Regulatory Authorities as required in connection with any filing, application, or request for Regulatory Approval in accordance with this Agreement; provided that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;

(e) subject to Section 7.2(e), is made by or on behalf of the receiving Party to a Patent authority as may be reasonably necessary or useful for purposes of Prosecuting a Patent in accordance with this Agreement;

provided that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available; or

(f) is made by or on behalf of the receiving Party to potential or actual investors, lenders, investment bankers, acquirers, merger partners, or collaborators as may be necessary in connection with their evaluation of such potential or actual investment, loans, acquisition, or collaboration; provided that such Persons shall be subject to written obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 8.

8.3 **Use of Name**. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo or trademark (or any abbreviation or adaptation thereof) of the other Party or any of its Affiliates or any of its or their Sublicensees, as applicable, in any publication, press release, marketing, or promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 8.3 shall not prohibit:

(a) either Party (each, as applicable, the "**Identifying Party**") from making any disclosure identifying the other Party to the extent required in connection with exercising its rights or carrying out obligations under this Agreement; or

(b) the Identifying Party from making any disclosure identifying the other Party that is required by Applicable Law or the rules of a stock exchange on which the securities of the other Party are listed (or to which an application for listing has been submitted); provided that (i) the Identifying Party shall first have given notice to the other Party and given the other Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the information relating to the other Party that is the subject of such order be held in confidence by such court or agency; (ii) if disclosed, the information relating to the other Party is used only for the purposes for which the order was issued; and (iii) the information relating to the other Party disclosed in response to such court or governmental order shall be limited to that which is legally required to be disclosed in response to such court or governmental order. With respect to any disclosures identifying the other Party pursuant to the requirements of the Shanghai Stock Exchange, in addition to complying with the foregoing requirements ((i) – (iii)), the Identifying Party shall (x) provide to the other Party a copy of any proposed disclosure no later than [***] prior to its submission; and (y) consider in good faith any comments and proposed edits made by the other Party with respect to the redaction of information in such disclosure to protect the other Party's names, logos, and trademarks.

8.4 **Public Announcements**. The Parties will agree upon the content of one (1) or more press releases which shall be issued upon the mutual agreement of the Parties substantially in the form(s) attached hereto as **Schedule 8.4**. Except as permitted pursuant to Section 8.2, neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment hereto that has already been publicly disclosed by such Party or by the other Party in accordance with this Agreement; provided that such information remains accurate as of such time and provided the frequency and form of such disclosure are reasonable. Notwithstanding the foregoing, Disc shall have the right without obtaining Mabwell's consent to announce the commencement of any clinical studies of Licensed Products and the achievement of any Regulatory Approvals for Licensed Products in the Licensed Territory.

8.5 **Publications**. The Parties recognize the desirability of publishing and publicly disclosing the results of and information regarding activities under this Agreement. Accordingly, Disc shall be free to publicly disclose the results and information regarding its activities under this Agreement, including the Disc Regulatory Results, subject to prior review by Mabwell as provided in Section 8.5(a), and Mabwell shall be free to publicly disclose the results of and information regarding its activities under this Agreement, including the Mabwell Regulatory Results, subject to prior review by Disc as provided in 8.5(b).

(a) Prior to publishing or disclosing any results of and information regarding its activities under this Agreement, including the Disc Regulatory Results, Disc shall provide Mabwell with drafts of proposed abstracts, manuscripts, or summaries of presentations at least [***] prior to any proposed publication or disclosure date. Mabwell shall respond promptly through its designated representative and in any event no later than [***] after receipt of such proposed publication or presentation or such shorter period as may be required by the publication or

presentation. Disc shall remove any Confidential Information of Mabwell identified by Mabwell in such proposed publication or presentation and shall give due regard to comments furnished by Mabwell, such comments not to be unreasonably rejected. In addition, Disc agrees to delay such publication or presentation to allow a reasonable period (not to exceed [***]) for Mabwell to file for Patent protection with respect to any patentable information or inventions Controlled by Mabwell and identified by Mabwell in such proposed publication or presentation.

(b) Prior to publishing or disclosing any results of and information regarding its activities under this Agreement, including the Mabwell Regulatory Results, Mabwell shall provide Disc with drafts of proposed abstracts, manuscripts, or summaries of presentations at least [***] prior to any proposed publication or disclosure date. Disc shall respond promptly through its designated representative and in any event no later than [***] after receipt of such proposed publication or presentation or such shorter period as may be required by the publication or presentation. Mabwell shall remove any Confidential Information of Disc identified by Disc in such proposed publication or presentation and shall give due regard to comments furnished by Disc, such comments not to be unreasonably rejected. In addition, Mabwell agrees to delay such publication or presentation to allow a reasonable period (not to exceed [***]) for Disc to file for Patent protection with respect to any patentable information or inventions Controlled by Disc and identified by Disc in such proposed publication or presentation.

8.6 **Return of Confidential Information**. Upon the effective date of the expiration or termination of this Agreement for any reason, either Party may request in writing, and the non-requesting Party shall either, (i) promptly destroy all copies of such Confidential Information in the possession or control of the non-requesting Party and certify such destruction in writing to the requesting Party; or (ii) promptly deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the non-requesting Party. Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain such Confidential Information solely (x) to the extent necessary or reasonably useful for purposes of performing any continuing obligations or exercising any ongoing rights hereunder; and (y) as already included in any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures in the ordinary course of business, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures and available solely to such non-requesting Party's information technology specialists (and not to its Representatives generally); but in each case ((x) and (y)), and all other cases, not for any other uses or purposes.

8.7 **Duration of Confidentiality and Non-Use Obligations**. The confidentiality and non-use obligations set forth in this Article 8 shall survive for a period of [***].

8.8 **Privileged Communications**. In furtherance of this Agreement, it is expected that the Parties may, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential in accordance with this Article 8, that they will not be deemed to waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between Mabwell and Disc, including the community of legal interests in avoiding infringement of any valid, enforceable Patents of Third Parties and maintaining the validity of the Licensed Patents. Each Party shall consult in a timely manner with the other Party before engaging in any conduct (*e.g.*, producing information or documents) in connection with litigation or other proceedings that could conceivably implicate privileges maintained by the other Party. Notwithstanding anything contained in this Section 8.8, nothing in this Agreement shall prejudice a Party's ability to take discovery of the other Party in disputes between them relating to the Agreement and no information otherwise admissible or discoverable by a Party shall become inadmissible or immune from discovery solely by this Section 8.8.

8.9 **Supersession of Existing Confidential Disclosure Agreement**. The Parties agree that this Agreement shall supersede the Confidential Disclosure Agreement between the Parties dated [***] with respect to the exchange of Confidential Information (as defined in Section 8.1) under this Agreement.

9. REPRESENTATIONS, WARRANTIES, AND COVENANTS

9.1 **Mutual Representations and Warranties**. Mabwell and Disc each represents and warrants to the other, as of the Execution Date:

(a) It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement;

(b) The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized (and to the extent required, will be ratified by such party's shareholders promptly following the Execution Date) by all necessary corporate action and do not violate (i) such Party's charter documents, bylaws, or other organizational documents; (ii) any agreement, instrument or contractual obligation to which such Party is bound; (iii) any requirement of any Applicable Law; or (iv) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to such Party;

(c) This Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity);

(d) It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder;

(e) Neither it nor any of its Affiliates has been debarred or is subject to debarment and neither it nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the FFDCA or any foreign equivalents or who is the subject of a conviction described in such section. It will inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 or any foreign equivalents or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates' knowledge, is threatened, relating to the debarment, or conviction of it or any such Person performing services hereunder; and

9.2 **Additional Representations and Warranties of Mabwell**. Mabwell further represents, warrants to Disc that:

(a) As of the Execution Date, Mabwell has the right to grant the licenses specified herein and all Patents and Know-How owned or in-licensed by Mabwell or any of its Affiliates that are necessary or reasonably useful for the Exploitation of Licensed Antibody or Licensed Products are included in the Licensed IP;

(b) As of the Execution Date, Mabwell has not received any written claim or demand alleging that the Licensed Patents or the Licensed Know-How are invalid or unenforceable;

(c) As of the Execution Date, To the Knowledge of Mabwell, no Person is infringing or threatening to infringe the Licensed Patents or misuse or misappropriate the Licensed Know-How;

(d) The Patents set forth on Schedule 1.92 are all of the existing Patents Controlled by Mabwell or any of its Affiliates as of the Execution Date that are necessary or reasonably useful to Exploit one or more Licensed Antibodies or Licensed Products in the Licensed Territory;

(e) As of the Execution Date, neither Mabwell or its Affiliates has assigned, transferred, conveyed, or licensed to any Third Parties any right, title or interest under the Licensed IP in a manner that would conflict with or adversely affect the license and rights granted to Disc under this Agreement;

(f) Mabwell and its Affiliates will not assign, transfer, convey, or license to any Third Parties or Affiliates any Licensed IP or any right, title and interest in and to Licensed Antibody or Licensed Product in a manner that would conflict with or adversely affect the license and rights granted to Disc under this Agreement;

(g) As of the Execution Date, neither Mabwell nor its Affiliates has created a lien on or otherwise encumbered the Licensed IP in a manner that would conflict with or adversely affect the license and rights granted to Disc under this Agreement;

(h) Mabwell and its Affiliates will not create a lien on or otherwise encumber the Licensed IP in a manner that would conflict with or adversely affect the license and rights granted to Disc under this Agreement;

(i) As of the Execution Date, Mabwell is not aware of any pending litigation against Mabwell or its Affiliates or Sublicensees (and has not received any communication relating thereto) that alleges that Mabwell's or its Affiliates' or Sublicensees' activities with respect to Licensed Antibodies, Licensed Products, Licensed Know-How or Licensed Patents have infringed or misappropriated, or would infringe or misappropriate, any of the intellectual property rights of any other Person. To the knowledge of Mabwell, any Exploitation of Licensed Antibodies s contemplated under this Agreement (a) does not and will not infringe any issued patent of any Third Party or misappropriate any Know-How or other intellectual property of any Third Party; and (b) will not infringe the claims of any Third Party patent application when and if such claims were to issue in their current form;

(j) As of the Execution Date, to the knowledge of Mabwell, no intellectual property rights of any Third Party were infringed or misappropriated during the creation of the Licensed Patents or Licensed Know-How;

(k) As of the Execution Date, all documents required to be filed and all payments required to be made in order to maintain each Licensed Patent have been filed or made, as the case may be, in a timely manner, and no action has been taken (or not been taken) that would constitute waiver, abandonment or any similar relinquishment of rights with respect to any such Patent other than any abandonment taken in the business judgment of Mabwell. As of the Execution Date, all Licensed Patents are and have been filed and maintained properly and correctly. Mabwell has complied with all Applicable Law, including any duties of candor to applicable patent offices, in connection with the filing, prosecution and maintenance of the Licensed Patents;

(l) The inventors named in each Licensed Patent owned or purported to be owned by Mabwell have assigned, and are under a contractual obligation to assign, to Mabwell their respective entire right, title and interest in and to the relevant Licensed Patent, and Mabwell shall be solely responsible for any remuneration that may owed to Mabwell's inventors under any applicable inventor remuneration laws;

(m) As of the Execution Date, Mabwell has furnished or made available to Disc all material scientific and technical information relating to safety and efficacy concerning Licensed Products and Licensed Antibodies (in each case in the form being developed by Mabwell or any of its Affiliates as of the Execution Date) known to Mabwell or any of its Affiliates, including all material regulatory filings and other material correspondence with Regulatory Authorities in the Licensed Territory relating to any such Licensed Product or Licensed Antibody, and to Mabwell's knowledge, such scientific and technical information is accurate, complete and true in all material respects;

(n) No funding, facilities, or personnel of any governmental authority or any public or private educational or research institutions were used to develop or create any Licensed IP existing as of the Execution Date, and neither Mabwell nor any of its Affiliates has entered into a government funding relationship as of the Execution Date that would result in rights to any Licensed Antibody or Licensed Product residing in the U.S. Government, the National Institutes of Health, or other government agency, and the licenses granted hereunder are not subject to overriding obligations to the U.S. Government as set forth in 35 U.S.C. §§ 200 et seq., or any similar obligations under the laws of any other country in the Licensed Territory; and

(o) As of the Execution Date, neither Mabwell nor any of its Affiliates have Exploited (other than in the discovery and research of the Licensed Antibody), are Exploiting, or intend to Exploit, whether directly or indirectly, any Competing Products in the Licensed Territory or in the Mabwell Territory.

9.3 **Additional Representations and Warranties of Disc**. Disc further represents and warrants to Mabwell as of the Execution Date that:

(a) Disc has the right to grant the licenses specified herein;

(b) There are no claims, judgments or settlements against or pending with respect to Disc or its commercial activities in the Licensed Territory, and to Disc's knowledge as of the Execution Date, no such claims, judgments or settlements are threatened in writing; and

(c) Disc has not commenced or threatened any proceeding, or asserted any allegation or claim, against any Person for infringement or misappropriation of any Patents in the Licensed Territory.

9.4 **Mutual Covenants**. Each Party hereby covenants to the other Party, as follows:

(a) It will not enter any agreement with a Third Party that would prevent or restrict it from granting the rights or exclusivity granted or intended to be granted to the other Party under this Agreement or performing its obligations under this Agreement, except as required by Applicable Laws; and

(b) It will comply with all Applicable Law (including applicable Anti-Corruption Laws) in the course of performing its obligations or exercising its rights pursuant to this Agreement.

9.5 **DISCLAIMER OF WARRANTIES**. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR PURPOSE, OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

9.6 **ADDITIONAL WAIVERS**.

(a) EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, DISC AGREES THAT: (I) THE LICENSED IP IS LICENSED "AS IS," "WITH ALL FAULTS," AND "WITH ALL DEFECTS," AND DISC EXPRESSLY WAIVES ALL RIGHTS TO MAKE ANY CLAIM WHATSOEVER AGAINST MABWELL FOR MISREPRESENTATION OR FOR BREACH OF PROMISE, GUARANTEE, OR WARRANTY OF ANY KIND RELATING TO THE LICENSED IP, AND (II) DISC IS SOLELY RESPONSIBLE FOR DETERMINING WHETHER THE LICENSED IP HAS APPLICABILITY OR UTILITY IN DISC'S CONTEMPLATED EXPLOITATION OF LICENSED PRODUCTS, AND DISC ASSUMES ALL RISK AND LIABILITY IN CONNECTION WITH SUCH DETERMINATION.

(b) EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, MABWELL AGREES THAT: (I) THE ARISING IP IS LICENSED "AS IS," "WITH ALL FAULTS," AND "WITH ALL DEFECTS," AND MABWELL EXPRESSLY WAIVES ALL RIGHTS TO MAKE ANY CLAIM WHATSOEVER AGAINST DISC FOR MISREPRESENTATION OR FOR BREACH OF PROMISE, GUARANTEE, OR WARRANTY OF ANY KIND RELATING TO THE ARISING IP, AND (II) MABWELL IS SOLELY RESPONSIBLE FOR DETERMINING WHETHER THE ARISING IP HAS APPLICABILITY OR UTILITY IN MABWELL'S CONTEMPLATED EXPLOITATION OF LICENSED PRODUCTS, AND MABWELL ASSUMES ALL RISK AND LIABILITY IN CONNECTION WITH SUCH DETERMINATION.

10. INDEMNITY, LIMITATION OF LIABILITY, AND INSURANCE

10.1**Indemnification of Mabwell**. Disc shall indemnify Mabwell, its Affiliates and Sublicensees (other than Disc, its Affiliates and Sublicensees), and its and their officers, directors, employees, subcontractors, and agents ("**Mabwell Indemnitees**") and defend and hold each of them harmless, from and against any and all losses, damages,

liabilities, costs, and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "**Third Party Claims**") arising from or occurring as a result of: (i) the breach by Disc of a representation, warranty, or covenant of this Agreement; (ii) the fraud, gross negligence, or willful misconduct of Disc or any Disc Indemnitee; (iii) the violation of any Applicable Law by Disc or any Disc Indemnitee; or (iv) the Exploitation of any Licensed Antibody or Licensed Product by or on behalf of Disc or any of its Affiliates or Sublicensees following the Effective Date, except in each case ((i)-(iv)), for those Losses for which Mabwell has an obligation to indemnify Disc pursuant to Section 10.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability.

10.2**Indemnification of Disc**. Mabwell shall indemnify Disc its Affiliates and Sublicensees, and its and their officers, directors, employees, subcontractors, and agents ("**Disc Indemnitees**")and defend and hold each of them harmless from and against any and all Losses in connection with any and all Third Party Claims arising from or occurring as a result of: (i) the breach by Mabwell of a representation, warranty, or covenant of this Agreement; (ii) the fraud, gross negligence, or willful misconduct of Mabwell or any Mabwell Indemnitee; (iii) the violation of any Applicable Law by Mabwell or any Mabwell Indemnitee, or (iv) the Exploitation of any Licensed Antibody or Licensed Product by or on behalf of Mabwell or any of its Affiliates or Sublicensees (for clarity, excluding Disc, its Affiliates and their Sublicensees) prior to and following the Effective Date; except, in each case ((i)-(iv)) for those Losses for which Disc has an obligation to indemnify Mabwell pursuant to Section 10.1 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

10.3**Indemnification Procedures.**

(a) **Notice of Claim**. All indemnification claims in respect of a Party or its indemnitees shall be made solely by such Party to this Agreement (each, an "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article 10, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims. The assumption of defense of any Third party Claim will not be construed as an acknowledgment that the indemnifying Party is liable to indemnify any Indemnified Party in respect of such Third Party Claim, nor will it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification.

(b) **Right to Participate in Defense**. Any Indemnified Party shall be entitled to participate in the defense of such Third Party Claim and to employ counsel of its choice for such purpose provided that the indemnifying Party shall ultimately control such claim. Such employment of counsel shall be at the Indemnified Party's sole cost and expense unless the employment thereof has been specifically authorized in writing by the indemnifying Party.

(c) **Settlement**. With respect to the judgment or settlement of any Third Party Claim relating solely to the payment of money damages and that shall not result in the applicable indemnitee(s) becoming subject to injunctive or other relief, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement, or otherwise dispose of such Third Party Claim, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Third Party Claims, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement, or otherwise dispose of such Loss; provided that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, delayed, or conditioned).

(d) **Cooperation**. The Indemnified Party shall and shall cause each indemnitee to cooperate in the defense or prosecution thereof and shall furnish such records, information, and testimony, provide such witnesses, and attend such conferences, discovery proceedings, hearings, trials, and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim and making Indemnified Parties and other employees and agents

available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder The indemnifying Party shall reimburse the Indemnified Party and its Representatives for reasonable and verifiable out-of-pocket expenses in connection therewith.

10.4**Special, Indirect and Other Losses**. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, TO THE MAXIMUM EXTENT PERMITTED UNDER LAW, AND EXCEPT (A) IN THE EVENT OF THE BREACH OF ARTICLE 8 BY OR WILLFUL MISCONDUCT, GROSS NEGLIGENCE, OR FRAUD OF A PARTY, AND (B) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 10, NEITHER PARTY NOR ANY OF ITS REPRESENTATIVES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, OR OTHERWISE FOR ANY CONSEQUENTIAL, SPECIAL, PUNITIVE, OR INDIRECT DAMAGES, OR FOR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, REGARDLESS OF WHETHER A PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR WHETHER AN AGREED-UPON REMEDY HAS FAILED OF ITS ESSENTIAL PURPOSE. NEITHER PARTY SHALL, AND SHALL REQUIRE THAT ITS AFFILIATES AND SUBLICENSEES DO NOT, MAKE ANY STATEMENTS, REPRESENTATIONS OR WARRANTIES OR ACCEPT ANY LIABILITIES OR RESPONSIBILITIES WHATSOEVER ON BEHALF OF THE OTHER PARTY, ITS AFFILIATES OR SUBLICENSEES THAT ARE INCONSISTENT WITH ANY DISCLAIMER, COVENANT, REPRESENTATION, WARRANTY, OR LIMITATION IN SECTION 9.5 OR THIS SECTION 10.4.

10.5**Insurance**. Disc shall have and maintain such types and amounts of insurance covering its Exploitation of Licensed Antibodies and Licensed Products as is (i) normal and customary in the pharmaceutical industry generally for parties similarly situated, and (ii) otherwise required by Applicable Law. Upon request by Mabwell, Disc shall provide to Mabwell evidence of its insurance coverage, including copies of applicable insurance policies.

11. TERM AND TERMINATION

11.1**Term and Expiration**. This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect until the date of expiration of the last Royalty Term for the last Licensed Product (such period, the "**Term**"). Following the expiration of the Royalty Term for a Licensed Product in a country, the license grants in Section 5.1 shall become fully-paid, royalty-free, perpetual, and irrevocable for such Licensed Product in such country.

11.2**Termination.**

(a) **Termination for Material Breach**.

(i) In the event that either Party (the "**Breaching Party**") is in material breach in the performance of any of its obligations under this Agreement, in addition to any other right and remedy the other Party (the "**Non-Breaching Party**") may have, the Non-Breaching Party may terminate this Agreement in its entirety by providing [***] (the "**Notice Period**") prior written notice (the "**Termination Notice**") to the Breaching Party and specifying the breach and its claim of right to terminate. Such termination shall become effective upon expiration of the Notice Period, unless (i) the Breaching Party cures the breach specified in the Termination Notice during the Notice Period, or (ii) if such breach is curable but cannot be cured within the Notice Period, if the Breaching Party in good faith provides additional written notice of its intention to pursue a cure and commences actions to cure such breach within the Notice Period and thereafter diligently continues such actions and cures such breach within [***] from the date such additional notice is sent (the "**Tolling Period**"). Subject to Section 11.2(a)(ii), any breach not cured within the Notice Period or the Tolling Period shall result in a termination that becomes effective on the later of the expiration of the Notice Period or if applicable, the Tolling Period.

(ii) If the alleged Breaching Party disputes the existence or materiality of a breach specified in a Termination Notice provided by the Non-Breaching Party in accordance with Section 11.2(a)(i), and such alleged Breaching Party provides the Non-Breaching Party notice of such dispute within the Notice Period after receiving such Termination Notice, such dispute shall be resolved in accordance with Section 13.5. During the pendency of a

Dispute under Section 13.5 relating to a Party's alleged material breach of this Agreement, all of the terms and conditions of this Agreement shall remain in effect, and the Parties shall continue to perform all of their respective obligations hereunder. Without limiting the foregoing, during the pendency of a Dispute under Section 13.5 relating to a Party's alleged material breach of this Agreement the Notice Period shall be tolled from the date the alleged Breaching Party notifies the Non-Breaching Party of such Dispute through the resolution of such Dispute in accordance with Section 13.5. For the avoidance of doubt, commencing on the date the alleged Breaching Party notifies the Non-Breaching Party of such Dispute, the Non-Breaching Party shall not have the right to terminate this Agreement pursuant to Section 11.2(a)(i) unless and until (x) the Parties' Senior Officers, the Parties' Chief Executive Officers, or the Arbitrators have determined in accordance with Section 13.5 that the alleged Breaching Party has in fact materially breached this Agreement, and (y) the Breaching Party has not cured such material breach during the Notice Period (as extended in accordance with the foregoing sentence).

(iii) In the event Mabwell provides written notice of a material breach of this Agreement to Disc pursuant to Section 11.2(a)(i) and the breach cited in such notice was caused by any Sublicensee, Disc shall provide written notice promptly back to Mabwell identifying such Sublicensee and shall diligently exercise its rights and remedies under the corresponding sublicense agreement to cause such Sublicensee to cure such breach within the Notice Period or the Tolling Period, as applicable (it being understood that Disc shall have the right to cure any such breach on behalf of such Sublicensee). Subject to Section 11.2(a)(ii), any such breach not cured within the Notice Period or the Tolling Period shall result in a termination that becomes effective on the later of the expiration of the Notice Period or if applicable, the Tolling Period; provided Mabwell may not terminate this Agreement pursuant to this Section 11.2(a) with respect to such breach caused by a Sublicensee that is not an Affiliate of Disc if such breach is not capable of cure within the Notice Period or Tolling Period, as applicable, and, prior to the expiration of the Notice Period or Tolling Period, as applicable, Disc terminates in its entirety the corresponding sublicense agreement and provides written notice of the same to Mabwell.

(b) **Termination by Disc**. Disc shall have the right to terminate this Agreement in its entirety, or on a region-by-region basis in the Licensed Territory (for the purpose of this clause, region means each of the following: [***], for any reason or no reason, at any time after the Effective Date on [***] prior written notice to Mabwell.

(c) **Termination for Insolvency**. To the extent permitted under Applicable Law, in the event that either Party (i) files for protection under bankruptcy or insolvency laws; (ii) makes an assignment for the benefit of creditors; (iii) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [***] after such filing; (iv) proposes a written agreement of composition or extension of its debts; (v) proposes or is a party to any dissolution or liquidation; (vi) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within [***] of the filing thereof; or (vii) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.

(d) **Termination for Patent Challenge**. If either Party or any of its Affiliates or Sublicensees (i) commences or actively, directly and voluntarily participates in any action or proceeding (including any patent opposition or re-examination proceeding), or otherwise asserts any claim, challenging or denying the validity or enforceability of any claim of any Licensed Patent or Arising Patent, as applicable, or (ii) voluntarily assists any other person or entity in bringing or prosecuting any action or proceeding (including any patent opposition or re-examination proceeding) challenging or denying the validity or enforceability of any claim of any Licensed Patent (each of (i) and (ii), a "**Patent Challenge**"), then the licensor of such Licensed Patent or Arising Patent shall have the right to terminate this Agreement upon [***] written notice to licensee; provided that, if a Sublicensee of a Party (and not a Party or any of its Affiliates itself) commences or assists in such Patent Challenge, such termination shall not be effective if each of such Sublicensee(s) withdraw(s) or cause(s) to be withdrawn all such Patent Challenges, or if a Party terminates its sublicense agreement with such Sublicensee, within [***].

11.3**Rights in Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement by Disc or Mabwell are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that Disc, as a licensee of such rights under this

Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction.

11.4**Consequences of Termination**. In the event of a termination of this Agreement in its entirety (but not in the event of expiration of this Agreement) or in a particular region, then on a Licensed Product-by-Licensed Product basis for all Licensed Products (each a "**Terminated Product**"), and on a country-by-country basis for all countries in the Licensed Territory or in the terminated region (each a "**Terminated Country**"), as applicable:

(a) **Termination of Licenses**.

(i) Except as set forth in Section 11.4(b) below, all rights and licenses granted by Mabwell to Disc hereunder shall immediately terminate in their entirety with respect to the termination of the entire Agreement, or with respect to the Terminated Products in the Terminated Country(ies), as applicable, and shall reverted back to Mabwell;

(ii) Except as otherwise agreed by the Parties in the Reversion Agreement pursuant to Section 11.6 below, all rights and licenses granted by Disc to Mabwell hereunder shall immediately terminate in their entirety with respect to the termination of the entire Agreement or with respect to the Terminated Product in the Terminated Country(ies), as applicable, and shall revert back to Disc;

(b) **Conversion of Sublicenses**. In the event that this Agreement is terminated by Mabwell pursuant to Section 11.2(a), 11.2(c), or 11.2(d), Mabwell agrees to grant to any Sublicensee with an active sublicense at the time of termination a direct license under terms and conditions substantially similar to those of this Agreement applicable thereto (provided that any financial terms in such direct license shall be the same as the sublicense but in no event less favorable to Mabwell than the financial terms in this Agreement), which license shall be of the same scope sublicensed to such Sublicensee, provided that such Sublicensee (i) agrees to be bound to Mabwell under such terms and conditions; and (ii) is not in breach of its sublicense agreement with Disc as of the effective date of such termination.

(c) **Ongoing Patent Prosecution or Enforcement or Defense Action**. In the event that this Agreement is terminated by Disc pursuant to Section 11.2(b), with respect to ongoing Prosecution activities and any Enforcement or Defense Action for a Licensed Patent or Joint Improvement Patent in a Terminated Country within a terminated region, Disc shall provide reasonable prior written notice to Mabwell of such intention, and Mabwell may, but is not obligated to, assume the control and direction of the Prosecution or Enforcement or Defense Action, as applicable, of such Patent in such Terminated Country (ies) at its sole cost and expense. In the event that Disc has terminated this Agreement with respect to the European Union region pursuant to Section 11.2(b), in the event that Unified Patent Court Agreement enters into force during the Term of this Agreement, Mabwell shall be solely responsible for making all decisions regarding Patents, including decisions regarding the opting-out or opting-in of existing European Patents into the jurisdiction of the Unified Patent Court or the registration of European Patents with Unitary Effect.

(d) **Transfer of Clinical Studies**. Unless expressly prohibited by any Regulatory Authority, if requested by Mabwell, Disc shall and hereby does, and shall cause its Sublicensees who have not retained a license under this Section 11.4(c) to, transfer control to Mabwell of any or all clinical studies involving Licensed Products being conducted by or on behalf of Disc or such Sublicensees in each relevant Terminated Product or Terminated Country, as applicable, as of the effective date of termination; for any such clinical trials that Mabwell does not request transfer, Disc and its Sublicensees shall promptly and orderly wind down such clinical trials in compliance with Applicable Laws at its own cost and expense.

(e) [***].

11.5 **Disc Continuation in Lieu of Termination**. If Disc is entitled to terminate this Agreement pursuant to Sections 11.2(a) (*i.e.*, Disc has the right to terminate this Agreement in accordance with the last sentence of Section 11.2(a)(i), subject to the last sentence of Section 11.2(a)(ii)), or 11.2(d) (*i.e.*, in the event (x) Mabwell's commences or assists in a Patent Challenge or (y) Mabwell's Sublicensee(s) commence(s) or assist(s) in a Patent

Challenge, and either (A) has not withdrawn or caused to be withdrawn such Patent Challenge, or (B) Mabwell has not terminated its sublicense agreement with such Sublicensee within such [***] period)), Disc may, at its sole discretion, upon written notice to Mabwell, elect not to do so and all applicable royalties, milestones and other amounts due to Mabwell under this Agreement after the date of such notice shall be reduced by [***]. If Disc elects to exercise its right pursuant to this Section 11.5 to not terminate, then Disc shall not be entitled to seek any damages against Mabwell under a breach of contract or other claim giving rise to Disc's termination right (provided that, for clarity, Disc shall still be entitled to bring an indemnification claim to the extent applicable pursuant to Article 10 or seek equitable remedies).

11.6**Product Reversion**.

(a) **Reversion License**. In connection with any termination of this Agreement by Mabwell pursuant to Sections 11.2(a), 11.2(c), or 11.2(d) or by Disc pursuant to Section 11.2(b), in its entirety or with respect to a Terminated Product or a Terminated Country, if requested by Mabwell, Disc shall, and hereby does effective as of the date of such termination, grant Mabwell an exclusive, perpetual, transferable license, with the right to grant sublicenses (through multiple tiers) under the Arising IP and Disc's interest in any Joint Improvement IP ("**Reversion IP**") to Exploit Licensed Antibodies and products containing such Licensed Antibodies, including all Terminated Products, in all Terminated Countries and also in Mabwell Territory, subject to a reasonable reversion royalty in each Terminated Country (for clarity, no reversion royalty shall apply in the Mabwell Territory) based on the development stage of the Terminated Product in Terminated Country at the time of termination and taking into account the reasonable and documented cost incurred by Disc in the Development of the Terminated Product in the Terminated Country (the "**Reversion License**"). Sections 6.3, 6.5, 6.6, 6.7, 6.8, 6.9 and 6.10 shall apply mutatis mutandis to such reversion royalty in the Reversion License. The Parties shall promptly negotiate the reversion royalty and memorialize in writing a separate Reversion License agreement containing such a license grant to the foregoing Reversion IP, the reversion royalty rate and royalty terms described in the immediately prior sentence, the Reversion Technology Transfer provision set forth in Section 11.6(b), the Assistance, Manufacture, and Trademarks provision set forth in Section 11.6(c), and any other provisions necessary to effectuate Mabwell's reversion rights contemplated in this Section 11.6. If the Parties are unable to agree on such reversion royalty or Reversion License agreement described in this Section 11.6(a) within [***], then the reversion royalty and Reversion License agreement shall be determined through binding baseball style arbitration as follows: The Parties shall jointly select an arbitrator to determine the reversion royalty and Reversion License agreement, which arbitrator shall be neutral and independent of both Parties and all of their respective Affiliates, shall have significant experience and expertise in licensing and partnering agreements in the pharmaceutical and biotechnology industries. If the Parties cannot agree on such arbitrator within [***], then such arbitrator shall be appointed by JAMS, which arbitrator must meet the foregoing criteria. Within [***] after an arbitrator is selected (or appointed, as the case may be), each Party will deliver to both the arbitrator and the other Party a detailed written proposal setting forth its proposed terms for the reversion royalty and Reversion License agreement (the **"Proposed Terms"** of the Party) and a memorandum (the **"Support Memorandum"**) in support thereof, not exceeding [***]. The Parties will also provide the arbitrator a copy of this Agreement, as may be amended at such time. Within [***] after receipt of the other Party's Proposed Terms and Support Memorandum, each Party may submit to the arbitrator (with a copy to the other Party) a response to the other Party's Support Memorandum, such response not exceeding [***]. Neither Party may have any other communications (either written or oral) with the arbitrator other than for the sole purpose of engaging the arbitrator or as expressly permitted in this Section 11.6(a); provided that, the arbitrator may convene a hearing if the arbitrator so chooses to ask questions of the Parties and hear oral argument and discussion regarding each Party's Proposed Terms. Within [***] after the arbitrator's appointment, the arbitrator will select one of the two Proposed Terms (without modification) provided by the Parties that the arbitrator believes is most appropriate. The decision of the arbitrator shall be final, binding, and unappealable. For clarity, the arbitrator must select one of the two sets of Proposed Terms, and may not combine elements of both Proposed Terms or take any other action.

(b) **Reversion Technology Transfer**. In the Reversion License agreement, Disc shall, and shall cause its Affiliates and any Sublicensees who have not retained a license under Section 11.4(b) to, when and as reasonably requested by Mabwell, promptly conduct a transfer to Mabwell (or its designated contract manufacturer(s) or other designees) of any and all Know-How, Materials, and Regulatory Documentation and Results that are then owned or Controlled by Disc or the applicable Affiliates or Sublicensees and are reasonably necessary to Develop, Commercialize, Manufacture, obtain Regulatory Approval for and Exploit any Terminated Products, and provide, at Mabwell's expense, for a period of time not to exceed [***] following the effective date of the termination, personnel and technical assistance necessary for Mabwell to continue to Develop, Manufacture or Commercialize the Terminated Product(s) in the Terminated Country(ies) (the "**Reversion Technology Transfer**").

(c) **Assistance, Manufacture, and Trademarks**. Upon Mabwell's reasonable request and at Mabwell's sole cost and expense, Disc shall in the Reversion License agreement:

(i) provide to Mabwell or its designated contract manufacturer(s) or other designees any assistance reasonably required for Mabwell or such designees to complete the Reversion Technology Transfer, including providing technical assistance or facilitating introductions as needed between Mabwell and any involved contract manufacturers;

(ii) at Mabwell's election, transfer to Mabwell, at a price equal to the manufacturing cost, all existing inventory of Terminated Products in the possession of Disc, its Affiliates or its Sublicensees who have not retained a license under Section 11.4(b); and

(iii) at Mabwell's sole discretion and direction, assign all trademarks and tradenames used in the Commercialization of the Terminated Products in the Licensed Territory (other than any housemarks, trademarks, names and logos of the corporate name of Disc, its Affiliate or its Sublicensees), Controlled by Disc, its Affiliates or Sublicensees in each Terminated Country, or if not permitted by Applicable Law, grant a right and license to such trademarks and tradenames for the Commercialization of each Terminated Product in each Terminated Country.

11.7**Remedies**. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

11.8**Accrued Rights; Surviving Obligations**. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Without limiting the foregoing, Sections 2.4, 3.2(d), 3.4, 3.5, 5.2, 5.5 (solely in the event of expiration (but not early termination) of this Agreement), 5.10, 6.5 through 6.10, 7.1, 7.2 (unless Disc terminates this Agreement pursuant to Section 11.2(a), 11.2(c), or 11.2(d), and solely with respect to Arising Patents), 7.3 (unless Disc terminates this Agreement pursuant to Section 11.2(a), 11.2(c), or 11.2(d), and solely with respect to Arising Patents), 9.5, 9.6, 10.1 through 10.4, 11.3, 11.4, 11.6 through 11.8 and Articles 1 (to the extent the definitions are used in other surviving provisions), 8 (for the period set forth in Section 8.7), and 12 shall survive the expiration of this Agreement or the termination of this Agreement, except if this Agreement is terminated pursuant to Section 12.3. In the event that this Agreement is terminated pursuant to Section 12.3, only Articles 1 (to the extent the definitions are used in other surviving provisions) and 8 (for the period set forth in Section 8.7) and Section 11.8 shall survive the termination of this Agreement.

12. Closing Condition

12.1**General**. Notwithstanding anything to the contrary in this Agreement, this Agreement is binding upon the Parties as of the Execution Date to the extent permitted by Applicable Law, but the provisions of Article 2 through Article 11 (other than Article 8) shall only take effect on the first Business Day following the satisfaction of the Closing Condition set forth in Section 12.2 (the "**Effective Date**").

12.2**Closing Conditions**. The obligations of each Party to consummate the transactions contemplated in this Agreement is subject to the fulfillment, or, to the extent permitted by Applicable Law, waiver by the Parties, of the following conditions (each such condition a "**Closing Condition**", and collectively, the "**Closing Conditions**"):

(a) except as disclosed pursuant to Section 12.3, the representations and warranties of each Party contained in this Agreement (i) that are not qualified by materiality, material adverse effect, substantial compliance or similar materiality qualifier will be true and correct in all material respects both when made and at the closing with the same force and effect as if made on the Execution Date and (ii) that are qualified by materiality, material adverse effect, substantial compliance or similar materiality qualifier will be true and correct in all respects both when made and at the closing with the same force and effect as if made on the Execution Date, except in each of (i) and (ii) as would not reasonably be expected, individually or in the aggregate, to have a material impact on the transaction contemplated by this Agreement;

(b) with respect to Mabwell, authorization, consent or approval by its shareholders required to be obtained pursuant to its corporate governance documents ("**Mabwell Shareholder Approval**"), will have been duly

obtained or made, which Mabwell shall obtain within [***] following the Execution Date and failure to meet this Closing Condition shall be deemed a material breach of this Agreement; and

(c) except as disclosed pursuant to Section 12.3, no Material Adverse Effect will have occurred or arisen since the Execution Date.

12.3**Disclosures Prior to Mabwell Shareholder Approval**. Prior to Mabwell Shareholder Approval, each Party shall provide the other Party, to the extent applicable to such Party, with a written disclosure describing any failure to satisfy any of the Closing Conditions set forth in Sections 12.2(a) and 12.2(c). To the extent a written disclosure is provided by a Party pursuant to the foregoing sentence, such written disclosure shall be sufficiently detailed to enable the other Party to decide whether to terminate this Agreement. If a Party provides a written disclosure pursuant to the first sentence of this Section 12.3, the other Party may terminate this Agreement in its entirety, in its sole discretion, effective immediately upon providing written notice to such Party within [***] of the other Party's receipt of such disclosure. Each Party's right to terminate this Agreement pursuant to this Section 12.3 shall be the sole and exclusive remedy for any failure of the other Party to satisfy any of the Closing Conditions set forth in Sections 12.2(a) and 12.2(c) and expressly excludes any other relief or remedy under this Agreement or provided by Applicable Law.

13. MISCELLANEOUS

13.1**Force Majeure**. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than with respect to any payment obligations) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions, or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party of any term or condition of this Agreement) (each of the foregoing, a "**Force Majeure Event**"). The non-performing Party shall notify the other Party of any such Force Majeure Event within [***] after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect (a "**Force Majeure Notice**"). The suspension of performance shall be of no greater scope and no longer duration than is necessary, and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

13.2**Export Control**. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

13.3**Assignment and Delegation**. Neither Party may transfer or assign its rights or delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part, without the prior written consent of the other Party, which consent shall not be unreasonably withheld, delayed, or conditioned, except (a) assignment to an Affiliate, provided that such Party shall remain jointly and severally liable with such Affiliate for the performance of its obligations under this Agreement, or (b) assignment to any successor in interest (whether by merger, acquisition, asset purchase, reorganization or otherwise) in connection with a sale of all or substantially all of the business to which this Agreement relates; or (c) in the case of Mabwell, sell or otherwise assign to any Third Party Mabwell's right to receive any payment (or portion thereof) under this Agreement and related right to receive financial report and conduct financial audit. Any attempted transfer, assignment or delegation in violation of this Section 13.3 shall be void and of no effect. For the avoidance of doubt, this Section 13.3 shall not require Disc to obtain Mabwell's consent to subcontract its rights and obligations hereunder in accordance with this Agreement.

13.4**Severability**. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid, or unenforceable provision, the Parties shall endeavor to add as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

13.5**Dispute Resolution.**

(a) Except as provided in this Section 13.5 or in Sections 2.5(e), 6.10, 11.6 (with respect to baseball arbitration) or 13.10, any dispute, controversy or claim between the Parties arising out of, in connection with or relating to this Agreement, or the breach, termination, enforcement, interpretation or validity thereof, or any document or instrument delivered in connection herewith (each, a "**Dispute**"), then either Party shall have the right to refer such Dispute to its respective Senior Officers for attempted resolution by good faith negotiations during a period of [***]. Any final decision mutually agreed to by such Senior Officers shall be conclusive and binding on the Parties. If such Senior Officers are unable to resolve any such Dispute within [***], the Dispute shall be referred to the Chief Executive Officer of each Party for attempted resolution by good faith negotiations during an additional period of [***]. Any final decision mutually agreed to by the Chief Executive Officers shall be conclusive and binding on the Parties. If the Chief Executive Officers are unable to resolve any such Dispute within [***], then either Party shall have the right to submit the Dispute to final and binding arbitration administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures in effect at the time of arbitration, except as they may be modified herein, upon written notice to the other Party (an "**Arbitration Notice**"). The seat, or legal place, of arbitration shall be New York, New York and the language of the arbitration shall be English. Unless otherwise agreed to by the Parties, the arbitration shall be conducted by a panel of three neutral, independent and impartial arbitrators (each, an "**Arbitrator**"). Each Arbitrator will have educational training and industry experience relevant to the particular dispute. Each Party will promptly select one (1) Arbitrator each, which selections will in no event be made later than [***] after receipt of the Arbitration Notice. The third Arbitrator will be chosen promptly by mutual agreement of the Arbitrators chosen by the Parties, but in no event later than [***] after the date that the last of such Arbitrators was appointed. No Party may select an Arbitrator that has (i) a direct or indirect pre-existing relationship or affiliation with such Party or its Affiliates or (ii) a direct or indirect financial interest in the outcome of such dispute. Any disputes concerning the scope or applicability of this agreement to arbitrate or the propriety of commencing the arbitration shall be determined by the Arbitrators, except that any dispute arising out of or related to the validity or infringement of any Patent shall be resolved by a court of competent jurisdiction.

(b) Each Party shall bear its own counsel fees, costs, and disbursements arising out of the dispute resolution procedures described in this Section 13.5, and shall pay an equal share of the fees and costs of the arbitrator and all other general fees related to any arbitration; provided that the arbitrator shall be authorized to determine whether a Party is the prevailing Party, and if so, to award to that prevailing Party its reasonable counsel fees, costs, and disbursements and the fees of the arbitrator. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding described in this Section 13.5 is pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement that are not the subject of such pending arbitration proceeding.

(c) Notwithstanding Sections 13.5(a) and 13.5(b), nothing contained in this Agreement shall deny any Party the right to seek interim injunctive or other interim equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed and maintained notwithstanding any ongoing arbitration proceeding. Except as may be necessary to prepare for or conduct the arbitration, or as may be necessary to confirm or challenge an award, or as may be necessary in connection with an application to a court for interim relief, the arbitration proceedings and any rulings and award of the arbitrator shall be deemed Confidential Information of both Parties under Article 8.

13.6**Governing Law, Jurisdiction and Service.**

(a) **Governing Law**. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

(b) **Jurisdiction**. Subject to Section 13.5, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction and venue of the state and federal courts of New York, New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit, or proceeding brought in any such court has been brought in an inconvenient forum.

(c) **Service**. Each Party further agrees that service of any process, summons, notice, or document by registered mail to its address set forth in Section 13.7(b) shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in arbitration or in any court of competent jurisdiction, including any dispute arising out of or related to the validity or infringement of any Patent.

13.7**Notices.**

(a) **Notice Requirements**. Any notice, request, demand, waiver, consent, approval, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement, and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 13.7(b) or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 13.7(a). Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or on [***] (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 13.7(a) is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

(b) **Address for Notice**.

If to Disc, to:

Disc Medicine, Inc.
321 Arsenal Street, Suite 101
Watertown, MA 02472
Attn: Joanne Bryce
Facsimile: [***]

with a copy (which shall not constitute notice) to:

Goodwin Procter LLP
601 S Figueroa Street, 41st Floor
Los Angeles, CA 90017
Attention: Beni Surpin
Facsimile: [***]

If to Mabwell, to:

505 Coast Boulevard South, Suite 301
La Jolla, CA 92037

Attn: Xin Du, Chief Executive Officer
Facsimile: [***]

with a copy (which shall not constitute notice) to:

Cooley LLP
10265 Science Center Drive
San Diego, CA 92121
Attention: Charity R. Williams
Facsimile: [***]

13.8**Entire Agreement; Amendments**. This Agreement, together with the Schedules attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof, and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto, including the Non-Binding Term Sheet Proposal between the Parties dated as of [***], are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release, or discharge shall be binding on the Parties unless in writing and duly executed by authorized representatives of both Parties. In the event of any inconsistencies between this Agreement and any Schedules hereto, the terms of this Agreement shall control.

13.9**English Language**. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

13.10**Equitable Relief**. Each Party acknowledges and agrees that the restrictions set forth in Article 8 are reasonable and necessary to protect the legitimate interests of the other Party, such other Party would not have entered into this Agreement in the absence of such restrictions, and any breach or threatened breach of any provision of such Article may result in irreparable injury to such other Party for which there will be no adequate remedy at law. Accordingly, notwithstanding anything to the contrary in Section 13.5, in the event of a breach or threatened breach of any provision of such Article, either Party shall be authorized and entitled to seek from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance, and an equitable accounting of all earnings, profits, and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such Party may be entitled in law or equity. Both Parties agree to waive any requirement that the other post a bond or other security as a condition for obtaining any such relief. Nothing in this Section 13.10 is intended or should be construed to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

13.11**Waiver and Non-Exclusion of Remedies**. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party, whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available, except as expressly set forth herein.

13.12**No Benefit to Third Parties**. Except as provided in Article 10, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their permitted successors and assigns, and they shall not be construed as conferring any rights on any other Persons.

13.13**Further Assurance**. Each Party shall duly execute and deliver or cause to be duly executed and delivered such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary in connection with this Agreement, as the other Party may reasonably request in connection with this Agreement, to carry out more effectively the

provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

13.14**Relationship of the Parties**. It is expressly agreed that Mabwell, on the one hand and Disc, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture, or agency. Neither Mabwell, on the one hand, nor Disc, on the other hand, shall have the authority to make any statements, representations, or commitments of any kind with respect to the other or to take any action that will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party, and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party. Neither Party shall treat or report the relationship arising under this Agreement as a partnership for United States tax purposes unless required pursuant to a determination under Section 1313 of the Internal Revenue Code of 1986, as amended.

13.15**References**. Unless otherwise specified, (a) references in this Agreement to any Section or Schedule shall mean references to such Section or Schedule of this Agreement; (b) references in any Section to any clause are references to such clause of such Section; and (c) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as originally executed or, if subsequently amended, replaced, or supplemented from time to time, as so amended, replaced, or supplemented and in effect at the relevant time of reference thereto.

13.16**No Strict Construction; Interpretation**. This Agreement has been prepared jointly and will not be strictly construed against either Party. Ambiguities, if any, in this Agreement will not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. Except where the context expressly requires otherwise, (a) whenever any provision of this Agreement uses the term “including” (or “includes”), such term will be deemed to mean “including without limitation” and “including but not limited to” (or “includes without limitations” and “includes but is not limited to”) regardless of whether the words “without limitation” or “but not limited to” actually follow the term “including” (or “includes”); (b) “herein,” “hereby,” “hereunder,” “hereof,” and other equivalent words will refer to this Agreement in its entirety and not solely to the particular portion of this Agreement in which any such word is used; (c) all definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural; (d) wherever used herein, any pronoun or pronouns will be deemed to include both the singular and plural and to cover all genders; (e) the Schedules to this Agreement, and the terms and conditions incorporated in such Schedules will be deemed integral parts of this Agreement and all references in this Agreement to this Agreement will encompass such Schedules and the terms and conditions incorporated in such Schedules; *provided that* in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions set forth in the Schedules, the terms of this Agreement will control; (f) in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions that may be set forth on any order, invoice, verbal agreement, or otherwise, the terms and conditions of this Agreement will govern; (g) unless otherwise provided, all references to Sections, Articles, and Schedules in this Agreement are to Sections, Articles, and Schedules of and to this Agreement; (h) any reference to any federal, national, state, local, or foreign statute or law will be deemed to also refer to all rules and regulations promulgated thereunder, and any reference to any law, rule, or regulation will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof; (i) wherever used, the word “shall” and the word “will” are each understood to be imperative or mandatory in nature and are interchangeable with one another; (j) the word “or” will be interpreted in the inclusive sense commonly associated with the term “and/or”; (k) references to a particular Person include such person’s successors and assigns to the extent not prohibited by this Agreement; (l) the section headings and captions used herein are inserted for convenience of reference only and will not be construed to create obligations, benefits, or limitations; (m) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (n) the word “notice” means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement; and (o) provisions that require that a Party, the Parties or any committee hereunder “agree,” “consent,” or “approve” or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise (but excluding e-mail and instant messaging).

13.17**Counterparts**. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement

may be executed by facsimile, PDF format via email, or other electronically transmitted signatures, and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

[*signature page follows*]

IN WITNESS WHEREOF, this Agreement is executed by the authorized representatives of the Parties as of the Execution Date.

DISC MEDICINE, INC.		**MABWELL THERAPEUTICS, INC.**	
By:	/s/ John Quisel	By:	/s/ Xin Du
Name:	John Quisel	Name:	Xin Du
Title:	Chief Executive Officer	Title:	Chief Executive Officer

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 Quarterly Report on Form 10-Q 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: May 15, 2023

/s/ John Quisel

John Quisel, J.D., Ph.D.
President and 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, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: May 15, 2023

/s/ Joanne Bryce
Joanne Bryce, CPA
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 Quarterly Report on Form 10-Q of Disc Medicine, Inc. (the "Company") for the quarter ended March 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 and results of operations of the Company.

Dated: May 15, 2023

/s/ John Quisel
John Quisel, J.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Joanne Bryce
Joanne Bryce, CPA
Chief Financial Officer
(Principal Financial and Accounting Officer)