#### 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

Commission file number 001-38129

to

Mersana Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

04-3562403

(I.R.S. Employer Identification No.)

840 Memorial Drive Cambridge, MA 02139

(Address of principal executive offices)

(Zip Code)

(617) 498-0020

(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	MRSN	The Nasdaq Global Select 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  $\boxtimes$  No  $\square$ 

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  $\boxtimes$  No  $\square$ 

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	$\boxtimes$	Smaller reporting company	$\boxtimes$
		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.  $\Box$ 

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

There were 114,385,810 shares of Common Stock (\$0.0001 par value per share) outstanding as of May 5, 2023.

#### **REFERENCES TO MERSANA**

Throughout this Quarterly Report on Form 10-Q, the "Company," "Mersana," "we," "us," and "our," except where the context requires otherwise, refer to Mersana Therapeutics, Inc. and its consolidated subsidiary, and "our board of directors" refers to the board of directors of Mersana Therapeutics, Inc.

# FORWARD LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q contains forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our clinical results and other future conditions. The words "aim," "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "goal," "intend," "may," "on track," "plan," "possible," "potential," "predict," "project," "seek," "should," "target," "will," "would" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- the initiation, cost, timing, progress and results of our current and future research and development activities, preclinical studies and clinical trials, including the expected timing of reporting of data from our ongoing clinical trials;
- the adequacy of our inventory of upifitamab rilsodotin, or UpRi, XMT-1660 and our other product candidates to support our ongoing and planned clinical trials, as well as the outcome of planned manufacturing runs;
- the timing of, and our ability to obtain and maintain, regulatory approvals for our product candidates;
- unmet needs of patients with ovarian cancer, breast cancer and other cancer indications;
- our ability to quickly and efficiently identify and develop additional product candidates;
- our ability to advance any product candidate into, and successfully complete, clinical trials;
- our intellectual property position, including with respect to our trade secrets;
- the potential benefits of strategic collaborations and our ability to enter into selective strategic collaborations;
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing; and
- the potential impact of the ongoing COVID-19 pandemic.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

The forward-looking statements contained herein represent our views as of the date of this Quarterly Report on Form 10-Q and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. We anticipate that subsequent events and developments will cause our views to change. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

This Quarterly Report on Form 10-Q may include industry and market data, which we may obtain from our own internal estimates and research, as well as from industry and general publications and research, surveys, and studies conducted by third parties. Industry publications, studies, and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that such studies and publications are reliable, we have not independently verified market and industry data from third-party sources.

#### **RISK FACTORS SUMMARY**

Our business is subject to varying degrees of risk and uncertainty. Investors should consider the risks and uncertainties summarized below, as well as the risks and uncertainties discussed in Part II, Item 1A, Risk Factors of this Quarterly Report on Form 10-Q.

Our business is subject to the following principal risks and uncertainties:

- We have incurred net losses since our inception, we have no products approved for commercial sale and we anticipate that we will continue to incur substantial operating losses for the foreseeable future.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- We have a credit facility that requires us to meet certain affirmative and negative covenants and places restrictions on our operating and financial flexibility.
- We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.
- We only have a limited number of product candidates being evaluated in clinical trials. A failure of any of our current or future product candidates in clinical development could adversely affect our business and may require us to discontinue development of other product candidates based on the same technology.
- We can provide no assurance that our product candidates will obtain regulatory approval or that the results of clinical trials will be favorable.
- Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure. We can provide no assurance of the successful and timely development of new antibody-drug conjugate, or ADC, products.
- If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.
- · We may encounter difficulties in managing our growth and expanding our operations successfully.

- Our activities, including our interactions with healthcare providers, third party payors, patients and government officials, are, and will continue to be, subject to extensive regulation involving health care, anti-corruption, data privacy and security and consumer protection laws. Failure to comply with applicable laws could result in substantial penalties, contractual damages, reputational harm, diminished revenues and curtailment or restructuring of our operations.
- We rely upon patents and other intellectual property rights to protect our technology. We may be unable to protect our intellectual property rights, and we may be liable for infringing the intellectual property rights of others.
- Unfavorable global economic or geopolitical conditions could adversely affect our business, financial condition or results of operations.

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# PART I – FINANCIAL INFORMATION

# Item 1. Financial Statements

# Mersana Therapeutics, Inc. Condensed Consolidated Balance Sheets (in thousands, except share and per share data) (unaudited)

		March 31, 2023	December 31, 2022	
Assets				
Current assets:				
Cash and cash equivalents	\$	122,825	\$ 128,885	
Short-term marketable securities		151,094	151,827	
Accounts receivable		_	30,000	
Prepaid expenses and other current assets		7,888	8,507	
Total current assets		281,807	 319,219	
Property and equipment, net		3,994	3,985	
Operating lease right-of-use assets		9,806	10,475	
Other assets, noncurrent		588	661	
Total assets	\$	296,195	\$ 334,340	
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable	\$	18,156	\$ 13,951	
Accrued expenses		32,588	43,184	
Deferred revenue		28,769	30,610	
Operating lease liabilities		2,904	2,798	
Other current liabilities		985	990	
Total current liabilities		83,402	 91,533	
Operating lease liabilities, noncurrent		7,773	8,575	
Long-term debt, net		25,004	24,929	
Deferred revenue, noncurrent		115,582	117,043	
Other liabilities, noncurrent		140	 203	
Total liabilities		231,901	 242,283	
Commitments (Note 11)				
Stockholders' equity:				
Preferred stock, \$0.0001 par value; 25,000,000 shares authorized; 0 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively		_	_	
Common stock, \$0.0001 par value; 350,000,000 shares authorized; 109,061,074 and 105,144,864 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively		11	11	
Additional paid-in capital		775,125	746,889	
Accumulated other comprehensive income (loss)		12	(152)	
Accumulated deficit		(710,854)	(654,691)	
Total stockholders' equity		64,294	 92,057	
Total liabilities and stockholders' equity	\$	296,195	\$ 334,340	

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

# Mersana Therapeutics, Inc. Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share data) (unaudited)

	Three Mo Mar	nths Ei ch 31,	nded
	 2023		2022
Collaboration revenue	\$ 7,802	\$	2,036
Operating expenses:			
Research and development	47,275		35,806
General and administrative	18,328		12,782
Total operating expenses	 65,603		48,588
Other income (expense):			
Interest income	2,621		18
Interest expense	 (983)		(724)
Total other income (expense), net	 1,638		(706)
Net loss	 (56,163)		(47,258)
Other comprehensive loss			
Unrealized gain on marketable securities	164		—
Comprehensive loss	\$ (55,999)	\$	(47,258)
Net loss attributable to common stockholders — basic and diluted	\$ (56,163)	\$	(47,258)
Net loss per share attributable to common stockholders — basic and diluted	\$ (0.52)	\$	(0.59)
Weighted-average number of shares of common stock used in net loss per share attributable to common stockholders — basic and diluted	 107,514,655		79,928,591

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

# Mersana Therapeutics, Inc. Condensed Consolidated Statements of Stockholders' Equity (in thousands, except share data) (unaudited)

	Common Stock Additional			Additional Paid-in	01	Accumulated Other Comprehensive		Accumulated		Stockholders'	
	Shares		Amount		Capital		Income (Loss)		Deficit		Equity
Balance at December 31, 2021	73,709,056	\$	7	\$	572,213	\$	_	\$	(450,479)	\$	121,741
Issuance of common stock from at-the-market transactions, net of issuance costs of \$1,322	13,169,903		2		60,460		_		_		60,462
Exercise of stock options	26,951		_		96		_		_		96
Vesting of restricted stock units	167,174		_		_		—		_		_
Stock-based compensation expense	_				5,485		_		_		5,485
Net loss					_		_		(47,258)		(47,258)
Balance at March 31, 2022	87,073,084	\$	9	\$	638,254	\$	_	\$	(497,737)	\$	140,526
Balance at December 31, 2022	105,144,864	\$	11	\$	746,889	\$	(152)	\$	(654,691)	\$	92,057
Issuance of common stock from at-the-market transactions, net of issuance costs of \$558	3,535,093		_		21,795		_		_		21,795
Exercise of stock options	8,826		_		34		_		_		34
Vesting of restricted stock units	372,291		_		_		_		_		_
Stock-based compensation expense	_				6,407		_		_		6,407
Other comprehensive gain					_		164		_		164
Net loss	_		—		—		—		(56,163)		(56,163)
Balance at March 31, 2023	109,061,074	\$	11	\$	775,125	\$	12	\$	(710,854)	\$	64,294

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

# Mersana Therapeutics, Inc. Condensed Consolidated Statements of Cash Flows (in thousands) (unaudited)

(unauticu)						
		Three Months Ended March 31,				
		2023	2022			
Cash flows from operating activities						
Net loss	\$	(56,163) \$	(47,258)			
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation		319	205			
Net amortization of premiums and discounts on marketable securities		(1,411)	—			
Stock-based compensation		6,407	5,485			
Other non-cash items		152	194			
Changes in operating assets and liabilities:						
Accounts receivable		30,000	_			
Prepaid expenses and other current assets		620	(462)			
Accounts payable		4,728	(2,524)			
Accrued expenses		(10,327)	(2,159)			
Operating lease right-of-use assets		669	889			
Operating lease liabilities		(697)	(579)			
Deferred revenue		(3,302)	38,254			
Net cash used in operating activities		(29,005)	(7,955)			
Cash flows from investing activities						
Maturities of marketable securities		66,000				
Purchase of marketable securities		(63,693)	_			
Purchase of property and equipment		(911)	(329)			
Net cash provided by (used in) investing activities		1,396	(329)			
Cash flows from financing activities						
Net proceeds from at-the-market facilities		21,730	60,374			
Proceeds from exercise of stock options		34	96			
Payment of debt issuance costs		(150)	—			
Payments under finance lease obligations		(65)	(76)			
Net cash provided by financing activities		21,549	60,394			
(Decrease) increase in cash, cash equivalents and restricted cash		(6,060)	52,110			
Cash, cash equivalents and restricted cash, beginning of period		129,363	178,425			
	\$	123,303 \$	230,535			
Cash, cash equivalents and restricted cash, end of period	φ	125,505 \$	230,333			
Supplemental disclosures of non-cash activities:						
Purchases of property and equipment in accounts payable and accrued expenses	\$	169 \$	457			
Common stock issuance costs in accounts payable and accrued expenses	\$	66 \$	—			
Cash paid for interest	\$	791 \$	531			

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

# 1. Nature of business and basis of presentation

Mersana Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing antibody-drug conjugates ("ADCs") that offer a clinically meaningful benefit for cancer patients with significant unmet need. The Company has leveraged over 20 years of industry learning in the ADC field to develop three proprietary and differentiated platforms that enable it to develop ADCs that are designed to have improved efficacy, safety and tolerability relative to existing ADCs and other approved therapies. The Company's platforms include Dolaflexin and Dolasynthen, each of which deliver the novel and proprietary auristatin DolaLock payload, as well as Immunosynthen, which delivers the novel stimulator of interferon genes ("STING") agonist ImmunoLock payload.

The Company's lead product candidate, upifitamab rilsodotin ("UpRi"), is a first-in-class Dolaflexin ADC targeting NaPi2b, an antigen broadly expressed in ovarian cancer and other cancers. The Company is currently evaluating UpRi in platinum-resistant ovarian cancer in a single-arm registrational trial, referred to as UPLIFT. The Company is also conducting a placebo-controlled Phase 3 clinical trial, referred to as UP-NEXT, to investigate UpRi as a monotherapy maintenance treatment following treatment with platinum doublets in recurrent platinum-sensitive ovarian cancer. Additionally, the Company is conducting a Phase 1 combination trial, referred to as UPGRADE-A. UPGRADE-A is exploring the combination of UpRi with carboplatin, a standard platinum chemotherapy broadly used in the treatment of platinum-sensitive ovarian cancer.

The Company is also investigating XMT-1660, a B7-H4-directed Dolasynthen ADC, in a Phase 1 clinical trial enrolling patients with solid tumors, including in breast, endometrial and ovarian cancers. The Company initiated a Phase 1 clinical trial to investigate XMT-2056, an Immunosynthen STING-agonist ADC that is designed to target a novel epitope of human epidermal growth factor receptor 2 ("HER2"), in January 2023, enrolling previously treated patients with advanced/recurrent solid tumors expressing HER2, including breast, gastric, colorectal and non-small cell lung cancers. In March 2023, following voluntary suspension by the Company, this clinical trial of XMT-2056 was placed on clinical hold by the U.S. Food and Drug Administration. The Company also has two additional earlier stage preclinical candidates, XMT-2068 and XMT-2175, that leverage the Company's Immunosynthen platform.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, the need for additional capital, risks of failure of preclinical studies and clinical trials, the need to obtain marketing approval and reimbursement for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development of technological innovations by competitors, reliance on third party manufacturers and the ability to transition from pilot-scale production to large-scale manufacturing of products.

The Company has incurred cumulative net losses since inception. For the three months ended March 31, 2023, the net loss was \$56.2 million, compared to \$47.3 million in the three months ended March 31, 2022. The Company expects to continue to incur operating losses for at least the next several years. As of March 31, 2023, the Company had an accumulated deficit of \$710.9 million. The future success of the Company is dependent on, among other factors, its ability to identify and develop its product candidates and ultimately upon its ability to attain profitable operations. The Company has devoted substantially all of its financial resources and efforts to research and development and general and administrative expense to support such research and development. Net losses and negative operating cash flows have had, and will continue to have, an adverse effect on the Company's stockholders' equity and working capital.

The Company believes that its currently available funds will be sufficient to fund the Company's operations through at least the next twelve months from the issuance of this Quarterly Report on Form 10-Q. Management's belief with respect to its ability to fund operations is based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, the Company may need to seek additional funding.



The Company's unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these financial statements should be read in conjunction with the audited 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 for the year ended December 31, 2022, filed with the SEC on February 28, 2023.

The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company's management, the accompanying unaudited condensed consolidated financial statements contain all adjustments that are necessary to present fairly the Company's financial position as of March 31, 2023, the results of its operations for the three months ended March 31, 2023 and 2022, the statements of stockholders' equity for the three months ended March 31, 2023 and 2022 and statements of cash flows for the three months ended March 31, 2023 and 2022. Such adjustments are of a normal and recurring nature. The results for the three months ended March 31, 2023 are not necessarily indicative of the results for the year ending December 31, 2023, or for any future period.

# 2. Summary of significant accounting policies

# **Principles of Consolidation**

The accompanying unaudited condensed consolidated financial statements include those of the Company and its wholly owned subsidiary, Mersana Securities Corp. All intercompany balances and transactions have been eliminated.

# Use of Estimates

The preparation of the Company's unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenue, expenses and related disclosure of contingent assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. On an ongoing basis, the Company's management evaluates its estimates which include, but are not limited to, management's judgments with respect to the identification of performance obligations and standalone selling prices of those performance obligations within its revenue arrangements, accrued preclinical, manufacturing and clinical expenses, valuation of stock-based awards and income taxes. Actual results could differ from those estimates.

### Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker, or decision making group, in deciding how to allocate resources and assess performance. The Company views its operations and manages its business as a single operating segment, which is the business of discovering and developing ADCs.

# Summary of Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements for the three months ended March 31, 2023 are consistent with those discussed in Note 2, *Summary of Significant Accounting Policies*, in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

#### Fair Value Measurements

Fair value is defined as the price that would be received upon sale of an asset or paid to transfer a liability between market participants at measurement dates. ASC 820, *Fair Value Measurement*, establishes a three-level valuation hierarchy for instruments measured at fair value. The hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The three levels are defined as follows:

Level 1—Inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2—Inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument.

Level 3—Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

### Concentration of Credit Risk and Off-balance Sheet Risk

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash equivalents and marketable securities. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government. The Company does not believe that it is subject to any significant concentrations of credit risk from these financial instruments. The Company has no financial instruments with off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

# Cash and Cash Equivalents

The Company considers all highly-liquid investments with an original maturity, or a remaining maturity at the time of purchase, of three months or less to be cash equivalents. The Company invests excess cash primarily in money market funds, commercial paper and government agency securities, which are highly liquid and have strong credit ratings. The Company determined that these investments are subject to minimal credit and market risks. Cash and cash equivalents are stated at cost, which approximates market value.

# **Recently Issued Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that the Company adopts as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards have or may have a material impact on the Company's condensed consolidated financial statements or disclosures.



# **3.** Collaboration agreements

# GSK

On August 6, 2022, the Company entered into a Collaboration, Option and License Agreement (the "GSK Agreement") with GlaxoSmithKline Intellectual Property (No. 4) Limited ("GSK"), pursuant to which the Company granted GSK an exclusive option to obtain an exclusive license (the "Option") to codevelop and to commercialize products containing XMT-2056 (the "Licensed Products"), exercisable within a specified time period (the "Option Period") after the Company delivers to GSK data resulting from completion of dose escalation with enrichment for breast cancer patients in a Phase 1 single-agent clinical trial of XMT-2056. GSK's exercise of the Option may require clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ("HSR Clearance" and GSK's exercise of the Option following any applicable HSR Clearance, the "GSK Option Exercise"). Prior to the GSK Option Exercise, the Company will lead and will be responsible for the costs of manufacturing, research, and early clinical development related to its XMT-2056 program.

Pursuant to the GSK Agreement, GSK paid the Company a non-refundable, upfront fee of \$100.0 million in August 2022. Following the GSK Option Exercise, if any, GSK is obligated to pay the Company an option exercise payment of \$90.0 million (the "Option Payment").

The GSK Agreement will terminate at the end of the Option Period if GSK does not exercise its Option. In the event of the GSK Option Exercise, unless earlier terminated, the GSK Agreement will continue in effect until the date on which the royalty term and all payment obligations with respect to all Licensed Products in all countries have expired.

#### Accounting Analysis

The Company assessed the GSK Agreement in accordance with ASC 606 and concluded that the contract counterparty, GSK, is a customer. The Company identified the following two material performance obligations under the GSK Agreement: (i) development activities, including manufacturing, research and early clinical development activities, necessary to deliver the package of data, information and materials specified in the GSK agreement (the "Development Activities") and (ii) the Option to co-develop and to commercialize Licensed Products (the "License Option").

The Company is recognizing revenue related to the Development Activities performance obligation over the estimated period of the pre-option development using a proportional performance model as the underlying activities are performed. The Company measures proportional performance based on the costs incurred relative to the total costs expected to be incurred.

The Company deferred revenue recognition related to the License Option. If the License Option is exercised and GSK obtains an exclusive license, the Company will recognize revenue as it fulfills its obligations under the GSK Agreement. If the Option is not exercised, the Company will recognize the entirety of the revenue in the period when the Option expires.

During the three months ended March 31, 2023, the Company recorded collaboration revenue of \$0.7 million related to its efforts under the GSK Agreement. As of March 31, 2023 and December 31, 2022 the Company had recorded \$97.3 million and \$98.0 million, respectively, in deferred revenue related to the unsatisfied performance obligations under the GSK Agreement. This deferred revenue will be recognized over the remaining performance period and classified as current or noncurrent on the consolidated balance sheets based upon the expected timing of satisfaction of the performance obligations.

#### Janssen

In February 2022, the Company entered into a research collaboration and license agreement with Janssen Biotech Inc. ("Janssen" and such agreement, the "Janssen Agreement") focused on the research, development and commercialization of novel ADCs for three oncology targets by leveraging Mersana's ADC expertise and Dolasynthen platform with Janssen's proprietary antibodies. Upon execution of the Janssen Agreement, the Company received a non-refundable upfront payment of \$40.0 million from Janssen. Janssen may select up to three targets and may substitute each target once prior to a substitution deadline. Janssen is not required to pay a fee for its first substitution right, but must pay a one-time fee for access to the subsequent substitution rights following its exercise of its second substitution right.

Pursuant to mutually agreed research and CMC plans, the Company will perform bioconjugation, production development, preclinical manufacturing, and certain related research and preclinical development activities, in order to progress the targets through investigational new drug application ("IND") submission for further development, manufacture and commercialization by Janssen. The Company estimates that its activities under the research plans for the targets will be performed through 2024.

The Company's CMC activities will be compensated by Janssen at agreed upon rates. Unless earlier terminated, the Janssen Agreement will expire upon the expiration of the last royalty term for a product under the Janssen Agreement.

Janssen may request that the Company perform clinical manufacturing services under a separate clinical supply agreement. Janssen may also request that the Company perform a technology transfer of bioconjugation and manufacturing process technology, at Janssen's cost, at an agreed upon rate.

# Accounting Analysis

The Company assessed the Janssen Agreement in accordance with ASC 606 and concluded that the contract counter party, Janssen, is a customer. The Company identified the following seven material performance obligations under the Janssen Agreement: (i) exclusive Janssen Licenses and research activities for each of the three designated targets, (ii) CMC activities for each of the three designated targets and (iii) the first target substitution right.

The Company determined that the consideration for CMC activities represents variable consideration. The Company has not included potential cost reimbursements within the transaction price as no CMC activities for any of the three targets have been initiated. The Company elected to apply the Right to Invoice practical expedient under ASC 606. As such, the Company will recognize revenue related to the CMC activities when the services are performed.

The Company is recognizing revenue related to the Janssen Licenses and research services performance obligation over the estimated period of the research services using a proportional performance model. The Company measures proportional performance based on the costs incurred relative to the total costs expected to be incurred.

The Company recognizes revenue related to the first target substitution right over time in congruence with the Janssen Licenses and research activities, upon the exercise of the option. If the first target substitution option is not exercised, the Company will recognize the entirety of the revenue in the period when the option expires.

During the three months ended March 31, 2023 and March 31, 2022, the Company recorded collaboration revenue of \$1.5 million and \$1.7 million, respectively, related to its performance obligations under the Janssen Agreement. As of March 31, 2023 and December 31, 2022, the Company had recorded \$16.2 million and \$15.8 million, respectively, in deferred revenue related to the Janssen Agreement that will be recognized over the remaining performance period and classified as current or noncurrent on the consolidated balance sheets based upon the expected timing of satisfaction of respective performance obligations.

# Merck KGaA and affiliates

### Immunosynthen Platform Agreement

In December 2022, the Company entered into a research collaboration and license agreement with Ares Trading S.A. ("MRKDG" and such agreement, the "2022 Merck KGaA Agreement"), a wholly owned subsidiary of Merck KGaA, Darmstadt, Germany, focused on the research, development and commercialization of novel ADCs for up to two specific target antigens by leveraging Mersana's ADC expertise and Immunosynthen platform with MRKDG's proprietary antibodies. In connection with the 2022 Merck KGaA Agreement, the Company received a non-refundable upfront payment of \$30.0 million. Pursuant to the 2022 Merck KGaA Agreement, the Company granted MRKDG two exclusive, non-transferable, worldwide licenses - a research license and a commercialization license (together, the "MRKDG Licenses").

Pursuant to mutually agreed research and CMC plans, the Company will perform bioconjugation, production development, preclinical manufacturing, and certain related research and preclinical development activities, in order to progress the targets through IND (or foreign equivalent) submission for further development, manufacture and commercialization by MRKDG. The Company estimates that its activities under the research plans for the targets will be performed through 2026.

The Company's CMC activities will be compensated by MRKDG at agreed upon rates. Unless earlier terminated, the 2022 Merck KGaA Agreement will expire upon the expiration of the last royalty term for a product under the 2022 Merck KGaA Agreement.

MRKDG may request that the Company perform clinical manufacturing services under a separate clinical supply agreement. MRKDG may also request that the Company perform a technology transfer of bioconjugation technology, at MRKDG's cost, at an agreed upon rate.

#### Accounting Analysis

The Company assessed the 2022 Merck KGaA Agreement in accordance with ASC 606 and concluded that the contract counter party, MRKDG, is a customer. The Company identified the following four material performance obligations under the 2022 Merck KGaA Agreement: (i) exclusive MRKDG Licenses and research activities for each of the two designated targets and (ii) CMC activities for each of the two designated targets.

The Company is recognizing revenue related to the MRKDG Licenses and research services performance obligation over the estimated period of the research services using a proportional performance model. The Company measures proportional performance based on the costs incurred relative to the total costs expected to be incurred.

During the three months ended March 31, 2023, the Company recorded collaboration revenue of \$3.1 million related to its efforts under the 2022 Merck KGaA Agreement. As of March 31, 2023 and December 31, 2022, the Company had recorded \$26.9 million and \$30.0 million, respectively, in deferred revenue related to the unsatisfied performance obligations under the 2022 Merck KGaA Agreement. This deferred revenue will be recognized over the remaining performance period and classified as current or noncurrent on the consolidated balance sheets based upon the expected timing of satisfaction of respective performance obligations.

### Dolaflexin Platform Agreement

In June 2014, the Company entered into a collaboration and commercial license agreement with Merck KGaA (the "2014 Merck KGaA Agreement"). Upon the execution of the 2014 Merck KGaA Agreement, Merck KGaA paid the Company a non-refundable technology access fee of \$12.0 million for the right to develop ADCs directed to six exclusive targets over a specified period of time. No additional fees are due when a target is designated and the commercial license to the target is granted. Merck KGaA will be responsible for the product development and marketing of any products resulting from this collaboration.



Under the terms of the 2014 Merck KGaA Agreement, the Company and Merck KGaA develop research plans to evaluate Merck KGaA's antibodies as ADCs incorporating the Company's technology. The Company receives reimbursement for its efforts under the research plans. The goal of the research plans is to provide Merck KGaA with sufficient information to formally nominate a development candidate and begin IND-enabling studies.

All six targets were designated prior to 2018. The Company has previously received \$3.0 million related to development milestones under the 2014 Merck KGaA Agreement. There have been no additional milestone payments during the three months ended March 31, 2023 or 2022.

In May 2018, the Company entered into a Supply Agreement with Merck KGaA (the "2018 Merck KGaA Supply Agreement"). Under the terms of the 2018 Merck KGaA Supply Agreement, the Company will provide Merck KGaA preclinical non-good manufacturing practice ("non-GMP") ADC drug substance and clinical good manufacturing practice ("GMP") drug substance for use in clinical trials associated with one of the antibodies designated under the 2014 Merck KGaA Agreement. The Company receives fees for its efforts under the 2018 Merck KGaA Supply Agreement and reimbursement equal to the supply cost. The Company may also enter into future supply agreements to provide clinical supply material should Merck KGaA pursue clinical development of any other candidates nominated under the 2014 Merck KGaA Agreement.

# Accounting Analysis

The Company concluded that Merck KGaA is a customer and accounted for the 2014 Merck KGaA Agreement in accordance with ASC 606. The Company identified the following performance obligations under the 2014 Merck KGaA Agreement: (i) exclusive license and research services for six designated targets, (ii) rights to future technological improvements and (iii) participation of project team leaders and providing joint research committee services.

The Company is recognizing revenue related to the exclusive license and research and development services performance obligation over the estimated period of the research and development services using a proportional performance model. The Company measures proportional performance based on the costs incurred relative to the total costs expected to be incurred. To the extent that the Company receives fees for the research services as they are performed, these amounts are recorded as deferred revenue. Revenue related to future technological improvements and joint research committee services will be recognized ratably over the performance period (which in the case of the joint research committee services approximate the time and cost incurred each period), which are 10 and 5 years, respectively. The Company is continuing to reassess the estimated remaining term at each subsequent reporting period.

As of March 31, 2023, the Company has completed its research service obligations associated with four of the six designated targets and the joint research committee services. Collaboration revenue recognized during the three months ended March 31, 2023 and 2022 was immaterial. There was no collaboration revenue or corresponding research and development expense recognized during the three months ended March 31, 2023 and 2022 related to the 2018 Merck KGaA Supply Agreement.

As of March 31, 2023 and December 31, 2022, the Company had recorded \$3.9 million in deferred revenue related to the 2014 Merck KGaA Agreement and 2018 Merck KGaA Supply Agreement, in the aggregate, that will be recognized over the remaining performance period.



### Summary of Contract Assets and Liabilities

The following table presents changes in the balances of the Company's contract liabilities:

	Balance at Beginning of Period			Additions	Deductions			Balance at End of Period
Three months ended March 31, 2023								
Contract liabilities:								
Total deferred revenue	\$	147,653	\$		\$	3,302	\$	144,351
Three months ended March 31, 2022								
Contract liabilities:								
Total deferred revenue	\$	3,944	\$	40,000	\$	1,746	\$	42,198

The Company did not record any contract assets associated with its collaboration agreements as of March 31, 2023 and March 31, 2022.

During the three months ended March 31, 2023 and 2022, the Company recognized the following revenues as a result of changes in the contract liability balances in the respective periods:

		Three months ended Marc	h 31,
	2	2023	2022
Revenue recognized in the period from:			
Amounts included in the contract liability at the beginning of the period	\$	5,110 \$	11

# Other Revenue

The Company has provided limited services for a collaborator, Asana BioSciences, LLC ("Asana Biosciences"). The Company did not recognize revenue related to these services during the three months ended March 31, 2023. During the three months ended March 31, 2022 the Company recognized revenue of \$0.3 million related to these services. During the three months ended March 31, 2023 the Company recognized revenue of \$2.5 million related to achievement of a development milestone under the research, development and license agreement for which performance obligations were previously completed.

### 4. Fair value measurements

The following table presents information about the Company's assets measured at fair value on a recurring basis and indicates the level within fair value hierarchy of the valuation techniques utilized to determine such value.

	March 31, 2023								
(in thousands)	 Total		Quoted Prices in Active Markets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)		
Cash equivalents									
Money market funds	\$ 51,394	\$	51,394	\$	—	\$			
U.S. treasury securities	9,972		9,972						
	\$ 61,366	\$	61,366	\$	_	\$	_		
Marketable securities									
U.S. treasury securities	\$ 77,095	\$	77,095	\$		\$			
U.S. government agency securities	73,999		_		73,999				
	\$ 151,094	\$	77,095	\$	73,999	\$	_		

		December 31, 2022								
(in thousands)	_	Total		Quoted Prices in Active Markets (Level 1)		Significant Other Observable Inputs (Level 2)		Significant Unobservable Inputs (Level 3)		
Cash equivalents										
Money market funds	\$	50,471	\$	50,471	\$	—	\$	—		
U.S. government agency securities		9,993		_		9,993		—		
	\$	60,464	\$	50,471	\$	9,993	\$	_		
Marketable securities	=				_					
U.S. treasury securities	\$	107,810	\$	107,810	\$	_	\$	_		
U.S. government agency securities		44,017		_		44,017		_		
	\$	151,827	\$	107,810	\$	44,017	\$			
							_			

There were no changes in valuation techniques or transfers between fair value measurement levels during the three months ended March 31, 2023 or during the year ended December 31, 2022.

Investments classified as Level 1 within the valuation hierarchy generally consist of U.S. treasury securities and money market funds, as the fair value is readily determinable based on active daily markets for identical securities. Investments classified as Level 2 within the valuation hierarchy generally consists of U.S. government agency securities, as the fair value is readily determinable based on active daily markets for similar securities and other observable inputs. The Company estimates the fair values of investments by taking into consideration valuations obtained from third-party pricing sources.

The carrying amounts reflected in the consolidated balance sheets for prepaid expenses and other current assets, accounts receivable, accounts payable and accrued expenses approximate their fair values due to their short-term nature.

As of March 31, 2023 and December 31, 2022, the carrying value of the Company's outstanding borrowing under the New Credit Facility (as defined in Note 7) approximated fair value (a Level 2 fair value measurement), reflecting interest rates currently available to the Company. The New Credit Facility is discussed in more detail in Note 7, *Debt*.

# 5. Cash, cash equivalents, and short-term marketable securities

#### Cash and cash equivalents

The following table summarizes the Company's cash, cash equivalents, and restricted cash as of March 31, 2023 and 2022.

	Three Mo March		Three Mor March	 		
(in thousands)	 Beginning of period		End of period		Beginning of period	End of period
Cash and cash equivalents	\$ 128,885	\$	122,825	\$	177,947	\$ 230,057
Restricted cash included in other assets, noncurrent	478		478		478	478
Total cash, cash equivalents and restricted cash per statement of cash flows	\$ 129,363	\$	123,303	\$	178,425	\$ 230,535

#### Marketable securities

The following tables summarize the Company's marketable securities held at March 31, 2023 and December 31, 2022.

	March 31, 2023						
(in thousands)	Amortized Cost		Gross Unrealized Gains		Gross Unrealized Losses		Fair Value
Marketable securities		-					
U.S. treasury securities	\$ 77,104	\$	30	\$	(39)	\$	77,095
U.S. government agency securities	73,981		33		(15)		73,999
Total	\$ 151,085	\$	63	\$	(54)	\$	151,094

		Decembe	r 31,	2022	
	 Amortized Cost	Gross Unrealized Gains		Gross Unrealized Losses	Fair Value
Marketable securities					
U.S. treasury securities	\$ 107,964	\$ 7	\$	(161)	\$ 107,810
U.S. government agency securities	44,016	24		(23)	44,017
Total	\$ 151,980	\$ 31	\$	(184)	\$ 151,827

All of the Company's marketable securities are due within one year or less. The Company did not realize any gains or losses recognized on the sale of marketable securities during the three months ended March 31, 2023, and, as a result, the Company did not reclassify any amounts out of accumulated comprehensive loss.

As of March 31, 2023, the Company's debt security portfolio consisted of 7 securities that were in an unrealized loss position and had an aggregate fair value of \$42.4 million. There were no securities in an unrealized loss position for greater than 12 months as of March 31, 2023. The unrealized losses on the Company's marketable securities were caused by market interest rate increases. The Company has the intent and ability to hold such securities until recovery. As a result, the Company did not record any charges for credit-related impairments for its marketable debt securities for the three months ended March 31, 2023.

# 6. Accrued expenses

Accrued expenses consisted of the following as of March 31, 2023 and December 31, 2022:

(in thousands)	March 31, 2023	December 31, 2022
Accrued clinical expenses	\$ 13,414	\$ 14,822
Accrued manufacturing expenses	7,801	11,536
Accrued payroll and related expenses	4,754	11,558
Accrued research and non-clinical expenses	3,488	2,767
Accrued professional fees	2,726	1,865
Accrued other	405	636
	\$ 32,588	\$ 43,184

# 7. Debt

On October 29, 2021, the Company entered into a loan and security agreement (the "New Credit Facility") with Silicon Valley Bank ("former SVB") and Oxford Finance LLC ("Oxford" and, together with former SVB and the other lenders from time to time a party thereto, the "Lenders"). In March 2023, Silicon Valley Bridge Bank, N.A ("SVBB"), as successor in interest to former SVB, replaced former SVB as a Lender, and then Silicon Valley Bank, a division of First-Citizens Bank & Trust Company ("SVB"), which assumed all deposits and loans of SVBB, subsequently replaced SVBB as a Lender. Pursuant to the New Credit Facility, as amended on February 17, 2022, October 17, 2022, December 27, 2022, and March 23, 2023, the Company can borrow term loans in an aggregate amount of \$100.0 million, which includes (i) \$40.0 million available at the option of the Company in up to four principal advances through June 30, 2023, (ii) an additional \$40.0 million in one principal advance, if the Company reaches certain development milestone events through September 30, 2023, and (iii) an additional tranche of \$20.0 million, subject to conditional approval from the Lenders. The New Credit Facility is secured by substantially all of the Company's personal property owned or later acquired, excluding intellectual property (but including the rights to payments and proceeds from intellectual property), and a negative pledge on intellectual property. The Company has drawn \$25.0 million under the New Credit Facility as of March 31, 2023.

Refer to Note 8, *Debt*, in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 for more information regarding the New Credit Facility. As of March 31, 2023, the Company was in compliance with all covenants under the New Credit Facility. There are no events of default under the New Credit Facility as of March 31, 2023.

The following is a summary of obligations under the New Credit Facility as of March 31, 2023:

(in thousands)	March 31, 2023
Total debt	\$ 25,000
Less: Current portion of long-term debt	 
Total debt, net of current portion	25,000
Debt financing costs, net of accretion	(302)
Accretion related to final payment	306
Long-term debt, net	\$ 25,004

Interest expense related to the New Credit Facility for the three months ended March 31, 2023 and 2022 was \$0.9 million and \$0.7 million, respectively.

# 8. Stockholders' equity

# Preferred stock

As of March 31, 2023, the Company had 25,000,000 shares of authorized preferred stock. No shares of preferred stock have been issued.

# At-the-market ("ATM") equity offering program

In May 2020, the Company established an ATM equity offering program (the "2020 ATM"), pursuant to which it was able to offer and sell up to \$100.0 million of its common stock from time to time at prevailing market prices. During the three months ended March 31, 2022, the Company sold 11,740,210 shares of common stock under the 2020 ATM, resulting in net proceeds of \$54.8 million. As of March 31, 2022, the 2020 ATM had been fully utilized.

In February 2022, the Company established a new ATM equity offering program (the "February 2022 ATM"), pursuant to which it was able to offer and sell up to \$100.0 million of its common stock from time to time at prevailing market prices. During the three months ended March 31, 2022, the Company sold 1,429,693 shares of common stock under the February 2022 ATM, resulting in net proceeds of \$5.8 million. During the three months ended March 31, 2023, the Company sold 256,386 shares of common stock under the February 2022 ATM, resulting in net proceeds of \$1.6 million. As of March 31, 2023, the February 2022 ATM had been fully utilized.

In November 2022, the Company established an additional ATM equity offering program (the "November 2022 ATM"), pursuant to which it is able to offer and sell up to \$150.0 million of its common stock from time to time at prevailing market prices. During the three months ended March 31, 2023, the Company sold 3,278,707 shares of common stock under the November 2022 ATM, resulting in net proceeds of \$20.2 million. As of March 31, 2023, approximately \$129.3 million remained unsold and available for sale under the November 2022 ATM.

### Warrants

In connection with a 2013 Series A-1 Preferred Stock issuance, the Company granted to certain investors warrants to purchase 129,491 shares of common stock. The warrants have a \$0.05 per share exercise price and a contractual life of 10 years. The fair value of these warrants was recorded as a component of equity at the time of issuance. As of March 31, 2023, there were warrants to purchase 22,590 shares of common stock outstanding. During the three months ended March 31, 2023, there were no exercises of warrants in exchange for common stock.

### Common stock

At the Company's 2022 Annual Meeting of Stockholders on June 9, 2022, the Company's stockholders approved an amendment to the Company's Fifth Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock, \$0.0001 par value per share, from 175,000,000 to 350,000,000. This increase became effective upon filing of a Certificate of Amendment with the Secretary of State of the State of Delaware on June 9, 2022.

The holders of the common stock are entitled to one vote for each share held. Common stockholders are not entitled to receive dividends, unless declared by the Board of Directors of the Company (the "Board").



As of March 31, 2023 and December 31, 2022, there were 15,769,504 and 11,944,664, respectively, shares of common stock reserved for the exercise of outstanding stock options, restricted stock units ("RSUs") and warrants.

	March 31, 2023	December 31, 2022
Stock options	12,299,527	10,051,283
Restricted stock units	3,447,387	1,870,791
Warrants	22,590	22,590
	15,769,504	11,944,664

#### 9. Stock-based compensation

#### Stock incentive plans

Prior to its initial public offering, the Company granted stock options pursuant to the Company's 2007 Stock Incentive Plan (the "2007 Plan"). The 2007 Plan expired in June 2017. Any cancellations or forfeitures of options granted under the 2007 Plan will increase the options available under the 2017 Stock Incentive Plan (the "2017 Plan"), as described below.

In June 2017, the Company's stockholders approved the 2017 Plan. Under the 2017 Plan, shares of common stock could be granted to the Company's employees, officers, directors, consultants and advisors in the form of options, RSUs or other stock-based awards. The number of shares of common stock issuable under the 2017 Plan will be cumulatively increased annually on January 1 by the lesser of (a) 4% of the outstanding shares on the immediately preceding December 31 or (b) such other amount specified by the Board. The terms of the awards are determined by the Board, subject to the provisions of the 2017 Plan. Any cancellations or forfeitures of options granted under the 2007 Plan, which expired in June 2017, would increase the number of shares that could be granted under the 2017 Plan. On January 1, 2023, the number of shares of common stock issuable under the 2017 Plan was increased by 4,205,794 shares. During the three months ended March 31, 2023, there were 1,738,539 shares available for future issuance under the 2017 Plan.

Under the 2017 Plan, both with respect to incentive stock options and nonqualified stock options, the exercise price per share will not be less than the fair market value of the common stock on the date of grant and the vesting period for options granted to employees is generally four years. Options granted under the 2017 Plan expire no later than 10 years from the date of grant. Options under the 2007 Plan were granted at an exercise price established by the Board (or an authorized committee thereof) that was not less than the fair market value of the underlying common stock on the date of grant and subject to such vesting provisions determined by the Board (or an authorized committee thereof). The Board may accelerate vesting or otherwise adjust the terms of granted options in the case of a merger, consolidation, dissolution, or liquidation of the Company.

### Inducement awards

From time to time, the Company grants to its employees, upon approval by the Board or an authorized committee thereof, options to purchase shares of common stock and/or RSUs as an inducement to employment in accordance with Nasdaq Listing Rule 5635(c)(4). Prior to February 2022, only options were granted, and they were granted outside of an existing equity incentive plan. These options are subject to terms substantially the same as the 2017 Plan.



In February 2022, the Board adopted the Company's 2022 Inducement Stock Incentive Plan (the "Inducement Plan"), which provides for the grant of nonstatutory options, stock appreciation rights, restricted stock, RSUs and other stock-based awards, with respect to an aggregate of 2,000,000 shares of the Company's common stock (subject to adjustment as provided in the Inducement Plan). During the three months ended March 31, 2023, the Company granted 236,870 RSUs and options to purchase shares of common stock to newly hired employees under the Inducement Plan. As of March 31, 2023, there were 1,105,305 shares available for future issuance under the Inducement Plan.

As of March 31, 2023, there were options to purchase 757,500 shares of common stock outstanding which were granted as inducement awards prior to the establishment of the Inducement Plan.

#### Stock option activity

A summary of stock option activity is as follows:

	Number of Shares	Weighted- Average Exercise Price
Outstanding at January 1, 2023	10,051,283	\$ 9.84
Granted	2,530,740	\$ 6.07
Exercised	(8,826)	\$ 3.80
Cancelled	(273,670)	\$ 10.08
Outstanding at March 31, 2023	12,299,527	\$ 9.07
Exercisable at March 31, 2023	5,902,352	\$ 9.51

The weighted-average grant date fair value of options granted during the three months ended March 31, 2023 and 2022 was \$6.06 and \$4.39 per share, respectively. The total intrinsic value of options exercised during the three months ended March 31, 2023 and 2022 was immaterial. The aggregate intrinsic value represents the difference between the exercise price and the selling price received by option holders upon the exercise of stock options during the period.

Cash received from the exercise of stock options was immaterial for the three months ended March 31, 2023 and 2022.

#### **Restricted stock units**

The Company periodically issues RSUs with a service condition to certain officers and other employees that typically vest between one year and four years from the grant date.

A summary of the RSU activity is as follows:

	Number of Shares
Unvested at January 1, 2023	1,870,791
Granted	2,023,466
Vested	(372,291)
Forfeited	(74,579)
Unvested at March 31, 2023	3,447,387

#### Employee stock purchase plan

During the year ended December 31, 2017, the Board adopted, and the Company's stockholders approved the 2017 employee stock purchase plan (the "2017 ESPP"). The number of shares of common stock issuable under the 2017 ESPP was increased by 450,000 on January 1, 2023. The Company did not issue any shares under the 2017 ESPP for the three months ended March 31, 2023 or 2022. As of March 31, 2023, there were 745,791 shares available for issuance under the 2017 ESPP.

#### Stock-based compensation expense

The Company uses the provisions of ASC 718, Stock Compensation, to account for all stock-based awards to employees and non-employees.

Stock-based compensation expense is recognized over the requisite service period, which is generally the vesting period, using the straight-line method.

The following table presents stock-based compensation expense by award type included within the Company's condensed consolidated statements of operations and comprehensive loss:

	Three	Three Months Ended March 31		
(in thousands)	2023			2022
Stock options	\$	4,219	\$	4,118
Restricted stock units		1,893		1,209
Employee stock purchase plan		295		158
Stock-based compensation expense included in total operating expenses	\$	6,407	\$	5,485

The following table presents stock-based compensation expense as reflected in the Company's condensed consolidated statements of operations and comprehensive loss:

	Thr	Three Months Ended March 31,		
(in thousands)	202	3	2	2022
Research and development	\$	3,332	\$	2,933
General and administrative		3,075		2,552
Stock-based compensation expense included in total operating expenses	\$	6,407	\$	5,485



As of March 31, 2023, there was \$36.7 million and \$21.4 million of unrecognized stock-based compensation expense related to unvested stock options and unvested RSUs, respectively, that is expected to be recognized over a weighted-average period of 2.2 years and 3.2 years, respectively.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions:

	Three Months March 31	
	2023	2022
Risk-free interest rate	3.6 %	1.6 %
Expected dividend yield	<u> </u>	<u> </u>
Expected term (years)	6.07	6.04
Expected stock price volatility	99 %	87 %

Expected volatility for the Company's common stock is determined based on its historical volatility. The risk-free interest rate is based on the yield of U.S. Treasury securities consistent with the expected term of the option. No dividend yield was assumed as the Company has not historically and does not expect to pay dividends on its common stock. The expected term of the options granted is based on the use of the simplified method, in which the expected term is presumed to be the mid-point between the vesting date and the end of the contractual term.

The fair value of RSUs is determined based on the closing price of the Company's common stock on the date of grant.

#### 10. Net loss per share

Basic net loss per share of common stock is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without further consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period determined using the treasury stock method.

For purposes of the diluted net loss per share calculation, stock options, unvested RSUs and warrants to purchase common stock are considered to be potentially dilutive securities, but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive and therefore, basic and diluted net loss per share were the same for all periods presented.

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to include them would be anti-dilutive (in common stock equivalent shares):

	Three months ended March 31, 2023	Three months ended March 31, 2022
Stock options	12,299,527	10,028,741
Unvested restricted stock units	3,447,387	1,456,440
Warrants	22,590	39,474
	15,769,504	11,524,655

# 11. Commitments

#### License agreements

During the three months ended March 31, 2023 and the Company did not record research and development expense related to non-refundable license payments. During the three months ended March 31, 2022, the Company recorded research and development expense related to non-refundable license payments of \$1.5 million.

During the three months ended March 31, 2023 and 2022, the Company did not record research and development expense related to development milestones.

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### 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 our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and the accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission, or SEC, on February 28, 2023.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forwardlooking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods.

The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, including those risks identified under Part II, Item 1A. Risk Factors.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

#### Overview

We are a clinical-stage biopharmaceutical company focused on developing antibody-drug conjugates, or ADCs, that offer a clinically meaningful benefit for cancer patients with significant unmet need. We have leveraged over 20 years of industry learning in the ADC field to develop three proprietary and differentiated technology platforms that enable us to develop ADCs designed to have improved efficacy, safety and tolerability relative to existing ADCs and other approved therapies. We believe that our innovative platforms and our proprietary payloads together enable a robust discovery pipeline for us and our collaborators. Our investments in our novel and proprietary auristatin DolaLock payload, as well as our novel and proprietary STING (stimulator of interferon genes) agonist ImmunoLock payload, together with the GMP supply chain established for Dolaflexin, Dolasynthen and Immunosynthen all enable our ability to apply these platforms to new and different targets and antibodies to create new product candidates. We call this our product engine. Our ADCs in preclinical studies and clinical trials include first-in-class molecules that target multiple tumor types with high unmet medical need.

Our goal is to become a leading oncology company by leveraging the potential of our innovative and differentiated ADC platforms and the experience and competencies of our management team to discover and develop promising ADC product candidates and to commercialize cancer therapeutics that address unmet medical needs or provide significant benefits to patients.

Our lead product candidate, upifitamab rilsodotin, which we refer to as UpRi, is a first-in-class Dolaflexin ADC targeting NaPi2b, an antigen broadly expressed in ovarian cancer and other cancers. We are currently evaluating UpRi in platinum-resistant ovarian cancer in a single-arm registrational trial, which we refer to as UPLIFT, for which we completed enrollment of approximately 270 patients in October 2022. We expect to report top-line data from UPLIFT in mid-2023 following the major oncology conferences scheduled for June, and, if the data are positive, to submit a biologics license application, or BLA, to the U.S. Food and Drug Administration, or FDA, under the accelerated approval pathway around the end of 2023. We also initiated screening of patients in UP-NEXT, our Phase 3 clinical trial of UpRi as monotherapy maintenance treatment following treatment with platinum doublets in recurrent platinum-sensitive ovarian cancer, in the third quarter of 2022, and we continue to enroll patients in this trial. If data from the trial are positive, we believe UP-NEXT could serve as a post-approval confirmatory trial in the United States, support potential approvals outside of the United States and support UpRi's expansion into earlier lines of therapy. Additionally, we are also conducting a Phase 1 combination trial, which we refer to as UPGRADE-A, exploring the combination of UpRi with carboplatin, a standard platinum chemotherapy broadly used in the treatment of platinum-sensitive ovarian cancer. We have completed the dose escalation portion of UPGRADE-A, initiated the dose expansion portion of UPGRADE-A in January 2023, and expect to present initial interim data from the trial in the second half of 2023. We may explore UpRi in combination with other therapies in a series of UPGRADE trials. Together, data from all of our clinical trials of UpRi have the potential to establish the safety and efficacy of UpRi across a wide range of ovarian cancer patients, from those who are platinum-resistant and heavily pre-treat

We are also developing two additional ADCs, XMT-1660 and XMT-2056. XMT-1660 is a B7-H4-directed Dolasynthen ADC designed with a precise, target-optimized drug-to-antibody ratio, or DAR, of 6 and our DolaLock microtubule inhibitor payload with controlled bystander effect. We are currently enrolling patients in our multicenter Phase 1 trial investigating the safety, tolerability and anti-tumor activity of XMT-1660 in patients with breast, endometrial and ovarian cancers. We began dosing patients in August 2022 and expect to the complete the dose escalation portion of the trial in 2023. The FDA has granted Fast Track designation to XMT-1660 for the treatment of adult patients with advanced or metastatic triple-negative breast cancer.

XMT-2056 is a systemically administered Immunosynthen STING agonist ADC (DAR 8) that is designed to target a novel epitope of human epidermal growth factor receptor 2, or HER2, distinct from that targeted by either trastuzumab or pertuzumab, and to locally activate STING signaling in both tumor-resident immune cells and in tumor cells, providing the potential to treat patients with HER2-high or -low tumors as monotherapy and in combination with standard-of-care agents. We initiated a multicenter Phase 1 open-label trial of XMT-2056 in previously treated patients with advanced/recurrent solid tumors expressing HER2, including breast, gastric, colorectal and non-small cell lung cancers, in January 2023. In March 2023, we announced that this Phase 1 trial of



XMT-2056 had been placed on clinical hold by the FDA following our communication to FDA that we were voluntarily suspending the trial due to a Grade 5 (fatal) serious adverse event, or SAE, that was deemed to be related to XMT-2056. The SAE occurred in the second patient who had been enrolled at the initial dose level in the dose escalation portion of the Phase 1 trial in previously treated patients with HER2+ recurrent or metastatic solid tumors. We have received additional laboratory data from this patient, but the SAE and its cause remain under investigation. We are evaluating next steps related to our development of XMT-2056 and preparing a response to the FDA's clinical hold letter.

We also have two earlier stage preclinical candidates, which we refer to as XMT-2068 and XMT-2175, that leverage our Immunosynthen platform.

We have entered into a global collaboration providing GlaxoSmithKline Intellectual Property (No. 4) Limited, or GSK, an exclusive option to co-develop and commercialize XMT-2056. In addition, we have established strategic research and development collaborations with Janssen Biotech, Inc., or Janssen, and Merck KGaA, Darmstadt, Germany, or Merck KGaA, and its affiliates for the development and commercialization of additional ADC product candidates leveraging our proprietary Dolasynthen, Dolaflexin and Immunosynthen platforms against a limited number of targets selected by our collaborators. We believe the potential of our ADC product candidates and platforms, supported by our scientific and technical expertise and enabled by our intellectual property strategy, all support our independent and collaborative efforts to discover and develop life-changing ADCs for patients fighting cancer.

Since inception, our operations have focused on building our platforms, identifying potential product candidates, producing drug substance and drug product material for use in preclinical studies, conducting preclinical and toxicology studies, manufacturing clinical trial material and conducting clinical trials, establishing and protecting our intellectual property, staffing our company and raising capital. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through our strategic collaborations, private placements of our convertible preferred stock and public offerings of our common stock, including through our at-the-market, or ATM, equity offering programs.

Since inception, we have incurred significant cumulative operating losses. For the three months ended March 31, 2023, our net loss was \$56.2 million, compared to \$47.3 million in the three months ended March 31, 2022. As of March 31, 2023, we had an accumulated deficit of \$710.9 million. We expect to continue to incur significant expenses and operating losses over the next several years. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue clinical development and manufacturing activities for UpRi and XMT-1660;
- continue to evaluate next steps regarding XMT-2056;
- prepare for a potential BLA submission for UpRi under the accelerated approval pathway around the end of 2023 and engage in preparations for a potential commercial launch of UpRi, if approved, in 2024;
- · continue diagnostic development efforts with respect to the NaPi2b biomarker;
- continue activities to discover, validate and develop additional product candidates, including XMT-2068 and XMT-2175;
- · maintain, expand and protect our intellectual property portfolio; and
- hire additional research, development and general and administrative personnel.



### **Financial Operations Overview**

#### Revenue

To date, we have not generated any revenue from the sale of products. All of our revenue has been generated from strategic collaborations.

In December 2022, we entered into a collaboration and commercial license agreement, or the 2022 Merck KGaA Agreement, with Ares Trading S.A., or MRKDG, a wholly-owned subsidiary of Merck KGaA, for the development and commercialization of ADC product candidates utilizing our Immunosynthen platform for up to two target antigens. MRKDG is responsible for generating antibodies against the target antigens, and we are responsible for performing bioconjugation activities to create ADCs as well as certain chemistry, manufacturing and controls development and early-stage manufacturing activities at their cost. MRKDG has the exclusive right to and is responsible for the further development and commercialization of these ADC product candidates. During the three months ended March 31, 2023, we recognized \$3.1 million of collaboration revenue related to the 2022 Merck KGaA Agreement.

In August 2022, we entered into a collaboration, option and license agreement, or the GSK Agreement, with GSK to provide GSK with an exclusive option to obtain an exclusive license to co-develop and to commercialize products containing XMT-2056, or Licensed Products. We are responsible for manufacturing, research and early clinical development related to our XMT-2056 program prior to GSK's exercise, if any, of its option. If GSK exercises its option, GSK will have the exclusive right to and will be responsible for the further co-development and commercialization of Licensed Products. During the three months ended March 31, 2023, we recognized \$0.7 million of collaboration revenue related to the GSK Agreement.

In February 2022, we entered into a research collaboration and license agreement, or the Janssen Agreement, with Janssen for the development and commercialization of ADC product candidates utilizing our Dolasynthen platform for up to three target antigens. Janssen is responsible for generating antibodies against the target antigens, and we are responsible for performing bioconjugation activities to create ADCs as well as certain chemistry, manufacturing and controls development and early-stage manufacturing activities at Janssen's cost. Janssen has the exclusive right to and is responsible for the further development and commercialization of these ADC product candidates. During the three months ended March 31, 2023 and 2022, we recognized \$1.5 million and \$1.7 million, respectively, of collaboration revenue related to performance under the Janssen Agreement.

In June 2014, we entered into a collaboration and commercial license agreement, or the 2014 Merck KGaA Agreement, with Merck KGaA for the development and commercialization of ADC product candidates utilizing our Dolaflexin platform for up to six target antigens. Merck KGaA is responsible for generating antibodies against the target antigens, and we are responsible for generating Dolaflexin and conjugating this to such antibodies to create the ADC product candidates. Merck KGaA has the exclusive right to and is responsible for the further development and commercialization of these ADC product candidates. In May 2018, we entered into a supply agreement, or the Merck KGaA Supply Agreement, with Merck KGaA for the supply of materials that could be used for investigational new drug, or IND, -enabling studies and clinical trials. For each of the three months ended March 31, 2023 and 2022, we recognized an immaterial amount of revenue related to the 2014 Merck KGaA Agreement and Merck KGaA Supply Agreement.

During the three months ended March 31, 2023 and 2022 we recognized \$2.5 million and \$0.3 million, respectively, of revenue related to achievement of a development milestone and services provided, respectively, related to Asana BioSciences, LLC, or Asana Biosciences.

For the foreseeable future, we expect substantially all of our revenue to be generated from our collaboration agreements with GSK, Janssen, Merck KGaA and its affiliate, MRKDG, and Asana BioSciences. Given the uncertain nature and timing of clinical development, we cannot predict when or whether we will receive further milestone payments or any royalty payments under these collaborations.



#### Expenses

#### Research and development expenses

Research and development expenses include our drug discovery efforts, manufacturing, and the development of our product candidates, which consist of:

- employee-related expenses, including salaries, benefits and stock-based compensation expense;
- costs of funding research and development performed by third parties that conduct research, preclinical activities, manufacturing and clinical trials on our behalf;
- laboratory supplies;
- · facility costs, including rent, depreciation and maintenance expenses; and
- upfront and milestone payments under our third-party licensing agreements.

Research and development costs are expensed as incurred. Costs of certain activities, such as manufacturing, preclinical studies and clinical trials, are generally recognized based on an evaluation of the progress to completion of specific tasks. Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations and information provided to us by the third parties with whom we contract.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials and manufacturing costs. We expect that our future research and development costs will continue to increase over current levels, depending on the progress of our clinical development programs. There are numerous factors associated with the successful development and commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at our current stage of development. Additionally, future commercial and regulatory factors beyond our control may impact our clinical development programs and plans.

We have not historically allocated all of our internal research and development expenses on a program-by-program basis as our employees and other resources are deployed across multiple projects under development. Internal research and development expenses are presented as one total. Our internal research and development costs are primarily personnel-related costs, stock-based compensation costs, and facility costs, including depreciation and lab consumables.



We incur significant external costs for manufacturing our product candidates and platforms and for clinical research organizations that conduct clinical trials on our behalf. We capture these external expenses for each product candidate in clinical development. Costs for our platforms with an associated product candidate in clinical development are typically allocated to our most clinically advanced product candidate based on that platform. In light of our decision to discontinue further clinical development of XMT-1592, a Dolasynthen ADC that had been in a Phase 1 dose exploration trial in patients with ovarian cancer and non-small cell lung cancer, in the second quarter of 2022, all costs associated with our Dolasynthen platform were prospectively reallocated to XMT-1660, which is now our lead Dolasynthen-based product candidate, following such decision. All external research and development expenses not attributable to our product candidates in clinical development are captured within preclinical and discovery costs. These costs relate to our product candidates XMT-2068 and XMT-2175 and additional earlier discovery stage programs and certain unallocated costs. The following table summarizes our external research and development expenses, presented by program as described above, for each of the three month periods ended March 31, 2023 and 2022.

		Three Months Ended March 31,				
(in thousands)	2023		2022			
UpRi external costs	\$ 16,854	\$	10,143			
XMT-1592 external costs	332		2,426			
XMT-1660 external costs	3,507					
XMT-2056 external costs	2,939		—			
Preclinical and discovery costs	1,539		7,495			
Internal research and development costs	22,104		15,742			
Total research and development costs	\$ 47,275	\$	35,806			

The successful development of our product candidates is highly uncertain. As such, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the remainder of the development of our product candidates. We are also unable to predict when, if ever, we will generate revenue from commercialization and sale of any of our product candidates that obtain regulatory approval. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- successful completion of preclinical studies and IND-enabling studies;
- successful enrollment in and completion of clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- · commercializing the product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the drugs following approval.

A change in the outcome of any of these variables with respect to the development, manufacture or commercialization of any of our product candidates would significantly change the costs, timing and viability associated with the development of that product candidate.



We expect our research and development expenses to increase as we continue our clinical development and manufacturing of UpRi and XMT-1660, continue to evaluate next steps regarding XMT-2056, advance our preclinical pipeline and invest in improvements in our ADC technologies.

#### General and administrative expenses

General and administrative expenses consist primarily of salaries and other employee-related costs, including stock-based compensation, for personnel in executive, finance, accounting, business development, legal operations, information technology and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters and fees for accounting and consulting services.

We expect our general and administrative expenses to increase in the future to support continued research and development activities, including increased costs related to the hiring of additional personnel, fees to outside consultants and patent costs, among other expenses.

#### Other income (expense)

Other income (expense) consists primarily of interest expense related to borrowings under our credit facility and associated amortization of the deferred financing costs and the accretion of debt discount. Interest income includes interest earned on cash equivalents and marketable securities.

#### **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, together with the changes in those items:

	Three Months Ended March 31,				
(in thousands)		2023		2022	Dollar Change
Collaboration revenue	\$	7,802	\$	2,036	\$ 5,766
Operating expenses:					
Research and development		47,275		35,806	11,469
General and administrative		18,328		12,782	5,546
Total operating expenses		65,603	_	48,588	 17,015
Other income (expense):					
Interest income		2,621		18	2,603
Interest expense		(983)		(724)	(259)
Total other income (expense), net		1,638		(706)	 2,344
Net loss	\$	(56,163)	\$	(47,258)	\$ (8,905)

#### Collaboration Revenue

Collaboration revenue increased by \$5.8 million, from \$2.0 million during the three months ended March 31, 2022 to \$7.8 million during the three months ended March 31, 2023, primarily attributable to \$3.1 million of collaboration revenue recognized under the 2022 Merck KGaA Agreement and \$2.5 million of collaboration revenue recognized for achieving a development milestone with Asana Biosciences.

Research and Development Expense

Research and development expense increased by \$11.5 million, from \$35.8 million for the three months ended March 31, 2022 to \$47.3 million for the three months ended March 31, 2023.

The increase in research and development expense was primarily attributable to the following:

- an increase of \$6.5 million related to manufacturing and clinical development activities for UpRi;
- an increase of \$4.1 million related to employee compensation (excluding stock-based compensation), primarily due to an increase in headcount supporting the growth of our research and development activities;
- an increase of \$1.3 million related to consulting and professional fees; and
- an increase of \$0.8 million related to manufacturing and clinical development activities for XMT-2056.

These increased costs were partially offset by a decrease of \$1.5 million related to non-refundable license payments under our third-party licensing agreements.

Stock-based compensation expense included in research and development expenses increased by \$0.4 million, primarily as a result of increased headcount.

#### General and Administrative Expense

General and administrative expense increased by \$5.5 million from \$12.8 million during the three months ended March 31, 2022 to \$18.3 million during the three months ended March 31, 2023. The increase in general and administrative expense was primarily attributable to an increase of \$2.6 million related to consulting and professional services in support of medical affairs and pre-commercial activities, and an increase of \$2.2 million related to employee compensation (excluding stock-based compensation), related to an increase in headcount. Stock-based compensation expense included in general and administrative expense increased \$0.5 million, also primarily as a result of increased headcount.

# Total Other Income (Expense), net

Total other income (expense), net increased by 2.3 million from (0.7) million during the three months ended March 31, 2022 to 1.6 million during the three months ended March 31, 2023. The increase to the net balance was primarily attributable to an increase in interest income earned on marketable securities.

#### Liquidity and Capital Resources

#### Sources of Liquidity

We have financed our operations to date primarily through our strategic collaborations, private placements of our convertible preferred stock and public offerings of our common stock, including our initial public offering, our follow-on public offerings in 2019 and 2020 and our ATM equity offering programs.

In May 2020, we established an ATM equity offering program, the 2020 ATM, pursuant to which we were able to offer and sell to the public through Cowen and Company, LLC, or Cowen, as sales agent, up to \$100.0 million of our common stock from time to time at prevailing market prices. During the three months ended March 31, 2022, we sold approximately 11.7 million shares of common stock under the 2020 ATM, resulting in gross and net proceeds of \$55.9 million and \$54.8 million, respectively. As of March 31, 2022, there were no amounts remaining unsold and available for sale under the 2020 ATM.

In February 2022, we entered into a new sales agreement, or the February 2022 ATM, with Cowen, as sales agent, under which we are able to offer and sell to the public through Cowen up to \$100.0 million of our common stock from time to time at prevailing market prices. During the three months ended March 31, 2022, we sold approximately 1.4 million shares of common stock under the February 2022 ATM, resulting in gross and net proceeds of \$5.9 million and \$5.8 million, respectively. During the three months ended March 31, 2023, we sold approximately 0.3 million shares of common stock under the February 2022 ATM, resulting in gross and net proceeds of \$1.6 million. As of March 31, 2023, there were no amounts remaining unsold and available for sale under the February 2022 ATM.

In November 2022, we entered into an additional sales agreement, or the November 2022 ATM, with Cowen, as sales agent, under which we are able to offer and sell up to the public through Cowen to \$150.0 million of our common stock from time to time at prevailing market prices. During the three months ended March 31, 2023, we sold approximately 3.3 million shares of common stock under the November 2022 ATM, resulting in gross and net proceeds of \$20.7 million and \$20.2 million, respectively. Approximately \$129.3 million remained unsold and available for sale under the November 2022 ATM as of March 31, 2023.

On May 8, 2019, we entered into a loan and security agreement, or the Prior Credit Facility, with Silicon Valley Bank, or former SVB, which was subsequently amended on June 29, 2019, August 28, 2020 and August 27, 2021. On October 29, 2021, we entered into a loan and security agreement, or the New Credit Facility, with Oxford Finance LLC as the collateral agent and a lender, former SVB as a lender, and the other lenders from time to time a party thereto, or together the Lenders. In March 2023, Silicon Valley Bridge Bank, N.A., or SVBB, as successor in interest to former SVB, replaced former SVB as a Lender, and then Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, or SVB, which assumed all deposits and loans of SVBB, subsequently replaced SVBB as a lender. The New Credit Facility, as amended on February 17, 2022, October 17, 2022, December 27, 2022 and March 23, 2023, provides in aggregate up to \$100 million in credit, which includes (i) \$40 million available at our option in up to four principal advances through June 30, 2023, (ii) an additional \$40 million, subject to conditional approval from the Lenders. The Company has drawn \$25 million under the New Credit Facility as of March 31, 2023. The New Credit Facility is secured by substantially all of our personal property owned or later acquired, excluding intellectual property (but including the right to payments and proceeds of intellectual property), and a negative pledge on intellectual property, which ensures that the Lenders' rights to repayment would be senior to the rights of the holders of our common stock in the event of liquidation. Upon entering into the New Credit Facility, we terminated all commitments by former SVB to extend further credit under the Prior Credit Facility and all guarantees and security interests granted by us to former SVB under the Prior Credit Facility.

As of March 31, 2023, we had cash, cash equivalents and marketable securities of \$273.9 million. In addition to our existing cash, cash equivalents and marketable securities, and available borrowings under the New Credit Facility, we are eligible to earn milestone and other payments under our collaboration agreements with GSK, Janssen, Merck KGaA and its affiliate MRKDG and Asana Biosciences. Our ability to earn the milestone payments and the timing of earning these amounts are dependent upon the timing and outcome of our development, regulatory and commercial activities and, as such, are uncertain at this time.

# Cash Flows

The following table provides information regarding our cash flows for the three months ended March 31, 2023 and 2022:

		Three Months Ended March 31,				
(in thousands)		2023		2022		
Net cash used in operating activities	\$	(29,005)	\$	(7,955)		
Net cash provided by (used in) investing activities		1,396		(329)		
Net cash provided by financing activities		21,549		60,394		
(Decrease) increase in cash, cash equivalents and restricted cash	\$	(6,060)	\$	52,110		

### Net Cash Used in Operating Activities

Net cash used in operating activities was \$29.0 million during the three months ended March 31, 2023 and primarily consisted of a net loss of \$56.2 million adjusted for changes in our net working capital, deferred revenue related to our collaboration agreements, and other non-cash items including stock-based compensation of \$6.4 million and net amortization of premiums and discounts on marketable securities of \$1.4 million. Net cash used in operating activities was \$8.0 million during the three months ended March 31, 2022 and primarily consisted of a net loss of \$47.3 million adjusted for changes in our net working capital and \$38.3 million in deferred revenue related to the Janssen Agreement, and other non-cash items including stock-based compensation of \$5.5 million and depreciation of \$0.2 million.

# Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$1.4 million during the three months ended March 31, 2023 as compared to net cash used in investing activities of \$0.3 million during the three months ended March 31, 2022. During the three months ended March 31, 2023, net cash provided by investing activities consisted primarily of maturities of marketable securities, partially offset by purchases of marketable securities. During the three months ended March 31, 2022, net cash used in investing activities consisted of purchases of equipment.

# Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$21.5 million during the three months ended March 31, 2023 as compared to \$60.4 million during the three months ended March 31, 2022. During the three months ended March 31, 2023, net cash provided by financing activities consisted primarily of proceeds from sales of common stock under our February 2022 ATM and November 2022 ATM of \$21.7 million. During the three months ended March 31, 2022, net cash provided by financing activities consisted primarily of proceeds from sales of common stock under our 2020 ATM and February 2022 ATM of \$60.4 million.

### Funding Requirements

We expect our cash expenditures to increase in connection with our ongoing activities, particularly as we continue the research and development and manufacturing of, initiate clinical trials of and seek marketing approval for our product candidates. In addition, as we prepare for and if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators.



As of March 31, 2023, we had cash, cash equivalents and marketable securities of \$273.9 million. In addition, we currently have the option to borrow \$15 million under the New Credit Facility through June 30, 2023. We believe our currently available funds plus available borrowings on the New Credit Facility will be sufficient to fund our current operating plan commitments into the second half of 2024. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we obtain;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- · the costs of securing manufacturing arrangements for clinical and commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve drug sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs 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. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of strategic collaborations, licensing arrangements, equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. We currently have access to the New Credit Facility, as described above, along with funds to potentially be earned in connection with our agreements with GSK, Janssen, Merck KGaA and its affiliate MRKDG and Asana BioSciences, if research and development activities are successful under our collaborations with those parties. Future additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.



If we raise funds through additional strategic collaborations 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 to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

#### **Contractual Obligations**

There were no material changes to our contractual obligations as reported in our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on February 28, 2023.

#### **Critical Accounting Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the financial statements prospectively from the date of change in estimates. There were no material changes to our critical accounting estimates as reported under the heading "Critical Accounting Policies and Significant Judgements and Estimates" in Part II, Item 7. Management's Discussion and Analysis of Financial Conditions and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on February 28, 2023.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk

#### Interest Rate Risks

We are exposed to market risk related to changes in interest rates. As of March 31, 2023, we had cash, cash equivalents and marketable securities of \$273.9 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments, including cash equivalents and marketable securities are invested in U.S. Treasury obligations, commercial paper, corporate bonds and U.S. government agency securities. However, we believe that due to the short-term duration of our investment portfolio and low-risk profile of our investments, an immediate 100 basis points change in the prime rate would not have a material effect on the fair market value of our investments portfolio.

The interest rate on our New Credit Facility is sensitive to changes in interest rates. Interest accrues on borrowings under the credit facility at a floating rate equal to the greater of (i) 8.50% and (ii) the prime rate plus 5.25%. We do not currently engage in any hedging activities against changes in interest rates. As of March 31, 2023, there was \$25.0 million outstanding under the New Credit Facility, and a potential change in the associated interest rates would be immaterial to the results of our operations.

#### Foreign Currency Exchange Rate Risks

We are currently not exposed to market risk related to changes in foreign currency exchange rates, but we may contract with vendors that are located in Asia and Europe and may be subject to fluctuations in foreign currency rates at that time.



#### **Item 4. Controls and Procedures**

#### Management's Evaluation of our Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2023, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

#### 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 quarter 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 become subject to various legal proceedings and claims that arise in the ordinary course of our business activities. We are not currently party to any material legal proceedings. Additionally, although the results of litigation and claims cannot be predicted with certainty, as of the date of this Quarterly Report on Form 10-Q, we do not believe we are party to any claim or litigation, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business.

#### Item 1A. Risk Factors

Our operations and financial results are subject to various risks and uncertainties, including those described below. The following information about these risks and uncertainties, together with the other information appearing elsewhere in this Quarterly Report on Form 10-Q, and our 2022 Annual Report on Form 10-K, filed with the Securities and Exchange Commission, or SEC, on February 28, 2023, including our consolidated financial statements and related notes thereto, should be carefully considered before making any decision to invest in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. We cannot provide assurance that any of the events discussed below will not occur.

#### Risks Related to Development and Approval of Our ADC Product Candidates

Failure of a discovery program or product candidate may occur at any stage of preclinical or clinical development, and, because our and our collaborators' discovery programs and our product candidates are in early stages of preclinical or clinical development, there is a high risk of failure. We or our collaborators may never succeed in obtaining regulatory approval and generating revenue from such discovery programs or product candidates.

The early clinical results for our lead product candidate, upifitamab rilsodotin, or UpRi, the results from our preclinical studies of XMT-1660 and XMT-2056 and the early results from preclinical studies or clinical trials of any other current or future product candidates are not necessarily predictive of the results from our ongoing or future discovery programs, preclinical studies or clinical trials. Promising results in preclinical studies and early encouraging clinical results of a drug candidate may not be predictive of similar results in later-stage preclinical studies or in humans during clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in earlier stages of clinical development, and we cannot be certain that we will not face similar setbacks. These companies' setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy events in preclinical or clinical trials, including previously unreported adverse events. Similarly, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In March 2023, we announced that the FDA had issued a clinical hold on our Phase 1 trial of XMT-2056 following our communication to the FDA that we were voluntarily suspending the trial due to a Grade 5 (fatal) serious adverse event, or SAE, that was deemed to be related to XMT-2056. The SAE occurred in the second patient who had been enrolled at the initial dose level in the dose escalation portion of the Phase 1 clinical trial. We are continuing to investigate this SAE and its cause, and we continue to evaluate next steps related to our development of XMT-2056, which may include clinical trial protocol changes.



Any clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In addition, clinical trial results for one of our product candidates, or for competitor products utilizing similar technology, may raise concerns about the safety or efficacy of other product candidates in our pipeline. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented from or delayed in obtaining marketing approval for our product candidates. For example, patients in our ongoing clinical trials of UpRi have experienced SAEs, including, without limitation, death, pneumonitis, renal impairment, abdominal pain, fatigue, vomiting, sepsis and pyrexia, and a patient in our Phase 1 clinical trial of XMT-2056 suffered a Grade 5 SAE, resulting in the clinical hold currently placed on the trial by the FDA. We expect that certain patients in our ongoing clinical trials of UpRi and XMT-1660 and in future clinical trials will experience additional SAEs, including those that may result in death, as our product candidates progress through clinical development.

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 dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. 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 have nonetheless failed to obtain FDA approval. Even if we or our collaborators believe that the results of clinical trials of our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

Alternatively, even if we obtain regulatory approval, that approval may be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a risk evaluation and mitigation strategy, or REMS, program. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

### Preliminary, interim and top-line 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 audit and verification procedures that could result in material changes in the final data.

From time to time, we may announce or publish preliminary, interim or top-line data from our clinical trials. Positive preliminary data may not be predictive of such trial's subsequent or overall results. Interim data from clinical trials that we may complete do not necessarily predict final results and 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. For example, we have reported interim data from our ongoing Phase 1b/2 clinical trial of UpRi, but we have not yet reported final data from the trial. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or top-line data we may publish. As a result, preliminary, interim and top-line data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

# We are currently evaluating a limited number of ADC product candidates in clinical trials. A failure of any of our product candidates in clinical development would adversely affect our business and may require us to discontinue development of other ADC product candidates based on the same technology.



UpRi, XMT-1660 and XMT-2056 are currently our only product candidates in clinical trials, and our clinical trial of XMT-2056 has been placed on clinical hold by the FDA. While we have certain other preclinical programs in development, it will take additional investment and time, and regulatory clearance, for such programs to reach the clinical stage of development. In addition, we have other product candidates in our current pipeline that are based on the same platforms as UpRi, XMT-1660 and XMT-2056. If a product candidate fails in development as a result of any underlying problem with our platforms, then we may be required to discontinue development of the product candidates that are based on the same technologies. If we were required to discontinue development of future product candidate, or if UpRi, XMT-1660 or XMT-2056 or any other current or future product candidate were to fail to receive regulatory approval or were to fail to achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability.

Events that may delay or prevent successful commencement, enrollment or completion of clinical trials of our product candidates could result in increased costs to us as well as a delay in obtaining, or failure to obtain, regulatory approval, or cause us to suspend or terminate a clinical trial, which could prevent us from commercializing our product candidates on a timely basis, or at all.

We cannot guarantee that clinical trials, including our ongoing and any future additional clinical trials of UpRi, XMT-1660, XMT-2056 or any of our other current or future product candidates, will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing, and other events may cause us to temporarily or permanently cease a clinical trial. Events that may prevent successful or timely commencement, enrollment or completion of clinical development include, among others:

- delays in reaching a consensus with regulatory agencies on trial design;
- delays in reaching, or failing to reach, agreement on acceptable terms with prospective clinical research organizations, or CROs, site management organizations, or SMOs, and clinical trial sites;
- difficulties in obtaining required Institutional Review Board, or IRB, or Ethics Committee, or EC, approval at each clinical trial site;
- challenges in recruiting and enrolling suitable patients to participate in clinical trials that meet the criteria of the protocol for the clinical trial;
- imposition of a clinical hold by regulatory agencies, IRBs or ECs for any reason, including safety concerns or after an inspection of clinical operations or trial sites;
- delays in necessary screenings caused by third parties with which we or any of our vendors or suppliers contract;
- failure by CROs, SMOs, other third parties or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's good clinical practices, or GCP, or applicable regulatory guidelines in other countries;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, including, for example, delays in the testing, validation, manufacturing or delivery of the product candidates to the clinical sites;
- patients not completing participation in a trial or not returning for post-treatment follow-up, including as a result of the ongoing COVID-19 pandemic;

- expected or unexpected safety issues, including occurrence of SAEs, associated with any product candidate in clinical trials that are viewed as
  outweighing the product candidate's potential benefits or reports that may arise from preclinical or clinical testing of other similar cancer therapies
  that raise safety or efficacy concerns about our product candidates;
- changes in regulatory requirements or guidance that require amending or submitting new clinical protocols or submitting additional data;
- · lack of adequate funding to continue one or more clinical trials; or
- geopolitical or other events, including the ongoing COVID-19 pandemic and the current conflict between Russia and Ukraine, that unexpectedly disrupt, delay or generally interfere in regional or worldwide operations of our clinical trial sites, CROs, SMOs or other operations applicable to the conduct of relevant development activities.

Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to commence, enroll or complete our current and anticipated clinical trials. In March 2023, we announced that our Phase 1 clinical trial of XMT-2056 had been placed on clinical hold by the FDA following a Grade 5 SAE. We are continuing to investigate this SAE and its cause, and we continue to evaluate next steps related to our development of XMT-2056, which may include clinical trial protocol changes. If we or our collaborators are not able to successfully complete clinical trials, we or they will not be able to obtain regulatory approval and will not be able to commercialize our product candidates or our collaborators' product candidates based on our technology.

### An inability to enroll sufficient numbers of patients in our clinical trials could result in increased costs and longer development periods for our product candidates.

Clinical trials require sufficient patient enrollment, which is a function of many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the nature and complexity of the trial protocol, including eligibility criteria for the trial;
- the design of the trial;
- the number of clinical trial sites and the proximity of patients to those sites;
- the standard of care in the diseases under investigation;
- the ability and commitment of clinical investigators to identify eligible patients;
- clinicians' and patients' perceptions of the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they are late-stage cancer patients, that they will not survive the full terms of the clinical trials; and
- the ability of our clinical trial sites to continue key activities, such as clinical trial site data monitoring and patient visits, due to factors related to the ongoing COVID-19 pandemic or other worldwide events.



In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our current and future product candidates. This competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such sites. Moreover, because our current and future product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in our ongoing or any future clinical trials.

Challenges in recruiting and enrolling suitable patients to participate in clinical trials that meet the criteria of the protocol could increase costs and result in delays to our current development plans for UpRi, XMT-1660 or any other current or future product candidate.

### Our product candidates or ADCs developed or commercialized by our competitors may cause undesirable side effects or have other properties that halt their clinical development, delay or prevent regulatory approval of our product candidates or limit their commercial potential.

Undesirable side effects caused by our product candidates or ADCs being developed or commercialized by our collaborators or competitors could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label, the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates or those of our competitors may only be uncovered with a significantly larger number of patients exposed to the drug. SAEs, including death, deemed to be caused by our product candidates or those of our competitors, either before or after receipt of marketing approval, could have a material adverse effect on the development of our product candidates and our business as a whole.

Patients in our ongoing clinical trials have experienced SAEs, including, without limitation, death, pneumonitis, renal impairment, abdominal pain, fatigue, vomiting, sepsis and pyrexia. For instance, in March 2023, we announced that our Phase 1 clinical trial of XMT-2056 had been placed on clinical hold by the FDA following a Grade 5 SAE. We expect that certain patients in ongoing and future trials will experience additional SAEs, including those that may result in death, as our product candidates progress through clinical development. These or additional undesirable side effects caused by our product candidates or those of our competitors, either before or after receipt of marketing approval, could result in a number of potentially significant negative consequences, including:

- our clinical trials may be put on hold;
- treatment-related side effects could affect patient recruitment for our clinical trials;
- we may be unable to obtain regulatory approval for our product candidates;
- regulatory authorities may withdraw or limit their approvals of our product candidates;
- regulatory authorities may require the addition of labeling statements, such as a contraindication, black box warnings or additional warnings;
- the FDA may require development of a REMS with Elements to Assure Safe Use as a condition of approval or post-approval;
- we may decide to remove such product candidates from the marketplace;
- we may be subject to regulatory investigations and government enforcement actions;

- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and could substantially increase commercialization costs.

### We may choose not to develop a potential product candidate, or we may suspend or terminate one or more discovery or preclinical programs or product candidates.

At any time and for any reason, we may determine that one or more of our discovery programs, preclinical programs or product candidates does not have sufficient potential to warrant the allocation of resources toward such program or product candidate. Furthermore, because we have limited financial and personnel resources, we have placed significant focus on the development of our lead product candidate, UpRi, and a limited number of other product candidates, including XMT-1660 and XMT-2056 and historically including XMT-1592. Accordingly, we may choose not to develop a product candidate or elect to suspend or terminate one or more of our discovery or preclinical programs. If we suspend or terminate a program or product candidate in which we have invested significant resources, we will have expended resources on a program or product candidate that will not provide a full return on our investment. For example, in May 2022, we decided to discontinue development of XMT-1592 based in part on the lower prevalence of the NaPi2b biomarker in non-small cell lung cancer, or NSCLC, and the increasingly competitive nature of such indication. We may also cease developing a product candidate for a particular indication. For example, in November 2021, we determined to cease developing UpRi as a single agent in patients with NSCLC and to develop XMT-1592 to potentially more productive uses, including existing or future programs or product candidates. If we do not accurately evaluate the commercial potential or target market for a particular future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular future product candidates through collaboration, licensing or other royalty arrangements.

#### We or our collaborators may fail to discover and develop additional potential product candidates.

Our and our collaborators' research programs to identify new product candidates will require substantial technical, financial and human resources, and we or our collaborators may be unsuccessful in our or their efforts to identify new product candidates. If we or our collaborators are unable to identify suitable additional product candidates for preclinical and clinical development, our or their ability to develop product candidates and our ability to obtain revenues from commercializing our products or to receive royalties from our collaborators' sales of their products in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price.

#### Risks Related to our Financial Position and Need for Additional Capital

### We have incurred net losses since our inception, we have no products approved for commercial sale and we anticipate that we will continue to incur substantial operating losses for at least the next several years. We may never achieve or sustain profitability.

We have incurred net losses since our inception. Our net loss was \$56.2 million for the three months ended March 31, 2023. As of March 31, 2023, we had an accumulated deficit of \$710.9 million. Our losses have resulted principally from costs incurred in our discovery and development activities. Our net losses may fluctuate significantly from quarter to quarter and year to year. To date, we have not commercialized any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in 2023, nor may we generate any product revenues thereafter if we are unable to apply for or obtain marketing approvals or gain market acceptance for any approved product(s). Absent the realization of sufficient revenues from product sales, we may never achieve profitability in the future.



We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities. To date, we have financed our operations primarily with the proceeds from our strategic collaborations, private placements of our preferred stock and public offerings of our common stock, including our initial public offering, our follow-on public offerings in 2019 and 2020 and our at-the-market, or ATM, equity offering programs. The amount of our future net losses will depend, in part, on the rate of our future expenditures. We have not completed pivotal clinical trials for any product candidate and have only a limited number of product candidates in current or planned clinical trials. It will be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues would depend upon the size of the market or markets in which our product candidates received such approval and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for our product candidates in those markets.

We expect to continue to incur significant expenses and operating losses over the next several years. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- continue clinical development activities for our lead product candidate, UpRi, and for XMT-1660;
- continue to evaluate next steps regarding XMT-2056;
- continue to develop a diagnostic assay for the NaPi2b biomarker;
- continue activities to discover, validate and develop additional product candidates;
- obtain marketing approvals for our current and future product candidates for which we complete clinical trials and obtain marketing approvals, either ourselves or through a third party, for any necessary companion or complementary diagnostics;
- develop a sustainable and scalable manufacturing process for our product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- address any competing technological and market developments;
- maintain, expand and protect our intellectual property portfolio; and
- hire additional research, development and general and administrative personnel.

If we are required by the FDA or any equivalent foreign regulatory authority to perform clinical trials or preclinical trials in addition to those we currently expect to conduct, or if there are any delays in completing the clinical trials of UpRi or any other current or future product candidates, our expenses could increase.

To become and remain profitable, we must succeed in developing our product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We may not succeed in these activities, and we may never generate revenue from product sales or strategic collaborations in an amount sufficient to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, discover or develop other product candidates or continue our operations.

### We have a credit facility that requires us to comply with certain affirmative and negative covenants and places restrictions on our operating and financial flexibility.

In October 2021, we entered into a Loan and Security Agreement, or the New Credit Facility, with Oxford Finance LLC as the collateral agent and a lender, Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, as a lender, and the other lenders party thereto, or together the Lenders. Pursuant to the New Credit Facility, as amended to date, we may borrow up to an aggregate of \$100 million, which includes \$40 million available in up to four principal advances through June 30, 2023, \$40 million in up to one principal advance through September 30, 2023, subject to meeting certain development milestones, and an additional tranche of \$20 million, which is subject to conditional approval from the Lenders. The New Credit Facility is secured by substantially all of our personal property owned or later acquired, excluding intellectual property (but including the right to payments and proceeds from intellectual property), and a negative pledge on intellectual property.

The New Credit Facility also includes customary representations and warranties, affirmative and negative covenants and conditions to drawdowns, as well as customary events of default. Certain of the customary negative covenants limit our ability, among other things, to incur future debt, grant liens, make investments, make acquisitions, distribute dividends, make certain restricted payments and sell assets, subject in each case to certain exceptions. Our failure to comply with these covenants would result in an event of default under the Loan and Security Agreement and could result in the acceleration of the obligations we owe pursuant to the New Credit Facility.

### We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Our cash, cash equivalents and marketable securities were \$273.9 million as of March 31, 2023. We have utilized substantial amounts of cash since our inception and expect that we will continue to expend substantial resources for the foreseeable future developing UpRi, XMT-1660, XMT-2056 and any other current or future product candidates. These expenditures may include costs associated with research and development, conducting preclinical studies and clinical trials, potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any, and potentially acquiring new technologies. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Our costs will increase if we experience any delays in our clinical trials for UpRi or any other current or future product candidates, including delays in enrollment of patients. We also incur costs associated with operating as a public company, hiring additional personnel and expanding our facilities.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing UpRi, XMT-1660, XMT-2056 and any other current or future product candidates and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for UpRi, XMT-1660, XMT-2056 and any other current or future product candidates if preclinical studies and clinical trials are successful;
- the cost of manufacturing UpRi, XMT-1660, XMT-2056 and any other current or future product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- the cost of commercialization activities for UpRi, XMT-1660, XMT-2056 and any other current or future product candidates, if any product candidates are approved for sale, including manufacturing, marketing, sales and distribution costs;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of any such litigation;



- the timing, receipt and amount of sales of, or royalties on, our future products, if any, or products developed by our collaborators;
- · the emergence of competing cancer therapies and other adverse market developments; and
- the requirement for or the cost of developing companion diagnostics and/or complementary diagnostics.

We currently have the option to borrow \$15 million under the New Credit Facility through June 30, 2023. We believe that our current cash, cash equivalents and marketable securities plus the available borrowings under the New Credit Facility will be sufficient to fund our current operating plan commitments into the second half of 2024. However, we have based these estimates on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us and we may need additional funds sooner than planned. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. Our ability to borrow funds under the New Credit Facility is subject to us complying with the applicable covenants at the time we request a drawdown. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our capital need through a variety of means, including through private and public equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of such equity or convertible debt securities may include liquidation or other preferences that are senior to or otherwise adversely affect the rights of our common stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring future debt, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness, each of which could adversely impact our ability to conduct our business and execute our operating plan. If we raise additional funds through strategic collaborations with third parties, we may have to relinquish valuable rights to our technologies, including our platforms, or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for UpRi, XMT-1660, XMT-2056 or any other current or future product candidates or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

### We may expend our resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific product candidates. As a result, we may forgo or delay pursuit of opportunities with other product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Failure to properly assess potential product candidates could result in our focus on product candidates with low market potential, which would harm our business and financial condition. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

#### **Risks Related to Our Reliance on Third Parties**

### Because we rely on third-party manufacturers and suppliers, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.

We rely on third-party contract manufactures to manufacture our preclinical and clinical trial product supplies, and we lack the internal resources and the capability to manufacture any product candidates on a clinical or commercial scale. The facilities used by our contract manufactures to manufacture the active pharmaceutical ingredient and final drug product must be acceptable to the FDA and other comparable foreign regulatory agencies pursuant to inspections that would be conducted after we submit our marketing application or relevant foreign regulatory submission to the applicable regulatory agency. There can be no assurance that our preclinical and clinical development product supplies will be sufficient, uninterrupted or of satisfactory quality or continue to be available at acceptable prices. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or applicable foreign regulatory agencies, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. Any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current good manufacturing practices. We have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. In the event that any of our manufacturers fails to comply with regulatory requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacturer or proprietary to the original manufacturer, and we may have difficulty transferring such skills or technology to another third party and a feasible alternative may not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget. Our reliance on contract manufacturers also exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may appro

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements and comply with cGMP could adversely affect our business in a number of ways, including:

- a delay or inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or delay or failure to receive regulatory approvals, for product candidates;
- loss of the cooperation of an existing or future strategic collaborator;



- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- a requirement to cease distribution or to recall batches of our product candidates;
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products; and
- fines, adverse publicity, and civil and criminal enforcement and sanctions.

### We, or our third-party manufacturers, may be unable to successfully scale-up manufacturing of our ADC product candidates in sufficient quality and quantity, which would delay or prevent us from developing our ADC product candidates and commercializing approved products, if any.

In order to conduct clinical trials of our product candidates and commercialize any approved product candidates, we, or our third-party manufacturers, will need to manufacture them in large quantities. We, or our third-party manufacturers, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we or any third-party manufacturer are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. We have evaluated which third-party manufacturers to engage for scale-up to commercial supply of our product candidates, including UpRi, and we have begun to transfer and scale-up certain manufacturing activities. If we are unable to obtain or maintain third-party manufacturing for commercial supply of our product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully.

# We rely on third parties to conduct preclinical studies and clinical trials for UpRi, XMT-1660, XMT-2056 and our other product candidates, and if such third parties do not properly, timely and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for UpRi, XMT-1660, XMT-2056 or any other current or future ADC product candidates.

We designed the ongoing and planned clinical trials for UpRi and XMT-1660 and the clinical trial of XMT-2056 that is currently on clinical hold, as well as the trial for XMT-1592 that closed in September 2022, and we intend to design any future clinical trials for any future product candidates that we may develop if preclinical studies are successful and we do not have a strategic collaborator responsible for such trial design. However, we rely on CROs, SMOs, clinical sites, investigators and other third parties to assist in managing, monitoring and otherwise carrying out many of these trials. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. These CROs, SMOs, investigators and other third parties are not our employees, and we have limited control over the amount of time and resources that they dedicate to our programs. We compete with many other companies for the resources of these third parties. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with whom we contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials being delayed or unsuccessful.

The third parties on whom we rely generally may terminate their engagements at any time, and having to enter into alternative arrangements would delay development and commercialization of our product candidates. 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.

The FDA and comparable foreign regulatory authorities require compliance with regulations and standards, including GCP, for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical trials to assure that the data and results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Although we rely, and intend to continue to rely, on third parties to conduct our clinical trials, they are not our employees, and we are responsible for ensuring that each of these clinical trials is conducted in accordance with its general investigational plan, protocol and other requirements. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For any violations of laws or regulations during the conduct of our clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

If these third parties do not successfully carry out their duties under their agreements, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to clinical trial protocols or to regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, the clinical trials of our product candidates may not meet regulatory requirements. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCPs or other regulatory requirements, the clinical data generated in our clinical trials may be deemed unreliable, third parties may need to be replaced, we may be subject to negative publicity, fines and civil or criminal sanctions, and preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates on a timely basis or at all.

# We depend on strategic relationships with other companies to assist in the research, development and commercialization of our ADC platforms and ADC product candidates. If our existing collaborators do not perform as expected, this may negatively affect our ability to commercialize our ADC product candidates or generate revenues through technology licensing or may otherwise negatively affect our business.

We have established strategic collaborations and intend to continue to establish strategic collaborations and other relationships with third parties to research, develop and commercialize our platforms and existing and future product candidates. In December 2022, we entered into a collaboration and license agreement with Ares Trading, S.A., an affiliate of Merck KGaA, for the research, development and commercialization of ADC product candidates leveraging our Immunosynthen platform, and in February 2022, we entered into a collaboration agreement with Janssen Biotech, Inc. for the research, development and commercialization of ADC product candidates leveraging our Dolasynthen platform. We had also entered into a collaboration agreement with Merck KGaA for the development and commercialization of ADC product candidates leveraging our Dolasynthen platform. We had also entered into a collaboration agreement with Merck KGaA for the development and commercialization of ADC product candidates leveraging our Dolasynthen platform. Additionally, in August 2022, we entered into an option, collaboration and license agreement, or the GSK Agreement, with GlaxoSmithKline Intellectual Property (No. 4) Limited, or GSK, pursuant to which we granted GSK an exclusive option to obtain an exclusive license to co-develop and to commercialize products containing XMT-2056. Under these arrangements, we will depend on our collaborators to design and conduct their clinical trials. As a result, we will not be able to control or oversee the conduct of these programs by our collaborators and those programs may not be successful, which may negatively impact our business operations. In addition, if any of these collaborators withdraw support for these programs or proposed products or otherwise impair their development or experience negative results, our business and our product candidates could be negatively affected.



Our collaborators may terminate their agreements with us for cause under certain circumstances or at will in certain cases and discontinue use of our technologies. In addition, we cannot control the amount and timing of resources our collaborators may devote to products utilizing or incorporating our technology. Moreover, our relationships with our collaborators may divert significant time and effort of our scientific staff and management team and require effective allocation of our resources to multiple internal and collaborative projects. Our collaborators may fail to perform their obligations under the collaboration agreements or may not perform their obligations in a timely manner. If conflicts arise between our collaborators and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. If any of our collaborators terminate or breach our agreements with them, or otherwise fail to complete their obligations in a timely manner, or if GSK ultimately decides not to exercise its option for a license to co-develop and commercialize XMT-2056, it may have a detrimental effect on our financial position by reducing or eliminating the potential for us to receive technology access and license fees, milestones and royalties, reimbursement of development costs, as well as possibly requiring us to devote additional efforts and incur costs associated with pursuing internal development of product candidates. Furthermore, if our collaborators may be unable to commercialize these product candidates, which would limit our ability to generate revenue and become profitable.

Our collaborators may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our collaborators. Competing products, either developed by our collaborators or to which our collaborators have rights, may result in the withdrawal of collaborators support for our product candidates. Even if our collaborators continue their contributions to the strategic relationships, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Additionally, if our collaborators pursue different clinical or regulatory strategies with their product candidates based on our platforms or technologies, adverse events with their product candidates could negatively affect our product candidates utilizing similar technologies. Any of these developments could harm our product development efforts.

### To date, we have depended on a small number of collaborators for a substantial portion of our revenue. The loss of any one of these collaborators could result in non-achievement of our expected revenue payments.

We have entered into strategic collaborations with a limited number of companies. To date, a substantial portion of our revenue has resulted from payments made under agreements with our strategic collaborators, and we expect that a portion of our revenue will continue to come from strategic collaborations. The loss of any of our collaborators, or the failure of our collaborators to perform their obligations under their agreements with us, including paying license or technology fees, milestone payments, royalties or reimbursements, could have a material adverse effect on our financial performance. Payments under our existing and future strategic collaborations are also subject to significant fluctuations in both timing and amount, which could cause our revenue to fall below the expectations of securities analysts and investors and cause a decrease in our stock price.

### We may seek to establish additional strategic collaborations, and if we are not able to establish them on commercially reasonable terms, or maintain them, we may have to alter our development and commercialization plans.

We continue to strategically evaluate our collaborations and, as appropriate, we expect to enter into additional strategic collaborations in the future, including potentially with major biotechnology or biopharmaceutical companies. We face significant competition in seeking appropriate collaborators for our product candidates and platforms, and the negotiation process is time-consuming and complex. In order for us to successfully collaborate with a third-party to leverage our platforms or advance our product candidates, potential collaborators must view these platforms and product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available platforms and products for licensing by other companies. Even if we are successful in our efforts to establish strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidates or platforms could delay the development and commercialization of existing or future product candidates and reduce their competitiveness even if they reach the market. If we are not able to generate revenue under our strategic collaborations when and in accordance with our expectations or the expectations of industry analysts, this failure could harm our business and have an immediate adverse effect on the trading price of our common stock.

If we fail to establish and maintain additional strategic collaborations related to our product candidates for which we have not yet entered into a strategic collaboration, we will bear all of the risk and costs related to the development of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise, such as regulatory expertise, for which we have not budgeted. If we are not successful in seeking additional financing, hiring additional employees or developing additional expertise, if necessary, our cash burn rate would increase or we would need to take steps to reduce our rate of product candidate development. This could negatively affect the development of any product candidate for which we do not currently have a collaborator.

#### **Risks Related to Commercialization of Our ADC Product Candidates**

### Our future commercial success depends upon attaining significant market acceptance of our ADC product candidates, if approved, among physicians, patients and health care payors.

Even if we obtain regulatory approval for UpRi or any other current or future product candidates that we may develop or acquire in the future, the product candidate may not gain market acceptance among physicians, health care payors, patients and the broader healthcare community. Market acceptance of any approved products depends on a number of factors, including:

- the efficacy and safety of the product, as demonstrated in clinical trials;
- the indications for which the product is approved and the label approved by regulatory authorities for use with the product, including any warnings that may be required on the label;
- acceptance by physicians and patients of the product as a safe and effective treatment;
- the cost, safety and efficacy of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

Perceptions of any product are influenced by perceptions of competitors' products. As a result, adverse public perception of our competitors' products may negatively impact the market acceptance of our product candidates. Market acceptance is critical to our ability to generate significant revenue and become profitable. Any therapeutic candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate significant revenue and our business would suffer.

# The incidence and prevalence for target patient populations of our drug candidates have not been established with precision. If the market opportunities for our drug candidates, including particularly UpRi, are smaller than we estimate, or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

The precise incidence and prevalence of ovarian cancer with NaPi2b expression are uncertain. Our estimates of both the number of people who have this disease, as well as the subset of people with ovarian cancer who have the potential to benefit from treatment with UpRi, are based on estimates. The total addressable market opportunity for UpRi for the treatment of ovarian cancer with NaPi2b positive expression, if UpRi is approved for sale for this indication, will ultimately depend upon, among other things, the diagnostic assay to identify patients with NaPi2b positive ovarian cancer, and patient access, drug pricing and reimbursement. The number of patients who can be treated with UpRi or any of our other current or future product candidates may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, we may face increasing difficulties in identifying or gaining access to new patients, or diagnostic assays to help identify patients may not be available, all of which would adversely affect our results of operations and our business.

### If we are unable to establish sales, marketing and distribution capabilities, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish a sales and marketing organization or pursue a collaborative arrangement for such sales and marketing.

In the future, we expect to build a focused sales and marketing infrastructure to market UpRi and XMT-1660 and any other current or future product candidates in the United States and certain foreign jurisdictions, if and when they are approved, and we may potentially do so for XMT-2056. There are risks involved with establishing our own sales, marketing and distribution capabilities.

For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians;
- the lack of adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and



• unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves.

In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute certain of our product candidates outside of the United States or may be unable to do so on terms that are favorable to us. We likely will have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

### Reimbursement may be limited or unavailable in certain market segments for our ADC product candidates, which could make it difficult for us to sell our products profitably.

In both domestic and foreign markets, sales of any of our product candidates, if approved, will depend, in part, on the extent to which the costs of our products will be covered by third-party payors, such as government health programs, commercial insurance and managed health care organizations. These third-party payors decide which drugs will be covered and establish reimbursement levels for those drugs. The containment of health care costs has become a priority of foreign and domestic governments as well as private third-party payors. The prices of drugs have been a focus in this effort. Governments and private third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability to sell our product candidates profitably. Cost-control initiatives could cause us to decrease the price we might establish for products, which could result in lower than anticipated product revenues.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Adverse pricing limitations may hinder our ability to recoup our investment in UpRi, XMT-1660, XMT-2056 or any other current or future product candidates, even if such product candidates obtain marketing approval.



Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. Further, there is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our products. If reimbursement is not available only to limited levels, we may not be able to commercialize certain of our products. In addition, in the United States, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs. Manufacturers further may be required to offer price concessions to achieve sales or favorable coverage.

#### Price controls may be imposed in the United States and foreign markets, which may adversely affect our future profitability.

In the United States, the prices of pharmaceutical products are increasingly subject to review and legislative actions to exert government regulation over the costs of such products. Further, in a number of foreign countries, including member states of the European Union, the pricing of prescription drugs is subject to governmental control. Additional countries may adopt similar approaches to the pricing of prescription drugs. In such countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other trials that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. We cannot be sure that such prices and reimbursement will be acceptable to us or our strategic collaborators. Publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic collaborators and the potential profitability of our products is unavailable or limited in scope or amount, our revenues from sales by us or our strategic collaborators and the potential profitability of our product candidates in those countries would be negatively affected.

### We face substantial competition, and if our competitors develop and market products that are more effective, safer or less expensive than any of our current or future product candidates, our commercial opportunities will be negatively impacted.

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many third parties compete with us in developing various approaches to cancer therapy. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations. Any treatments developed by our competitors could be superior to our product candidates. It is possible that these competitors will succeed in developing technologies that are more effective than our platforms or product candidates or that would render our platforms obsolete, noncompetitive or not economical. We anticipate that we will face increased competition in the future as additional companies enter our market and scientific developments surrounding other cancer therapies continue to accelerate.

We are also aware of multiple companies with ADC technologies that may be competitive to our platforms, including Daiichi Sankyo Company, Limited; ImmunoGen, Inc.; Gilead Sciences, Inc.; Pfizer Inc.; and Seagen Inc. These companies or their partners and collaborators, including Astellas Pharma Inc.; AstraZeneca plc; AbbVie Inc.; Genentech, a member of the Roche Group; and Takeda Pharmaceuticals, Inc., to Takeda, may develop product candidates that compete in the same indications as our current and future product candidates. Multiple companies are also developing ADCs that could compete with our Immunosynthen product candidates, including Bolt Biotherapeutics, Inc. and Takeda, albeit with differing immune stimulating approaches. We expect to compete based on our innovative technology and the efficacy, safety and tolerability profile of our ADCs compared to other product candidates, but if our ADCs are not demonstrably superior in these respects, we may not be able to compete effectively. Products we may develop in the future are also likely to face competition from other products and therapies, some of which we may not currently be aware.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approval and marketing than we do. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, establishing clinical trial sites, recruiting patients and in manufacturing pharmaceutical products and may succeed in discovering, developing and commercializing products in our field before we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through strategic relationships with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to our programs.

In addition, if our product candidates are approved and commercialized, we may face competition from biosimilars. The route to market for biosimilars was established with the passage of the Health Care Reform Act in March 2010. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, establishes a pathway for FDA approval of follow-on biologics and provides 12 years of data exclusivity for reference products. The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Further, since the BPCIA was enacted as part of the overall Health Care Reform Act, current litigation challenges to that Act, discussed more in full below, could impact the validity of the BPCIA. As a result, there still remains significant uncertainty as to the ultimate impact, implementation and regulatory interpretation of the BPCIA.

In Europe, the European Medicines Agency, or EMA, has issued guidelines for approving products through an abbreviated pathway, and biosimilars have been approved in Europe. If a biosimilar version of one of our potential products were approved in the United States or Europe, it could have a negative effect on sales and gross profits of the potential product and our financial condition.

With respect to our current and potential future product candidates, we believe that our ability to compete effectively and develop products that can be manufactured cost-effectively and marketed successfully will depend on our ability to:

- advance our technology platforms;
- · obtain and maintain intellectual property protection for our technologies and products;
- obtain required government and other public and private approvals on a timely basis;
- attract and retain key personnel;
- commercialize effectively;
- obtain reimbursement for our products in approved indications;

- comply with applicable laws, regulations and regulatory requirements and restrictions with respect to the commercialization of our products, including with respect to any changed or increased regulatory restrictions; and
- enter into additional strategic collaborations to advance the development and commercialization of our product candidates.

#### **Risks Related to Our Intellectual Property**

### If we are unable to obtain or protect intellectual property rights related to our technology and ADC product candidates, or if our intellectual property rights are inadequate, we may not be able to compete effectively.

Our success depends in large part on our ability to obtain and maintain protection with respect to our intellectual property and proprietary technology. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our platforms and our product candidates, including UpRi, XMT-1660 and XMT-2056. The patent position of biopharmaceutical companies is generally uncertain because it involves complex legal and factual considerations and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights is highly uncertain. The standards applied by the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in patents. In addition, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The patent prosecution process is expensive, complex and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that we fail to identify patentable aspects of our patents and development output before it is too late to obtain patent protection. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents.

The patent applications that we own or in-license may fail to result in issued patents, and even if they do issue as patents, such patents may not cover our platforms and product candidates in the United States or in other countries. 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 United States and abroad. Such challenges may result in 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 technology and product candidates. For example, even if patent applications we license or own do successfully issue as patents and even if such patents cover our platforms and product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not provide adequate protection or exclusivity for our ADC platform or product candidates, prevent others from designing around our claims or otherwise provide us with a competitive advantage. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If patent applications we own or have in-licensed with respect to our platforms or our product candidates fail to issue as patents, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity, it could dissuade companies from collaborating with us. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful development and commercialization of any product candidate. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by the USPTO or a third-party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have

a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent and the protection it affords is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, our owned or in-licensed patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a drug under patent protection could be further reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from similar or generic products. The launch of a generic version of one of our products in particular would be likely to result in an immediate and substantial reduction in the demand for our product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. 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, may affect patent litigation and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. These provisions also allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. The USPTO developed additional regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and prospects.

Any loss of patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar to or the same as our product candidates.

### Issued patents covering UpRi, XMT-1660, XMT-2056 and any other current or future ADC product candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign authority.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering UpRi, XMT-1660, XMT-2056 or any other current or future product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity 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, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our licensors, our patent counsel and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our product candidates. Any such loss of p

### If we fail to comply with our obligations under any license, strategic collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our ADC product candidates.

We rely, in part, on license, collaboration and other agreements. We may need to obtain additional licenses from others to advance our research or allow commercialization of our product candidates and it is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive. These 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 use. 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.

In addition, our existing licenses and collaboration agreements, including our licenses with Ares Trading S.A., a wholly owned subsidiary of Merck KGaA, Darmstadt, Germany, or Merck KGaA, and Merck KGaA for intellectual property covering the Immunosynthen and Dolaflexin platforms; our potential license with GlaxoSmithKline Intellectual Property (No. 4) Limited, or GSK, for intellectual property covering XMT-2056; our license with Janssen Biotech, Inc., or Janssen, for intellectual property covering the Dolasynthen platform; our license with with Recepta Biopharma S.A., or Recepta, for intellectual property covering the NaPi2b antibody in UpRi; and our license with Synaffix B.V., or Synaffix, for intellectual property covering components included in the Dolasynthen platform, impose, and any future licenses, collaborations or other agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, including, in the case of our agreements with Merck KGaA, the license for the rights covering the Immunosynthen and Dolaflexin platforms; in the case of our agreement with GSK, the potential license for the rights covering XMT-2056; in the case of our agreement with Synaffix, the license for the rights covering components in the Dolasynthen platform. Any of the foregoing could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Disputes may arise regarding intellectual property subject to a licensing, collaboration or other agreements, including:

- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology to or from third parties are 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 have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

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 the technology that we license from third parties. For example, pursuant to our license agreement with Recepta, Ludwig Institute for Cancer Research Ltd., a co-owner of the intellectual property, retains control of such activities. Therefore, we cannot be certain that these patents and applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our licensors fail to obtain or maintain such intellectual property, or lose rights to such intellectual property, the rights we have licensed and our exclusivity may be reduced or eliminated and our right to develop and commercialize any of our products that are subject to such licensed rights could be adversely affected.

Moreover, our rights to our in-licensed patents and patent applications are dependent, in part, on inter-institutional or other operating agreements between the joint owners of such in-licensed patents and patent applications. If one or more of such joint owners breaches such inter-institutional or operating agreements, our rights to such in-licensed patents and patent applications may be adversely affected. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate and our business, financial condition, results of operations and prospects could suffer.

### We may become involved in lawsuits to protect or enforce our intellectual property or to defend against intellectual property claims, which could be expensive, time consuming and unsuccessful.

Competitors and other third parties may infringe our patents or misappropriate or otherwise violate our owned and in-licensed intellectual property rights. To counter infringement or unauthorized use, litigation or other intellectual property proceedings may be necessary to enforce or defend our owned and inlicensed intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Such litigation or proceedings can be expensive and time consuming, and any such claims could provoke defendants to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Many of our current and potential competitors have the ability to dedicate substantially greater resources to litigate intellectual property rights than we can and have more mature and developed intellectual property. Even if resolved in our favor, litigation or other intellectual property proceedings could result in substantial costs and diversion of management attention and resources, which could harm our business and financial results.

In addition, in a litigation or other proceeding, a court or administrative judge may decide that a patent owned by or licensed to us is invalid or unenforceable, or a court may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. During the course of any patent or other intellectual property litigation or other proceeding, there could be public announcements of the results of hearings, rulings on motions and other interim proceedings or developments and if securities analysts or investors regard these

announcements as negative, the perceived value of our product candidates, programs or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations and prospects.

#### Third-party claims of intellectual property infringement or misappropriation may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability and the ability of our strategic collaborators to develop, manufacture, market and sell product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, reexamination, inter partes review, derivation and post grant review proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we, our customers, licensees or parties indemnified by us are employing their proprietary technology without authorization or have infringed upon, misappropriated or otherwise violated their intellectual property or other rights, regardless of their merit. For example, we may be subject to claims that we are infringing the patent, trademark or copyright rights of third parties, or that our employees have misappropriated or divulged their former employers' trade secrets or confidential information. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates, that we failed to identify. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until issued as patents. Except for certain exceptions, including the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing, and sometimes not at all. Therefore, patent applications covering our platforms or our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platforms, our product candidates.

Even if we believe a third party's claims against us are without merit, a court of competent jurisdiction could hold that such third party's patent is valid, enforceable and covers aspects of our product candidates, including the materials, formulations, methods of manufacture, methods of analysis, or methods for treatment, in which case, such third party would be able to block our ability to develop and commercialize the applicable technology or product candidate until such patent expired or unless we obtain a license and we may be required to pay such third-party monetary damages, which could be substantial. Such licenses may not be available on acceptable terms, if at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property and it could require us to make substantial licensing and royalty payments. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

Parties making claims against us may also obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our technologies or one or more of our product candidates. Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, in addition to potential injunctive relief, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain

one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may face a claim of misappropriation if a third party believes that we inappropriately obtained and used trade secrets of such third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, we may be required to obtain a license to such trade secrets which may not be available on commercially reasonable terms or at all and may be non-exclusive, and we may be required to pay damages, which could be substantial. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

#### We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world where we expect there to be significant markets for our products could be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. In addition, our intellectual property license agreements may not always include worldwide rights. For example, certain U.S. and foreign issued patents and patent applications are licensed to us by Recepta on a worldwide basis, except that Recepta retains exclusive rights in such patents and patent applications in Brazil. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. 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 or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Additionally, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our licensed and owned patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign invalidated or interpreted narrowly, could put our patent applications at risk of not issuing as patents, 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 or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.



### Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our platform technology and discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants and outside scientific advisors, contractors and collaborators. We cannot guarantee that we have entered into such agreement with each party that may have or have had access to our trade secrets or proprietary technology and processes. Additionally, our confidentiality agreements and other contractual protections may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement or misappropriation. We may not have adequate remedies in the case of a breach of any such agreements, and our trade secrets and other proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, some courts outside and within the United States sometimes are less willing to protect trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business.

### We may be subject to claims by third parties asserting that our licensors, employees, consultants, advisors or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our and our licensors' employees, including our senior management, consultants or advisors are currently, or previously were, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or knowhow 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 current or former employer. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property 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 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.

#### If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our owned or in-licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

## Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and patent applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

#### Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make ADC products that are similar to any product candidates we may develop or utilize similar ADC-related technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our license partners or current or future strategic collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our license partners or current or future strategic collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;



- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- 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 intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

#### **Risks Related to Regulatory Approval and Other Legal Compliance Matters**

#### Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. We are not permitted to market our product candidates in the United States or in other countries until we receive approval of a biologics license application, or BLA, from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in development. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction. While we have announced that we expect data from our UPLIFT clinical trial of UpRi in mid-2023 which, if positive, we expect would support our submission of a BLA for UpRi for the treatment of platinum-resistant ovarian cancer under the FDA's accelerated approval pathway around the end of 2023, there can be no guarantee that these data will be positive or sufficient to support approval of UpRi by the FDA. Additionally, we have no experience as a company in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process.

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we



ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Finally, our ability to develop and market new drug products may be threatened by ongoing litigation challenging the FDA's approval of mifepristone. Specifically, on April 7, 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and the distribution of which is governed by various measures adopted under a Risk Evaluation and Mitigation Strategy, or REMS. In reaching that decision, the district court made a number of findings that numerous representatives of the pharmaceutical and biotechnology industry believe will chill the development, approval and distribution of new drug products in the United States. Among other determinations, the district court substituted its scientific judgement for that of the FDA and it held that FDA must provide a special justification for any differences between an approved drug's labeling and the conditions that existed in the drug's clinical trials. Further, the district court read the jurisdictional requirements governing litigation in federal court so as to potentially allow virtually any party to bring a lawsuit against the FDA in connection with its decision to approve an NDA or BLA or establish requirements under a REMS. On April 13, 2023, the district court decision was stayed, in part, by the U.S. Court of Appeals for the Fifth Circuit. Thereafter, on April 21, 2023, the U.S. Supreme Court entered a stay pending disposition of the appeal of the district court decision in the Court of Appeals for the Fifth Circuit or the Supreme Court. Depending on the outcome of this litigation and the regulatory uncertainty it has engendered, our abilities to develop new drug product candidates and to maintain an approval, if any, with respect to our existing drug product candidates and measures adopted under a REMS, if any, are at risk and could be delayed, undermined or subject to protracted litigation.

## Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we may be granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions and any of our product candidates that may be approved for marketing in a foreign jurisdiction will be subject to risks associated with foreign operations.

We intend to market our current product candidates, UpRi, XMT-1660 and XMT-2056, if approved, in international markets either directly or through collaborations. In order to market and sell our products in the European Union and other foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive necessary approvals to commercialize our products in any market.

In many countries outside the United States, a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-U.S. regulatory approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we fail to obtain the non-U.S. approvals required to market our product candidates outside the United States or if we fail to comply with applicable non-U.S. regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

In addition, following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. After lapse of a transition period, the United Kingdom is no longer part of the European Single Market and European Union Customs Union as of January 1, 2021. A trade and cooperation agreement that outlined the future trading relationship between the United Kingdom and the European Union was agreed to in December 2020 and entered into force on May 1, 2021. As of January 1, 2021, the Medicines and



Healthcare products Regulatory Agency, or the MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland will continue to be subject to EU rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law of the body of EU law instruments governing medicinal products that pre-existed prior to the United Kingdom's withdrawal from the European Union.

Since a significant proportion of the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit may have a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom. For example, the United Kingdom is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA, and a separate marketing authorization will be required to market our product candidates in the Unitel December 31, 2023, it is possible for the MHRA to rely on a decision taken by the European Commission on the approval of a new marketing authorization via the centralized procedure. However, it is unclear whether the MHRA in the United Kingdom is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive after such time. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

## Any product candidate for which we obtain marketing approval is subject to ongoing regulation and could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements, when and if any of our product candidates are approved.

Any product candidate for which we obtain marketing approval will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a risk evaluation and mitigation strategy. Accordingly, if we receive marketing approval for one or more of our product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we fail to comply with these requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability.

We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the



approved indications and in accordance with the provisions of the approved labeling. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug or biologic. Moreover, with passage of the Preapproval Information Exchange Act in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. Violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

Failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- · refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

Similar restrictions apply to the approval of our products in the European Union. The holder of a marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include compliance with the European Union's stringent pharmacovigilance or safety reporting rules, which can impose post-authorization studies and additional monitoring obligations; the manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory; and the marketing and promotion of authorized drugs, which are strictly regulated in the European Union and are also subject to EU Member State laws.

Accordingly, in connection with our currently approved products and assuming we, or our collaborators, receive marketing approval for one or more of our product candidates, we, and our collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including

manufacturing, production, product surveillance and quality control. If we, and our collaborators, are not able to comply with post-approval regulatory requirements, our or our collaborators' ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

## We may seek certain designations for our product candidates, including but not limited to Breakthrough Therapy, Fast Track and Priority Review designations in the United States, and PRIME Designation in the European Union, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We have in the past sought and may also in the future seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product 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 products 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.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The FDA has granted Fast Track designation for UpRi for the treatment of patients with platinum-resistant high-grade serous ovarian cancer who have received up to three prior lines of systemic therapy or patients who have received four prior lines of systemic therapy regardless of platinum status, and the FDA has granted Fast Track designation for XMT-1660 for the treatment of adult patients with advanced or metastatic triple-negative breast cancer.

We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, 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.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products 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 qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In the European Union, we may seek PRIME designation for our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the European Union or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the European Union and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the



eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims.

The benefits of a PRIME designation include the appointment of a CHMP rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

### We have received orphan drug designations for XMT-2056 and UpRi, but we may not be able to obtain orphan drug exclusivity for any additional product candidates, and even if we do, that exclusivity may not prevent the FDA or EMA from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing 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 EMA from approving another marketing application for the same product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

In order for the FDA to grant orphan drug exclusivity to one of our products, the agency must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. In particular, the concept of what constitutes the "same drug" for purposes of orphan drug exclusivity remains in flux in the context of gene therapies, and the FDA issued final guidance suggesting that it would not consider two genetic medicine products to be different drugs solely based on minor differences in the transgenes or vectors within a given vector class. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA 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 the patients with the rare disease or condition. In May 2022, the FDA granted orphan drug designation to XMT-2056 for the treatment of patients with gastric cancer, and in December 2022, the European Commission granted orphan medicinal product designation to UpRi for the treatment of ovarian cancer, but we may not be able to obtain orphan drug exclusivity for any additional product candidates in the future.

In 2017, Congress passed FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. Under Omnibus legislation signed by President Trump on December 27, 2020, the requirement for a product to show clinical superiority applies to drugs and biologics that received orphan drug designation before enactment of FDARA in 2017 but have not yet been approved or licensed by the FDA.

The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that,



for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." The court concluded that orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA or Congress may change the 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, we may lose any expected benefits of the orphan drug designation we have received for XMT-2056, and our business could be adversely impacted.

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.

The same is true of the COVID-19 pandemic or any similar event that may occur in the future. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. The FDA has now indicated that it can and will conduct timely reviews of applications for medical products in line with its user fee performance goals, including conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, in the event of a resurgence of the COVID-19 pandemic or another similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may also experience delays in their regulatory activities.

Accordingly, 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.

# We are currently conducting clinical trials for UpRi, and may conduct future clinical trials for our other product candidates, at sites outside of the United States. The FDA may not accept data from trials conducted in such locations, or the complexity of regulatory burdens may otherwise adversely impact us.

We are currently conducting clinical trials for UpRi outside of the United States, and we plan to continue to conduct clinical trials for UpRi and our current and future other product candidates outside of the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with GCPs. If the foreign data is the sole basis for a marketing application, then the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful and the FDA must be able to validate the data through an on-site inspection, if necessary. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any clinical trial that we conduct outside the United States, it would likely result in the need for additional clinical trials, which would be costly and timeconsuming and could delay or permanently halt our development of the applicable product candidates.

Our ability to successfully initiate, enroll and complete a clinical trial in any country outside of the United States is subject to numerous additional risks unique to conducting business in jurisdictions outside the United States, including:

- difficulty in establishing or managing relationships with qualified CROs, physicians and clinical trial sites;
- different local standards for the conduct of clinical trials;
- difficulty in complying with various and complex import laws and regulations when shipping drug to certain countries;
- the potential burden of complying with a variety of laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments;
- lack of consistency in standard of care from country to country;
- diminished protection of intellectual property in some countries;
- foreign exchange fluctuations;
- · cultural differences in medical practice and clinical research; and
- changes in country or regional regulatory requirements.

Further, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of the FDORA, Congress required sponsors to develop and submit a diversity action plan for each phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Similarly, the regulatory landscape related to clinical trials in the European Union recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states, leading to a single decision per member state.

In addition, the ongoing COVID-19 pandemic and the current conflict between Russia and Ukraine may also have an impact on our ability to successfully conduct trials outside of the United States. For example, we are conducting UPLIFT in countries where clinical trial site staff continue to be diverted to care for COVID-19 patients and where regulatory authorities are short staffed, due in part to continuing impacts of the COVID-19 pandemic. Additionally, we do business with a CRO that has had employees and operations in Ukraine that have been adversely impacted by Russian hostilities, though such employees and operations are not directly involved with our clinical trials. If we have difficulty conducting our clinical trials in jurisdictions outside the United States as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which could have a material adverse effect on our business.

On January 30, 2023, the Biden administration announced that it will end the public health emergency declarations related to COVID-19 on May 11, 2023. On January 31, 2023, the FDA indicated that it would issue a Federal Register notice describing how the termination of the public health emergency will impact the FDA's COVID-19 related guidance. On March 13, 2023, the FDA announced that it will end 22 COVID-19-related policies when the public health emergency ends on May 11, 2023, and allow 22 to continue for 180 days. The FDA plans to retain 24 COVID-19-related policies with appropriate changes and 4 whose duration is not tied to the end of the public health emergency. At this point, it is unclear how, if at all, these developments will impact our efforts to develop and commercialize our product candidates.

# Accelerated approval by the FDA, even if granted for UpRi or any other current or 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 marketing approval.

We intend to seek approval of UpRi and may seek approval any of our other current and 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, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA or other applicable regulatory agency makes the determination regarding whether a surrogate endpoint is reasonably likely to predict long-term clinical benefit.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and otherwise evaluate our ability to seek and receive such accelerated approval. As a condition of approval, the FDA requires that a sponsor of a product receiving accelerated approval perform an adequate and well-controlled post-marketing confirmatory clinical trial or trials. These confirmatory trials must be completed with due diligence and we may be required to evaluate different or additional endpoints in these post-marketing confirmatory trials. These confirmatory trials must be completed with due diligence and we may be required to evaluate different or additional endpoints in these post-marketing confirmatory trials. These confirmatory trials may require enrollment of more patients than we currently anticipate and will result in additional costs, which may be greater than the estimated costs we currently anticipate. In addition, the FDA currently requires as a condition for accelerated approval preapproval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

There can be no assurance that the FDA will agree with any proposed surrogate endpoints or that we will decide to pursue or submit an BLA for accelerated approval or any other form of expedited development, review or approval for UpRi or any of our other current or future product candidates. Similarly, there can be no assurance that, after feedback from FDA, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all.

The FDA may withdraw approval of a product candidate approved under the accelerated approval pathway if, for example, the trial required to verify the predicted clinical benefit of our product candidate fails to verify such benefit or does not demonstrate sufficient clinical benefit to justify the risks associated with the drug. The FDA may also withdraw approval if other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use, we fail to conduct any required post approval trial of our product candidate with due



diligence or we disseminate false or misleading promotional materials relating to our product candidate. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period for commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

With passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded, require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to the FDA every six months until the study is completed; and use expedited procedures to withdraw accelerated approval of a new drug application or BLA after the confirmatory trial fails to verify the product's clinical benefit. Further, FDORA requires the agency to publish on its website "the rationale for why a post-approval study is not appropriate or necessary" whenever it decides not to require such a study upon granting accelerated approval.

Accordingly, 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 we or our third-party collaborators are unable to successfully develop and commercialize any required companion diagnostics or appropriate complementary diagnostics for our product candidates or to engage a third party to do so, or we or they experience significant delays in doing so, we may not realize the full potential of our product candidates.

We expect that a companion or complementary diagnostic may be necessary in connection with UpRi, and a companion or complementary diagnostic may be necessary in connection with any of our other current or future product candidates. If a companion diagnostic is required for the label of any of our product candidates, our ability to market such product candidates will be conditioned on the commercial availability of an approved companion diagnostic. Similarly, if a complementary diagnostic is necessary for any of our product candidates, we may not realize the full potential of such product candidates if such complementary diagnostic is not available.

We may seek approval for any such companion diagnostic or complementary diagnostic, or we may contract with third parties to create and obtain approval for a companion or complementary diagnostic, including our NaPi2b assay. To be successful in developing and commercializing such a companion or complementary diagnostic, we need to address a number of scientific, technical and logistical challenges. We have little experience in the development and commercialization of companion or complementary diagnostics and may not be successful in developing and commercializing either our NaPi2b assay or any other appropriate companion or complementary diagnostics to pair with UpRi or any of our other current or future product candidates. Companion and complementary diagnostics are subject to regulation by the FDA and equivalent foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. Given our limited experience in developing diagnostics, we will rely in part or in whole on third parties for their design, manufacture and commercialization. We, our collaborators or such third parties may encounter difficulties in developing and obtaining approval for the companion or complementary diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility or clinical validation. Any delay or failure by us, our collaborators or such third parties to develop or obtain regulatory approval of the companion or complementary diagnostics for our ability to recognize the full potential of our product candidates. If we, or any third parties that we may contract with to assist us, are unable to successfully develop and commercialize companion or complementary diagnostics for our product candidates, or experience delays in doing so:

• our product candidates may not receive marketing approval if safe and effective use of a product candidate depends on the availability of a companion diagnostic and such diagnostic is not commercially available or otherwise approved or cleared by the appropriate regulatory authority; and



• we may not realize the full commercial potential of any product candidates that receive marketing approval if, among other reasons, we are unable to appropriately select patients who are likely to benefit from therapy with our products, if approved.

If any of these events were to occur, our business would be harmed, possibly materially.

In addition, third-party collaborators may encounter production difficulties that could constrain the supply of the companion or complementary diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics or complementary in the clinical community. If such companion or complementary diagnostics fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales of our product candidates, if approved. In addition, any diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic or complementary that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. Additionally, we may need to enter into contracts with more than one third party in order to gain widespread availability and acceptance of any companion or complementary diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

#### Our activities, including our interactions with healthcare providers, third party payors, patients and government officials, are, and will continue to be, subject to extensive regulation involving health care, anti-corruption, data privacy and security and consumer protection laws. Failure to comply with applicable laws could result in substantial penalties, contractual damages, reputational harm, diminished revenues and curtailment or restructuring of our operations.

Our activities may now or in the future be directly or indirectly subject to various federal and state laws related to health care, anti-corruption, data privacy and security consumer protection. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws include, but are not limited to:

- federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;
- the federal anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving or providing any remuneration, directly or indirectly, to induce, either the referral of an individual for, or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid;
- the federal anti-kickback prohibition known as Eliminating Kickbacks in Recovery Act, enacted in 2018, which prohibits certain payments related to referrals of patients to certain providers (recovery homes, clinical treatment facilities and laboratories) and applies to services reimbursed by private health plans as well as government health care programs;
- the federal law known as Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program (which may include private health plans) or making false statements relating to healthcare matters;
- the Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;

- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called "federal sunshine" law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with teaching hospitals, physicians and certain non-physician practitioners to the federal government for re-disclosure to the public;
- the privacy, security and breach provisions of HIPAA, which impose obligations on certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) and certain of their "business associate" contractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal and state laws and regulations, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure and protection of health-related and other personal information.
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the Foreign Corrupt Practices Act, or FCPA, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and
- state law analogues of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including private health plans, state privacy laws, state consumer protection laws, and state laws regulating interactions between pharmaceutical manufacturers and healthcare providers, requiring disclosure of such financial interactions or mandating adoption of certain compliance standards, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

In addition, the regulatory approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the health care laws mentioned above, among other foreign laws. Efforts to ensure that our business arrangements will comply with applicable health care laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

#### Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for our product candidates.

In the United States and some foreign jurisdictions, there have been and continue to be a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.



In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act. These Medicare sequester reductions were suspended and reduced through the end of June 2022, with the full 2% cut resuming thereafter.

Under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010, or PAYGO, sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriation Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our products or product candidates for which we may obtain regulatory approval or the frequency with which any such product is prescribed or used.

Since enactment of the ACA, there have been and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts for Jobs Act, or the Tax Act, in 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA and therefore because the mandate was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court heard this case on November 10, 2020 and on June 17, 2021, dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to undermine or delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden revoked those orders and issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care and consider actions that will protect and strengthen that access. Under this order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we

might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

# The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, the Center for Medicare & Medicaid Services, or CMS, issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. The final rule is currently the subject of ongoing litigation, but at least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada with the intent of developing SIPs for review and approval by the FDA. Further, on November 20, 2020, HHS finalized 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 final rule would also eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It was originally set to go into effect on January 1, 2022, but with passage of the IRA, has been delayed by Congress to January 1, 2023.

On July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The order directs the Department of Health and Human Services, or HHS, to create a plan within 45 days to combat "excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging." On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

More recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first



due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Service, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 additional Medicare Part D drugs in 2027, 15 additional Medicare Part B or Part D drugs in 2028, and 20 additional Medicare Part B or Part D drugs per year in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on any of our product candidates, if approved, or the full value of our patents protecting any such approved drug products if prices are set after any such approved products have been on the market for nine years.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated \$4,000 a year in 2024 and, thereafter beginning in 2025, at \$2,000 a year. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or "catastrophic period" of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications. Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

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 healthcare organizations 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 healthcare 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 product candidates or additional pricing pressures.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific products and therapies. In many countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a

product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our business could be materially harmed.

# We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security, and a failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, European Union and United Kingdom. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or the EEA, and the processing of personal data that takes place in the EEA, is regulated by the General Data Protection Regulation, or GDPR, which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our collaborators' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.



The GDPR places restrictions on the cross-border transfer of personal data from the European Union to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the European Union to other countries. In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. While we were not self-certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States generally and increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and collaborators.

# 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 further expand our operations outside the United States, we will need to dedicate additional resources to comply with U.S. laws regarding international operations and the laws and regulations in each jurisdiction in which we operate and plan to operate. The FCPA prohibits any U.S. individual or business from paying, offering or 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 company, 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. Further, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of E.U. Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain E.U. Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual E.U. Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the E.U. Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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.

# We and our third-party contract manufacturers must comply with environmental, health and safety laws and regulations, and failure to comply with these laws and regulations could expose us to significant costs or liabilities.

We and our third-party manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In the event of contamination or injury, or failure to comply with environmental, health and safety laws and regulations, we could be held liable for any resulting damages and any such liability could exceed our assets and resources. We could also incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. 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.

Environmental, health and safety laws and regulations are becoming increasingly more stringent. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of our third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products.

# Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, 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. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, 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 be in compliance with such 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 ourselves 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, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operat



#### **Risks Related to our Business and Industry**

## If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop our ADC product candidates, conduct our clinical trials and commercialize our ADC product candidates.

Our ability to compete in the highly competitive biotechnology and biopharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on members of our senior management, including Anna Protopapas, our President and Chief Executive Officer. The loss of the services of any of our senior management could impede the achievement of our research, development and commercialization objectives. Also, each of these persons may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, sales and marketing personnel will also be critical to our success. We conduct our operations at our facility in Cambridge, Massachusetts, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. 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 or have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

#### We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we have needed to and expect that we will continue to need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company or disrupt our operations.

# If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our ADC product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop causes, or is perceived to cause, injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- injury to our reputation;
- decreased demand for our product candidates or products that we may develop;



- withdrawal of clinical trial participants;
- costs to defend the related litigations;
- a diversion of management's time and our resources;
- · substantial monetary awards to clinical trial participants or patients;
- · product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- · the inability to commercialize our product candidates; and
- a decline in our stock price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical trials in the amount of \$10 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance, we might have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could adversely affect our business, financial condition, results of operations and prospects.

#### We may acquire assets or form strategic alliances in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional technologies and assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are unable to successfully integrate them with our existing technologies. 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 be assured that, following any such acquisition, we will achieve the expected synergies to justify the transaction. Our internal computer systems, or those of our strategic and other third-party collaborators or other contractors or consultants, may fail or suffer security breaches, which could adversely affect our business, including through material disruptions of our programs or business operations.

Our internal information technology systems and those of our current or future strategic and other third-party collaborators and other contractors and consultants are vulnerable to service interruptions or security breaches, including from cyber-attacks, computer viruses, ransomware, malware, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If a failure, accident or security breach were to occur and cause interruptions in our operations or the operations of those third parties with which we contract, it could result in a material disruption of our programs and our business operations. We could lose access to our trade secrets or other proprietary information or experience other disruptions, which could require a substantial expenditure of resources to remedy. For example, the loss of clinical trial data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.



We could also be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in our information systems and networks, including personal information of our employees or others. Outside parties may attempt to penetrate our systems or those of the third parties with which we contract or to coerce or fraudulently induce our employees or employees of such third parties to disclose sensitive information to gain access to our data. The number and complexity of these threats continue to increase over time. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, such risks cannot be eliminated. Furthermore, there can be no assurance that we, or those third parties with which we contract, will promptly detect any such disruption or security breach, if at all. Additionally, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities, our competitive position and the market perception of the effectiveness of our security measures could be harmed, our credibility could be damaged and the further development of our product candidates could be delayed.

#### **Risks Related to Our Common Stock**

#### If our stock price is volatile, our stockholders could incur substantial losses.

Our stock price has been and may continue to be volatile. During the period from May 4, 2020 to May 4, 2023, the closing price of our common stock ranged from a high of \$27.59 per share to a low of \$2.84 per share. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this "Risk Factors" section, and others beyond our control, including:

- results and timing of preclinical studies and clinical trials of our current or future product candidates, including UpRi, XMT-1660 and XMT-2056, including, for example, the clinical hold placed by the FDA on our trial of XMT-2056 in March 2023;
- results of clinical trials of our competitors' products;
- failure to adequately protect our trade secrets;
- · the terms on which we raise additional capital or our ability to raise it;
- commencement or termination of any strategic collaboration or licensing arrangement;
- regulatory developments, including actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry;

- changes in the structure of healthcare payment systems;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us (including pursuant to outstanding warrants or through our ATM offering programs), our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- · changes in market conditions for biopharmaceutical stocks; and
- changes in general market and economic conditions.

In addition, the stock market has historically experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. As a result of this volatility, stockholders may not be able to sell their common stock at or above the price for which they paid for their shares. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products, or to a lesser extent our markets. Furthermore, as a result of this volatility, we may not be able to maintain compliance with listing requirements of the Nasdaq Stock Market. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

#### We do not expect to pay any cash dividends for the foreseeable future.

We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our operations. In addition, our New Credit Facility contains terms and any future debt financing arrangement may contain additional terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment.

#### Provisions in our amended and restated certificate of incorporation, as amended, our amended and restated by-laws and Delaware law may have antitakeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation, as amended, amended and restated by-laws and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. Our amended and restated certificate of incorporation, as amended, and amended and restated by-laws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;



- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- · expressly authorize our board of directors to have discretion to modify, alter or repeal our amended and restated by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation, as amended, and amended and restated by-laws.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, as amended, second amended and restated by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

#### Our ability to use net operating losses and certain tax credit carryforwards may be subject to certain limitations.

For the years ended December 31, 2022, 2021 and 2020, we recorded no income tax benefit for the net operating losses, or NOLs, incurred in each year. due to the uncertainty of realizing a benefit from those items. We have incurred NOLs since our inception. As of December 31, 2022, we have federal NOLs of approximately \$432.8 million and state NOLs of approximately \$365.3 million. Of the \$432.8 million of federal NOLs, \$34.1 million expire at various dates through 2037. The remaining \$398.7 million of federal NOLs do not expire. The state NOLs will expire at various dates through 2042. As of December 31, 2022, we had federal and state research and development tax credit carryforwards of approximately \$17.4 million and \$5.1 million, respectively, which expire at various dates through 2042. Under the Tax Act, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the Tax Act. In addition, under Section 382 of the Internal Revenue Code, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income or taxes may be limited. Our past issuances of stock and other changes in our stock ownership may have resulted in ownership changes within the meaning of Section 382 of the Code; accordingly, our prechange NOLs may be subject to limitation under Section 382. If we determine that we have not undergone an ownership change, the Internal Revenue Service could challenge our analysis, and our ability to use our NOLs to offset taxable income could be limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in ownership changes under Section 382 of the Code further limiting our ability to utilize our NOLs. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. We have determined that ownership changes have occurred since our inception and that certain NOLs and research and development tax credit carryforwards will be subject to limitation. We may also have incurred subsequent ownership changes. Furthermore, our ability to utilize our NOLs and research and development

tax credit carryforwards is conditioned upon our attaining profitability and generating U.S. federal taxable income. We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for at least the next several years; thus, we do not know when we will generate the U.S. federal taxable income necessary to utilize our NOLs. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

#### Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

Changes in tax law may adversely affect our business or financial condition. The Tax Act, as amended by the CARES Act, significantly revises the Code. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% and limitation of the deduction for NOLs to 80% of current year taxable income for losses arising in taxable years beginning after December 31, 2017, though any such NOLs may be carried forward indefinitely. In addition, beginning in 2022, the Tax Act eliminates the option to deduct research and development expenditures currently and requires corporations to capitalize and amortize them over five years.

In addition to the CARES Act, as part of Congress' response to the COVID-19 pandemic, economic relief legislation was enacted in 2020 and 2021 containing tax provisions. The IRA, which was signed into law in August 2022, also introduced new tax provisions, including a one percent excise tax imposed on certain stock repurchases by publicly traded corporations. The one percent excise tax generally applies to any acquisition of stock by the publicly traded corporation (or certain of its affiliates) from a stockholder of the corporation in exchange for money or other property (other than stock of the corporation itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases.

Regulatory guidance under the Tax Act, the IRA, and additional legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen their impact on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the IRA, and additional tax legislation.

# Our amended and restated certificate of incorporation, as amended, designates the state or federal courts within the State of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation, as amended, provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware will be the exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, as amended, or our amended and restated by-laws, (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation, as amended, or amended and restated by-laws or (5) any other action asserting a claim against us that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein. Any person or entity that purchases or otherwise acquires any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation, as amended, described above. This choice of forum 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 employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

This exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, which provides for exclusive jurisdiction of the federal courts. It



could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act of 1933, as amended, or the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder, provided, that with respect to claims under the Securities Act, our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

# If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock or fail to regularly publish reports on us, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

# A portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a significant number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

We have registered substantially all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

#### **General Risk Factors**

#### Unfavorable global economic or geopolitical 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, geopolitical considerations and global financial market conditions, including changes in inflation, interest rates and overall economic conditions and uncertainties. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. We cannot assure stockholders that deterioration of the global credit and financial markets would not negatively impact our stock price, our current portfolio of cash equivalents or investments, or our ability to meet our financing objectives. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. A weak or declining economy, could also strain our suppliers and vendors involved in our clinical development activities.

Additionally, Russia's invasion of Ukraine in February 2022 and the global response, including the imposition of sanctions by the United States and other countries, could create or exacerbate risks facing our business. We have evaluated our operations, vendor contracts and clinical trial arrangements, and at present we do not expect the conflict to directly have a materially adverse effect on our financial condition or results of operations. However, if the hostilities persist, escalate or expand, other risks we have identified in this report may be exacerbated. For example, if our supply arrangements or clinical sites are disrupted due to expanded sanctions or involvement of countries where we have operations or relationships, our business could be materially disrupted. Further, the use of state-sponsored cyberattacks could expand as part of the conflict, which could adversely affect our ability to



maintain or enhance our cyber security and data protection measures. Any of the foregoing could harm our business, and we cannot anticipate all of the ways in which the current economic and geopolitical climate and financial market conditions could adversely impact our business.

#### We, or the third parties upon whom we depend, may be adversely affected by serious disasters.

Any unplanned event, such as a flood, fire, explosion, earthquake, extreme weather condition, medical epidemic, power shortage, telecommunication failure or other natural or human-made accident or incident that results in us being unable to fully use our facilities, or the facilities of third parties with which we contract, may have a material and adverse effect on our ability to operate our business and may have significant negative consequences on our financial and operating conditions. Loss of access to these facilities or operations may result in increased costs, delays in the development of our current or future product candidates or the interruption of our business operations for a substantial period of time.

There can be no assurance that the amounts of insurance that we maintain will be sufficient to satisfy any damages and losses in the event a serious disaster or similar event occurs. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs and commercialization efforts may be harmed.

#### Our business is subject to risks arising from the outbreaks of disease, such as epidemics or pandemics, including the ongoing COVID-19 pandemic.

The widespread infection of COVID-19 in the United States and abroad has caused significant volatility and uncertainty in U.S. and international markets, which could result in a prolonged economic downturn that may disrupt our business, including by adversely affecting our ability to conduct financings on terms acceptable to us, if at all.

In addition, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- Our clinical trials may be adversely affected, delayed or interrupted, including, for example, site initiation, patient recruitment and enrollment, availability of clinical trial materials, and data analysis. Some patients and clinical investigators may not be able to comply with clinical trial protocols and patients may choose to withdraw from our trials or we may have to pause enrollment or we may choose to or be required to pause enrollment and or patient dosing in our ongoing clinical trials in order to preserve health resources and protect clinical trial participants, which could delay our clinical trials or impact the strength or validity of our clinical trial data. It is unknown how long these pauses or disruptions could continue.
- We currently rely on third parties to, among other things, manufacture raw materials, manufacture our product candidates for our clinical trials, ship investigational drugs and clinical trial samples, perform quality testing and supply other goods and services to run our business. If any such third party in our supply chain for materials are adversely impacted by restrictions resulting from the coronavirus pandemic, including staffing shortages, raw material supplies, production slowdowns or disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials and conduct our research and development operations.
- Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trials sites and other important agencies and contractors.



- Our employees and contractors conducting research and development activities may not be able to access our laboratory for an extended period of time as a result of the closure of our offices and the possibility that governmental authorities further modify current restrictions. As a result, this could delay timely completion of preclinical activities, including completing IND-enabling studies or our ability to select future development candidates, and initiation of additional clinical trials for other of our development programs.
- Health regulatory agencies globally may experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical trials and, as a result, review, inspection, and other timelines may be materially delayed. It is unknown how long these disruptions could continue, were they to occur. Any prolongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development of our product candidates. For example, regulatory authorities may require that we not distribute a product candidate lot until the relevant agency authorizes its release. Such release authorization may be delayed as a result of the COVID-19 pandemic and could result in delays to our clinical trials.
- The ongoing COVID-19 pandemic may cause the trading prices for shares of our common stock and other biopharmaceutical companies' shares to be highly volatile. As a result, we may face difficulties raising capital through sales of shares of our common stock, or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

The COVID-19 pandemic continues to evolve. The ultimate impact of the coronavirus pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, the emergence and severity of new variants of the virus, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19, the timing, availability, efficacy, adoption and distribution of vaccines or other preventative treatments and other actions taken to contain coronavirus or address its impact in the short and long term, among others. We do not yet know and are unable to predict the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy.

#### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 6. Exhibits.	
<u>Exhibit Number</u>	<b>Description</b>
3.1	Fifth Amended and Restated Certificate of Incorporation, as amended, as of June 9, 2022 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 10, 2022).
3.2	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on March 31, 2023).
10.1*	Fourth Amendment to Loan and Security Agreement, dated March 23, 2023, between Oxford Finance LLC, the Lenders named therein including Silicon Valley Bridge Bank, N.A., and Mersana Therapeutics, Inc.
10.2*†	Collaboration and Commercial License Agreement, dated June 23, 2014, by and between Mersana Therapeutics, Inc. and Merck KGaA.
10.3*†	Amendment 1 to the Collaboration and Commercial License Agreement, dated June 1, 2016, by and between Mersana Therapeutics, Inc. and Merck KGaA.
10.4*†	Amendment 2 to the Collaboration and Commercial License Agreement, dated August 12, 2016, by and between Mersana Therapeutics, Inc. and Merck KGaA.
10.5*†	Amendment 3 to the Collaboration and Commercial License Agreement, dated February 28, 2017, by and between Mersana Therapeutics, Inc. and Merck KGaA.
10.6*†	License, Development and Commercialization Agreement, dated July 9, 2015, by and between Mersana Therapeutics, Inc. and Recepta Biopharma S.A.
10.7*†	Agreement Regarding LICR Technology, dated July 9, 2015, by and between Ludwig Institute for Cancer Research, Recepta Biopharma S.A. and Mersana Therapeutics, Inc.
31.1	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the</u> <u>Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of</u> 2002.
31.2	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the</u> <u>Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of</u> 2002.
32.1#	<u>Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C.</u> 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 - the cover page XBRL tags are embedded within the Inline XBRL document (included in Exhibit 101).

\*Filed herewith.

†Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

#The certification attached as Exhibit 32.1 accompanying this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

### **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.

### Mersana Therapeutics, Inc.

Dated: May 9, 2023

By: /s/ Anna Protopapas

Anna Protopapas President and Chief Executive Officer (Principal Executive Officer and Authorized Signatory)

By: /s/ Brian DeSchuytner

Brian DeSchuytner SVP, Chief Financial Officer (Principal Financial Officer)

Dated: May 9, 2023

#### FOURTH AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FOURTH AMENDMENT TO LOAN AND SECURITY AGREEMENT (this "Amendment") is entered into as of March 23, 2023, by and among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 115 South Union Street, Suite 300, Alexandria, Virginia 22314 ("Oxford"), as collateral agent (in such capacity, "Collateral Agent"), the Lenders listed on <u>Schedule 1.1</u> to the Loan Agreement (as defined below) or otherwise a party thereto from time to time including Oxford in its capacity as a Lender, OXFORD FINANCE FUNDING IX, LLC, a Delaware limited liability company, OXFORD FINANCE FUNDING XIII, LLC, a Delaware limited liability company, OXFORD FINANCE FUNDING ZUII, LLC, a Delaware limited liability company, each with offices located at 115 South Union Street, Suite 300, Alexandria, Virginia 22314, and SILICON VALLEY BRIDGE BANK, N.A., a national association with an office located at 275 Grove Street, Suite 2-200, Newton, MA 02466 ("Bank" or "SVB") (each a "Lender" and collectively, the "Lenders"), and MERSANA THERAPEUTICS, INC., a Delaware corporation with offices located at 840 Memorial Drive, Cambridge, MA 02139 ("Borrower").

A. Collateral Agent, Borrower and Lenders have entered into that certain Loan and Security Agreement dated as of October 29, 2021 (as amended, supplemented or otherwise modified from time to time, without limitation, by that certain First Amendment to Loan and Security Agreement dated as of February 17, 2022, that certain Second Amendment to Loan and Security Agreement dated as of October 17, 2022 and that certain Third Amendment to Loan and Security Agreement dated as of December 27, 2022, collectively, the "Loan Agreement") pursuant to which Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof; and

B. Collateral Agent and the Required Lenders have agreed to amend certain provisions of the Loan Agreement, subject to, and in accordance with, the terms and conditions set forth herein, and in reliance upon the representations and warranties set forth herein.

#### Agreement

NOW, THEREFORE, in consideration of the promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Borrower, the Required Lenders and Collateral Agent hereby agree as follows:

1. Definitions. Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

2. Consent. On March 10, 2023, the California Department of Financial Protection and Innovation shut down SVB and appointed the Federal Deposit Insurance Corporation as receiver. As a result, Borrower and it Subsdiaries did not have access to their cash and cash equivalents held with SVB or its trustees or affiliates for several days. As a result of losing access to its cash and cash equivalents, Borrower was required to take certain actions to ensure it had accounts to operate its business at all times. Some of these actions may have deviated from the requirements set forth in Section 6.6 of the Loan Agreement, including requirements to maintain all accounts of Borrower and its Subsidiaries (excluding Mersana Securities) with SVB and to provide prior to establishing any Collateral Accounts. Each of SVB and Oxford provided e-mail consent to such actions prior to the date hereof. Collateral Agent and Required Lenders hereby document that each has consented to any such actions that may have violated Section 6.6 of the Loan Agreement that occurred prior to the date hereof.

#### 3. Amendment to Loan Agreement.

3.1 Section 6.6(a) (Operating Accounts). Section 6.6(a) of the Loan Agreement is amended and restated as follows:

"(a) Maintain account balances in the Collateral Accounts of Borrower and its Subsidiaries (excluding Mersana Securities) at Bank in an aggregate amount of not less than an amount equal to the lesser of (i) one hundred five percent (105.00%) of the outstanding principal amount of the Term Loans advanced solely by SVB (and for purposes of clarity, no other Lender) and (ii) the Dollar value of all Collateral Accounts of Borrower and its Subsidiaries (excluding Mersana Securities) at all financial institutions; provided, however, that all Collateral Accounts (other than Excluded Accounts) of Borrower shall be maintained in accounts which are subject to a Control Agreement in favor of Collateral Agent. Borrower may conduct its banking activities, including, without limitation, cash management, letters of credit and business credit cards, with financial institutions which are not Bank and Bank's Affiliates."

**3.2** Silicon Valley Bank. The references in the Loan Agreement to "Silicon Valley Bank" in Section 10, Section 12.12 and Schedule 1.1 are hereby replaced with "Silicon Valley Bridge Bank, N.A."

#### 4. Limitation of Amendment.

**4.1** The amendment set forth in Section 2 above is effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right, remedy or obligation which Lenders or Borrower may now have or may have in the future under or in connection with any Loan Document, as amended hereby.

**4.2** This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents are hereby ratified and confirmed and shall remain in full force and effect.

5. Representations and Warranties. To induce Collateral Agent and the Required Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and the Required Lenders as follows:

**5.1** Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date) and (b) no Event of Default has occurred and is continuing;

5.2 Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

**5.3** The organizational documents of Borrower delivered to Collateral Agent on the Effective Date, and updated pursuant to subsequent deliveries by or on behalf of the Borrower to the Collateral Agent, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

**5.4** The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not contravene (i) any material law or regulation binding on or affecting Borrower, (ii) any material contractual restriction with a Person binding on Borrower, (iii) any material order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (iv) the organizational documents of Borrower;

**5.5** The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made;

**5.6** This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

6. Loan Document. Borrower, Lenders and Collateral Agent agree that this Amendment shall be a Loan Document. Except as expressly set forth herein, the Loan Agreement and the other Loan Documents shall continue in full force and effect without alteration or amendment. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements.

7. **Post-Closing.** Notwithstanding anything in the Loan Agreement to the contrary, Collateral Agent and Required Lenders hereby agree that Borrower shall have (a) for any Collateral Account (other than Excluded Accounts) opened by Borrower with a financial institution other than Bank prior to the date of this Amendment, thirty (30) days from the date such Collateral Account is opened (or such later date as the Collateral Agent may agree) to deliver a fully-executed Control Agreement with respect to such Collateral Account and (b) for any Collateral Account (other than Excluded Accounts) opened within thirty (30) days after the date of this Amendment (or such later date as the Collateral Agent may agree), thirty (30) days from the date such Collateral Account and the collateral Agent may agree), thirty (30) days from the date such Collateral Account is

opened (or such later date as the Collateral Agent may agree) to deliver a fully-executed Control Agreement with respect to such Collateral Account.

#### 8. Release by Borrower.

**8.1** FOR GOOD AND VALUABLE CONSIDERATION, Borrower hereby forever relieves, releases, and discharges Collateral Agent and each Lender and their respective present or former employees, officers, directors, agents, representatives, attorneys, and each of them, from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of execution of this Amendment solely to the extent such claims arise out of or are in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, servicing and/or enforcement of any of the foregoing (collectively "Released Claims").

**8.2** In furtherance of this release, Borrower expressly acknowledges and waives the provisions of California Civil Code Section 1542 (and any similar provision under the laws of any state), which states:

"A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

**8.3** By entering into this release, Borrower recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected in relation to the Released Claims; accordingly, if Borrower should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, Borrower shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Borrower acknowledges that it is not relying upon and has not relied upon any representation or statement made by Collateral Agent or Lenders with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.

**8.4** This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Borrower acknowledges that the release contained herein constitutes a material inducement to Collateral Agent and the Lenders to enter into this Amendment, and that Collateral Agent and the Lenders would not have done so but for Collateral Agent's and the Lenders' expectation that such release is valid and enforceable in all events.

9. Effectiveness. This Amendment shall be deemed effective as of the date hereof upon the due execution of this Amendment by the parties thereto.

**10. Counterparts.** This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument. Delivery by electronic transmission (e.g. ".pdf") of an executed counterpart of this Amendment shall be effective as a manually executed counterpart signature thereof.

11. Governing Law. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of New York.

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IN WITNESS WHEREOF, the parties hereto have caused this Fourth Amendment to Loan and Security Agreement to be executed as of the date first set forth above.

### **BORROWER:**

MERSANA THERAPEUTICS, INC.

By <u>/s/ Brian DeSchuytner</u> Name: Brian DeSchuytner Title: Chief Financial Officer and Treasurer

### COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By <u>/s/ Colette H. Featherly</u> Name: Colette H. Featherly Title: Senior Vice President

#### LENDER:

OXFORD FINANCE FUNDING IX, LLC

By <u>/s/ Colette H. Featherly</u> Name: Colette H. Featherly Title: Secretary

OXFORD FINANCE FUNDING XIII, LLC

By <u>/s/ Colette H. Featherly</u> Name: Colette H. Featherly Title: Secretary

OXFORD FINANCE FUNDING 2020-1, LLC

By <u>/s/ Colette H. Featherly</u> Name: Colette H. Featherly Title: Secretary

SILICON VALLEY BRIDGE BANK, N.A.

By <u>/s/ Nathan Meaux</u> Name: Nate Meaux Title: Senior Vice President

[Signature Page to Fourth Amendment to Loan and Security Agreement]

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

### COLLABORATION AND COMMERCIAL

## LICENSE AGREEMENT

### between

### MERSANA THERAPEUTICS, INC.

and

### MERCK KGaA

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### COLLABORATION AND COMMERCIAL LICENSE AGREEMENT

This Collaboration and Commercial License Agreement, effective as of June 23, 2014 ("**Effective Date**"), is by and between Mersana Therapeutics, Inc., a Delaware corporation, having its principal place of business at 840 Memorial Drive Cambridge, MA 02139 ("**Mersana**") and Merck KGaA, a corporation with general partners having its principal place of business at Frankfurter Str. 250, 64293 Darmstadt, Germany ("**Merck**"). Mersana and Merck may be referred to in this Agreement individually as a "**Party**" or collectively as the "**Parties**".

#### BACKGROUND

WHEREAS, Mersana Controls certain intellectual property rights relating to Antibody-drug conjugates;

WHEREAS, Merck is engaged in the Development and Commercialization of pharmaceutical products;

WHEREAS, Mersana and Merck desire to establish a cooperative relationship in order to Develop and Commercialize new Antibody-drug conjugates as pharmaceutical drug products; and

WHEREAS, Merck desires to license from Mersana and Mersana wishes to license to Merck, on an exclusive basis, the right to Develop and Commercialize Antibody-drug conjugates as pharmaceutical drug products as set forth herein.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

#### 1. Definitions and Interpretation.

1.1. <u>Definitions</u>. For the purposes of this Agreement the following words and phrases will have the following meanings:

**1.1.1. "ADC**" means an Antibody Directed to a Designated Target conjugated to one or more Cytotoxic Compounds using Mersana Platform Technology, which ADC is created pursuant to this Agreement.

1.1.2. "ADC Materials" is defined in Section 2.2.1.3.

**1.1.3.** "Affiliate" of a Party means a corporation or other business entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such Party. As used in this Section 1.1.3, the term "control" means the direct or indirect ownership of fifty percent (50%) or more of the stock having the right to vote for directors thereof or the ability to otherwise control the management thereof.

**1.1.4.** "Agreement" means this Collaboration and Commercial License Agreement, together with all schedules, amendments and supplements hereto.

**1.1.5.** "Antibody" means an unconjugated polyclonal or monoclonal antibody (whether (a) fully human, fully mouse, humanized, phage display, chimeric, polyclonal, polyclonal mixes or any other type of antibody, (b) multiple or single chain, recombinant, *in vivo, in vitro* or naturally occurring or a combination of any of the foregoing in any species or (c) monospecific, bi-specific, or multi-specific or any analog, derivative, fragment or modification thereof (including a full antibody, scFv, scFvFc, Fab, minibody, etc.)).

**1.1.6. "Antigen"** means (a) any protein (including any glyco- or lipo-protein), carbohydrate, compound or other composition that stimulates the production of Antibodies or against which Antibodies are Directed, or (b) any naturally occurring isoform or variants thereof. The whole

protein, carbohydrate, compound or other composition as well as a portion of the whole is considered the same Antigen.

**1.1.7.** "Applicable Law" means a law or statute, any rule or regulation issued by a Governmental Authority or Regulatory Authority and any judicial, governmental, or administrative order, judgment, decree, or ruling, in each case as applicable to the subject matter and the parties at issue and having a binding effect on it and them.

1.1.8. "Available" is defined in Section 2.4.2.1.

1.1.9. "Bankruptcy Code" is defined in Section 11.4.

1.1.10. "BLA" is defined in the definition of Regulatory Approval.

1.1.11. "Breaching Party" is defined in Section 11.3.

**1.1.12.** "Business Day" means a day on which national banks located in the Commonwealth of Massachusetts and Germany are open for commercial banking business other than a Saturday or Sunday.

**1.1.13.** "Calendar Quarter" means a three (3) month period beginning on January 1, April 1, July 1 or October 1 of any Calendar Year, except that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.

**1.1.14.** "Calendar Year" means, (a) for the first Calendar Year, the period commencing on the Effective Date and ending on December 31 of the year during which the Effective Date occurs, (b) for the last Calendar Year, the period commencing on January 1 of the last year of the Term, and ending on the last day of the Term, and (c) each interim period of twelve (12) months commencing on January 1 and ending on December 31.

**1.1.15.** "Change in Control" means, with respect to a Party, (a) a merger or consolidation in which (i) such Party is a constituent party, or (ii) a subsidiary of such Party is a constituent party, and such entity in clause (i) or (ii) issues shares of its capital stock pursuant to such merger or consolidation, except in the case of either clause (i) or (ii) any such merger or consolidation involving such Party or a subsidiary of such Party in which the shares of capital stock of such entity outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or are exchanged for shares of capital stock which represent, immediately following such merger or consolidation more than fifty percent (50%) by voting power of the capital stock of (A) the surviving or resulting corporation or (B) the parent corporation of such surviving or resulting corporation, in the case that the surviving or resulting corporation is a wholly owned subsidiary of another corporation or series of related transactions, by such Party or a subsidiary of such Party of all or substantially all of the assets of such Party or such subsidiary of such Party taken as a whole (except where such sale, lease, transfer, exclusive license or other disposition is only to a wholly owned subsidiary of such Party or a subsidiary of such Party or "group," as such terms are defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended, and the rules thereunder (collectively, the "**Exchange Act**") in a single transaction or series of related transactions, becomes the beneficial owner as defined under the Exchange Act, directly or indirectly, whether by purchase or acquisition or agreement to act in concert or otherwise, of fifty percent (50%) or more by voting power of the then-outstanding capital stock or other equity interests of such Party or a subsidiary of such Party or a subsidiary of such Party or a box and to a bone find the more such as defined under the Exchange Act, directly or indir

1.1.16. "Claim" is defined in Section 12.1.1.

**1.1.17.** "Clinical Trial" means a clinical trial in human subjects that has been approved by a Regulatory Authority and an Institutional Review Board or Ethics Committee, and is designed to

measure the safety and/or efficacy of a Licensed Product. Clinical Trials shall include Phase I Clinical Trials, Phase II Clinical Trials and Phase III Clinical Trials.

**1.1.18. "Combination Product**" means a pharmaceutical product that consists of an ADC and other active compounds or active ingredients sold as a single formulation or any combination of a Licensed Product sold together with another pharmaceutical product for a single invoiced price.

**1.1.19. "Commercialize"** or "**Commercializing**" means to market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize a compound or product. When used as a noun, "**Commercialization**" means activities involved in Commercializing.

**1.1.20.** "Commercially Reasonable Efforts" means: (a) with respect to the efforts to be expended by a Party with respect to any objective, such reasonable, diligent, and good faith efforts as such Party would normally use to accomplish a similar objective under similar circumstances; and (b) with respect to any objective relating to Development or Commercialization of a Licensed Product by a Party, the application by such Party, consistent with the exercise of its prudent scientific and business judgment, of diligent efforts and resources to fulfill the obligation in issue, consistent with the level of efforts such Party would devote to a product at a similar stage in its product life as such Licensed Product and having profit potential and strategic value comparable to that of such Licensed Product, taking into account, without limitation, commercial, legal and regulatory factors, target product profiles, product labeling, past performance, the regulatory environment and competitive market conditions in the therapeutic area, safety and efficacy of such Licensed Product, the strength of its proprietary position and such other factors as such Party may reasonably consider, all based on conditions then prevailing. For clarity, Commercially Reasonable Efforts will not mean that a Party guarantees that it will actually accomplish the applicable task or objective.

**1.1.21.** "Competing Product" means with respect to a Licensed Product in a country of the Territory, [\*\*], the Manufacture, use or sale of which in such country would infringe a pending or granted claim of a Mersana Patent Right or Mersana Platform Patent Right in such country, and which in the case of a pending claim, such pending claim were to be granted in the form in which it is pending at the time of the first sale of such Antibody drug conjugate in such country.

**1.1.22.** "Confidential Information" of a Party, means information relating to the business, operations or products of a Party or any of its Affiliates, including any Know-How, that such Party discloses to the other Party under this Agreement, or information of a Party that otherwise becomes known to the other Party by virtue of this Agreement; *provided*, that notwithstanding anything to the contrary, (a) Confidential Information constituting Mersana Know-How, Mersana Platform Know-How or Mersana Regulatory Documentation will be Confidential Information of Mersana (and Mersana will be deemed the disclosing Party and Merck the receiving Party with respect thereto) and (b) Confidential Information constituting Merck Know-How, Product Know-How or Merck Regulatory Documentation will be Confidential Information of Merck (and Merck will be deemed the disclosing Party and Mersana the receiving Party with respect thereto).

**1.1.23.** "Control" means, with respect to any information or intellectual property right, possession, whether directly or indirectly, by a Party or its Affiliates (including, except as described below, a Future Acquirer) of the ability (whether by sole, joint or other ownership interest, license or otherwise, other than pursuant to the grants set forth in this Agreement) to grant the right to access or use, or to grant a license or a sublicense to, such information or intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party. Notwithstanding the foregoing, any information or intellectual property right Controlled by a Future Acquirer of Mersana will not be treated as "Controlled" by Mersana or its Affiliates for purposes of this Agreement to the extent, but only to the extent, that such intellectual property (a) is Controlled by such Future Acquirer of Mersana prior to the time such Future Acquirer qualifies as such, other than pursuant to a license or other grant of rights (whether directly or indirectly) by Mersana or its Affiliates, or (b) is Controlled by such Future Acquirer subsequent to the time that such Future Acquirer qualifies as such but either (i) was not Controlled by Mersana or any of its existing Affiliates prior to the time such Future Acquirer qualifies as such or (ii) did not come under the Control of such Future Acquirer due to any

license or other grant of rights by Mersana or its Affiliates or any reference or access to any Merck Technology, Product Technology, Mersana Technology, Mersana Platform Technology or any other Confidential Information of Merck or information or intellectual property right Controlled by Mersana or any of its Affiliates (other than information or intellectual property Controlled by a Future Acquirer that would be excluded by clause (a) or (b)(i) of this Section 1.1.23).

**1.1.24.** "Cytotoxic Compound" means the Mersana Cytotoxic Compounds, the Merck Cytotoxic Compounds and the Public Domain Cytotoxic Compounds.

1.1.25. "Designated Target" means each Antigen designated by Merck under Section 2.4.

**1.1.26. "Develop**" or "**Developing**" means to discover, research or otherwise develop a process, compound or product, including conducting non-clinical and clinical research and development activities. When used as a noun, "**Development**" means activities involved in Developing.

**1.1.27.** "Directed" means, with respect to one or more Antigens, that an Antibody, Antibody drug conjugate or an ADC is selected, generated or optimized to preferentially bind to such Antigen or Antigens. For clarity, in the case of a bi-specific or multi-specific Antibody, such Antibody will be deemed to be Directed to those two (2) or more Antigens to which such Antibody has been selected, generated or optimized to preferentially bind.

**1.1.28.** "**Drug Master File**" means a voluntary submission to the FDA that may be used to provide confidential, detailed information about an ADC, Licensed Product, or Mersana Cytotoxic Compound, Merck Cytotoxic Compound, Public Domain Cytotoxic Compound or any other Mersana Technology or Mersana Platform Technology used to create an ADC or a Licensed Product, and Manufacturing (including the facilities used therefor) any of the foregoing.

1.1.29. "Effective Date" is defined in the introduction to this Agreement.

1.1.30. "Estimated Pre-Payment" is defined in Section 6.2.2.1(b).

**1.1.31. "European Union**" means the economic, scientific and political organization of member states of the European Union as it may be constituted from time to time.

1.1.32. "Event of Force Majeure" is defined in Section 13.1.

**1.1.33.** "Exchange Act" is defined in the definition of Change in Control.

1.1.34. "Exclusive License" is defined in Section 3.2.

**1.1.35. "Exploit"** means make, have made, import, use, sell or offer for sale, including to research, Develop, Commercialize, register, Manufacture, have Manufactured, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of. "**Exploitation**" means the act of Exploiting a compound, product or process.

1.1.36. "Extensions" is defined in Section 8.3.7.

**1.1.37.** "FD&C Act" means the United States Federal Food, Drug & Cosmetic Act, as amended, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.1.38. "FDA" means the United States Food and Drug Administration, and any successor agency thereto.

1.1.39. "Field" means diagnoses, prevention, control, palliation, or treatment of human and animal conditions, diseases or

disorders.

**1.1.40.** "First Commercial Sale" means, with respect to any Licensed Product and with respect to any country of the Territory, the first commercial transfer or disposition for value of a Licensed Product by Merck, its Affiliates or Sublicensees to a Third Party following, if required by Applicable Law, Regulatory Approval and Pricing Approval of such Licensed Product and, when Regulatory Approval and Pricing Approval are not required by Applicable Law for the Licensed Product, the first commercial sale in that country, in each case for use or consumption of such Licensed Product in such country by the general public; *provided*, that sales for clinical study purposes or compassionate, named patient (paid or unpaid) or similar use will not constitute a First Commercial Sale.

**1.1.41.** "Fleximer®" means Mersana's biodegradable polymer platform, poly(hydroxymethylethylene)hydroxymethyl formal, in any of its forms and sizes and varieties that are incorporated into an ADC or otherwise delivered to Merck pursuant to a Research Plan.

**1.1.42.** "**FTE**" means one person (or the equivalent of one person) working full time for a twelve (12) month period in a Development, regulatory or other relevant capacity employed or contracted by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof will be [\*\*] hours per year.

1.1.43. "FTE Fees" is defined in Section 6.2.1.

1.1.44. "FTE Rate" means the fully-loaded annual cost for the work of one FTE of [\*\*].

**1.1.45.** "Future Acquirer" means a Third Party to any Change in Control transaction involving Mersana and such Third Party or any of such Third Party's Affiliates, existing immediately prior to such Change in Control.

**1.1.46.** "Future Mersana In-License" means an agreement between Mersana or an Affiliate of Mersana and a Third Party, entered into after the Effective Date, pursuant to which Mersana has, but for the second proviso of this Section 1.1.46, acquired Control of certain Mersana Technology or Mersana Platform Technology; *provided* that such agreement will not be deemed to be a Future Mersana In-License unless and until the Parties have agreed upon the economic terms pursuant to which Merck may access such Mersana Technology or Mersana Platform Technology in *Provided further* that such Mersana Technology or Mersana Platform Technology or Mersana

1.1.47. "Gatekeeper" means the [\*\*] as may be agreed by the Parties in writing from time to time.

**1.1.48. "GLP Toxicology Studies**" means, with respect to a Licensed Product, animal studies conducted in accordance with GLP and intended to support an IND for such Licensed Product.

**1.1.49.** "Good Clinical Practices" means the then-current standards for good clinical practices for pharmaceuticals, as set forth in the FD&C Act and applicable regulations and guidance promulgated thereunder, including the Code of Federal Regulations, as amended from time to time, or under any other Applicable Laws.

**1.1.50.** "Good Laboratory Practices" or "GLP" means the then-current standards for good laboratory practices for pharmaceuticals, as set forth in the FD&C Act and applicable regulations and guidance promulgated thereunder, including the Code of Federal Regulations, as amended from time to time, or under any other Applicable Laws.

**1.1.51. "Good Manufacturing Practices"** means the then-current standards for good manufacturing practices for pharmaceuticals, as set forth in the FD&C Act and applicable regulations and guidance promulgated thereunder, including the Code of Federal Regulations, as amended from time to time, or under any other Applicable Laws.

1.1.52. "Governmental Authority" means an applicable multi- or supra-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.1.53. "IFRS" means International Financial Reporting Standards.

1.1.54. "IND" means (a) in the United States, an Investigational New Drug Application, as defined in the FD&C Act, filed with the FDA that is required to be filed with the FDA before conducting a Clinical Trial (including all supplements and amendments that may be filed with respect to the foregoing); and (b) any foreign counterpart of the foregoing.

1.1.55. "Indemnitee" is defined in Section 12.2.

1.1.56. "Indemnitor" is defined in Section 12.2.

1.1.57. "Joint Intellectual Property Committee" or "JIPC" is defined in Section 2.5.4

1.1.58. "Joint Know-How" means Know-How that is invented, conceived, or developed jointly by or on behalf of both Parties in the course of conducting their activities under this Agreement. If any Know-How would otherwise constitute both Product Know-How and Joint Know-How, then such Know-How will be deemed to be Product Know-How. If any Know-How would otherwise constitute both Mersana Platform Know-How and Joint Know-How, then such Know-How will be deemed to be Mersana Platform Know-How.

1.1.59. "Joint Patent Right" means a Patent Right that claims Joint Know-How.

1.1.60. "Joint Project Team" or "JPT" is defined in Section 2.5.3.1.

1.1.61. "Joint Technology" means the Joint Know-How and the Joint Patent Rights.

1.1.62. "Know-How" means proprietary technical information, processes, formulae, data, inventions, methods, knowledge, discoveries, inventions, know-how, trade secrets and other information, whether or not patentable, but that is not generally known, including any tangible embodiments of the foregoing.

1.1.63. "Liability" is defined in Section 12.1.1.

1.1.64. "Licensed Product" means a [\*\*] that incorporates one or more ADCs Directed to a Designated Target.

1.1.65. "Linker" is defined in the definition of Mersana Platform Know-How.

1.1.66. "Major Market Country" means each of the United States, Japan, France, Germany, Italy, Spain and the United

Kingdom.

1.1.67. "Manufacture" or "Manufacturing" means to make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, ship or store a compound or product or any intermediate or component thereof. When used as a noun, "Manufacture" or "Manufacturing" means activities involved in Manufacturing a compound or product or any intermediate or component thereof.

1.1.68. "Merck" is defined in the introduction to this Agreement.

1.1.69. "Merck Antibody" means an Antibody Directed to a Designated Target [\*\*] Merck to Mersana for inclusion in an ADC under a Research Program.

**1.1.70. "Merck Cytotoxic Compound"** means any [\*\*] that Merck, or its Affiliates Control as of the Effective Date or at any time during the Term.

**1.1.71.** "Merck Know-How" means Know-How, excluding Product Know-How (a) that is Controlled by Merck or any Affiliate of Merck as of the Effective Date or at any time during the Term and (b) that is necessary or useful to Exploit ADCs or Licensed Products.

1.1.72. "Merck Patent Right" means a Patent Right that claims Merck Know-How.

**1.1.73. "Merck Regulatory Documentation**" means Regulatory Documentation owned or Controlled by Merck or any of its Affiliates on or after the Effective Date relating to an ADC or a Licensed Product.

1.1.74. "Merck Technology" means the Merck Patent Rights and the Merck Know-How.

1.1.75. "Mersana" is defined in the introduction to this Agreement.

**1.1.76.** "Mersana Cytotoxic Compound" means [\*\*] that Mersana or its Affiliates Control as of the Effective Date or at any time during the Term. Mersana Cytotoxic Compounds include the compounds listed on <u>Schedule 1.1.76</u>.

**1.1.77.** "Mersana Know-How" means Know-How, excluding Mersana Platform Know-How, (a) that is Controlled by Mersana or any Affiliate of Mersana as of the Effective Date or at any time during the Term and (b) that is necessary or useful to Exploit ADCs or Licensed Products.

**1.1.78. "Mersana Patent Right**" means a Patent Right that claims Mersana Know-How. Mersana Patent Rights existing as of the Effective Date include all Patent Rights listed on <u>Schedule 1.1.78</u>

#### 1.1.79. "Mersana Platform Know-How" means Know-How

(a) that is Controlled by Mersana or any Affiliate of Mersana as of the Effective Date or at any time during the Term, including pursuant to Section 8.2.1, and any Know-How that is invented, conceived, or developed (A) by either or both Parties, or its or their Affiliates or Third Parties acting on its or their behalf, in each case in the course of conducting its or their activities under this Agreement or (B) by or on behalf of any Sublicensee in the course of conducting activities under a permitted sublicense hereunder, and

(b) to the extent relating to or consisting of

(i) a Mersana Cytotoxic Compound,

(ii) [\*\*],

(iii) the conjugation of a Mersana Cytotoxic Compound to a linker,

(iv) the conjugation of a pharmaceutical compound to a Linker,

(v) [\*\*],

(vi) [\*\*].

If any Know-How would otherwise constitute both Mersana Platform Know-How and Joint Know-How, then such Know-How will be deemed to be Mersana Platform Know-How. It is

agreed that all Know-How to the extent solely related to a Designated Target, Licensed Product, an ADC or a Merck Cytotoxic Compound shall not constitute Mersana Platform Know-How.

**1.1.80.** "Mersana Platform Patent Right" means a Patent Right that claims Mersana Platform Know-How. Mersana Platform Patent Rights existing as of the Effective Date includes all Patent Rights listed on <u>Schedule 1.1.80</u>.

**1.1.81.** "Mersana Platform Technology" means the Mersana Platform Know-How and the Mersana Platform Patent Rights. To the extent and subject to the proviso in the first sentence of Section 3.2, the rights granted to Mersana under the TUBE Agreement and the MGH Agreement shall be included in Mersana Platform Technology when the conditions set forth in such proviso have been met.

1.1.82. "Mersana Prosecution Patent Rights" is defined in Section 10.2.3.

**1.1.83.** "Mersana Regulatory Documentation" means Regulatory Documentation owned or Controlled by Mersana or any of its Affiliates on or after the Effective Date relating Mersana Technology or Mersana Platform Technology, in each case, that is necessary or useful to Exploit an ADC or a Licensed Product.

1.1.84. "Mersana Technology" means the Mersana Patent Rights and the Mersana Know-How.

1.1.85. "Mersana Trademarks" is defined in Section 8.6.3.

1.1.86. "MGH Agreement" is defined in Schedule 1.1.94.

1.1.87. "MGH Agreement Term" means the period commencing on the Effective Date and ending on the date of the [\*\*].

1.1.88. "MGH Patents" means the Patent Rights set forth in rows 1-7 of Schedule 1.1.80.

**1.1.89.** "NDA" is defined in the definition of Regulatory Approval.

**1.1.90.** "Net Sales" means the gross amounts invoiced by Merck, its Affiliates and Sublicensees for sales of a Licensed Product to independent or unaffiliated Third Party purchasers of such Licensed Product, *less the following deductions* with respect to such sales to the extent that such amounts are either included in the billing as a line item as part of the gross amount invoiced, or otherwise documented in accordance with IFRS to be specifically attributable to actual sales of such Licensed Product.

- (a) trade discounts, including trade, cash and quantity discounts or rebates, credits or refunds (including inventory management fees, discounts or credits);
- (b) allowances or credits actually granted upon claims, returns or rejections of products, including recalls, regardless of the party requesting such recall;
- (c) bad debts *provided* that the amount of any bad debts deducted pursuant to this Section 1.1.90(c) and actually collected in a [\*\*] shall be included in Net Sales for such [\*\*];
- (d) charges included in the gross sales price for freight, insurance, transportation, postage, handling and any other charges relating to the sale, transportation, delivery or return of such Licensed Product;
- (e) customs duties, sales, excise and use taxes and any other governmental charges (including value added tax) actually paid in connection with the transportation,

distribution, use or sale of such Licensed Product (but excluding what is commonly known as income taxes);

- (f) rebates and chargebacks or retroactive price reductions made to federal, state or local governments (or their agencies), or any Third Party payor, administrator or contractor, including managed health organizations; and
- (g) cash considerations given directly or indirectly to Third Parties related to import, distribution or promotion of the Licensed Product, unless such consideration is given in return for a separable service received, which alternatively available from a Third Party (specifically excluding any commissions paid to sales personnel, sales representatives and sales agents who are employees or consultants of the selling Party or its Affiliates or any Sublicensees).

If a Licensed Product under this Agreement is sold in form of a Combination Product, then Net Sales for such Combination Product shall be determined on a [\*\*] by mutual agreement of the Parties in good faith taking into account the perceived relative value contributions of the Licensed Product and the other ingredient or component in the Combination Product, as reflected in their respective market prices. In case of disagreement, an independent expert agreed upon by both Parties or, failing such agreement, designated by the International Chamber of Commerce, shall determine such relative value contributions and such determination shall be final and binding upon the Parties. The Parties shall commence discussions to reach agreement on the method for determining Net Sales pursuant to this paragraph no later than [\*\*] months prior to the anticipated commercial launch of such Combination Product; *provided* that, in the event such method is not determined pursuant to this paragraph prior to the commercial launch of such Combination Product, then Merck shall in any event make payment to Mersana attributing not less than [\*\*] of sales of such Combination Product to Net Sales, and the Parties shall reconcile such payments to actual Net Sales as determined pursuant to this paragraph when such method has been so determined. If the agreed attributed value percentage is not equal to [\*\*], the reconciliation between the Parties shall be made within [\*\*] days of such agreement.

In the event a Licensed Product is "bundled" for sale together with one or more other products in a country (a "**Product Bundle**"), then Net Sales for such Licensed Product shall be determined on a [\*\*] by mutual agreement of the Parties in good faith taking into account the relative value contributions of the Licensed Product and the other products in the Product Bundle, as reflected in their individual sales prices. In case of disagreement, an independent expert agreed upon by both Parties or, failing such agreement, the International Chamber of Commerce shall determine such relative value contributions and such determination shall be final and binding upon the Parties. The Parties shall commerce discussions to reach agreement on the method for determining Net Sales pursuant to this paragraph no later than [\*\*] months prior to the anticipated commercial launch of such Product Bundle; *provided* that, in the event such method is not determined pursuant to this paragraph prior to the commercial launch of such Product Bundle, then Merck shall in any event make payment to Mersana attributing not less than [\*\*] of sales of such Product Bundle to Net Sales, and the Parties shall reconcile such payments to actual Net Sales as determined pursuant to this paragraph when such method has been so determined. If the agreed attributed value percentage is not equal to [\*\*], the reconciliation between the Parties shall be made within [\*\*] days of such agreement.

All of the foregoing deductions from the gross invoiced sales prices of Licensed Products will be determined in accordance with IFRS. In the event that Merck, its Affiliates or Sublicensees make any adjustments to such deductions after the associated Net Sales have been reported pursuant to this Agreement, the adjustments will be reported and reconciled in the next report and payment of any royalties due.

For clarification, sale of Licensed Products by Merck, its Affiliates or Sublicensees to another of these entities for resale by such entity to a Third Party shall not be deemed a sale for purposes of this definition of "**Net Sales**". Further, transfers or dispositions of the Licensed Products:

(i) in connection with patient assistance programs,



(ii) for charitable or promotional purposes,

(iii) for preclinical, clinical, regulatory or governmental purposes, or compassionate use or other similar programs, or

(iv) for use in any tests or studies reasonably necessary to comply with any Applicable Law, regulation or request by a Regulatory Authority shall not, in each case, be deemed sales of such Licensed Products for purposes of this definition of "**Net Sales**."

**1.1.91.** "**Non-GLP Toxicology Studies**" means, with respect to a Licensed Product, pilot toxicology studies carried out in one or more animal species and intended to determine the therapeutic index or tolerability of such Licensed Product to support its selection for GLP Toxicology Studies.

1.1.92. "Notice of Dispute" is defined in Section 13.6.1.

**1.1.93.** "Notice Period" is defined in Section 11.3.

**1.1.94.** "Original Mersana In-License" means the MGH Agreement and the TUBE Agreement listed on <u>Schedule 1.1.94</u> between Mersana and a Third Party, entered into prior to the Effective Date, pursuant to which Mersana has acquired Control of certain Mersana Platform Technology; *provided* that (a) the TUBE Agreement will not be deemed to be an Original Mersana In-License unless and until the Parties enter into a sublicense pursuant to the proviso in Section 3.2 and (b) the MGH Agreement will be deemed an Original Mersana In-License only during the MGH Agreement Term.

1.1.95. "Overage" is defined in Section 6.2.2.2.

1.1.96. "Party" and "Parties" are defined in the introduction to this Agreement.

**1.1.97.** "**Patent Right**" means any and all national, regional and international (a) issued patents and pending patent applications (including provisional patent applications), (b) patent applications filed either from the foregoing or from an application claiming priority to the foregoing, including all provisional applications, converted provisionals, substitutions, continuations, in-part, divisions, renewals and continued prosecution applications, and all patents granted thereon, (c) patents-of-addition, revalidations, reissues, reexaminations and extensions or restorations (including any supplementary protection certificates and the like) by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, utility models, petty patents, innovation patents and design patents, (e) other forms of government-issued rights substantially similar to any of the foregoing, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing and (f) United States and foreign counterparts of any of the foregoing.

**1.1.98.** "**Performance Specifications**" are set forth in Exhibit 1.1.98 and will be adapted to each Research Program by mutual agreement of the Parties and documented in a more detailed fashion in each Research Plan.

**1.1.99.** "**Phase I Clinical Trial**" means a Clinical Trial that provides for the first introduction into humans of a pharmaceutical product with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of such product, in a manner that is generally consistent with 21 CFR § 312.21(a), as amended (or its successor regulation).

**1.1.100.** "**Phase II Clinical Trial**" means a Clinical Trial, the principal purpose of which is to make a preliminary determination as to whether a pharmaceutical product is safe for it intended use and to obtain sufficient information about such product's efficacy, in a manner that is generally consistent with 21 CFR § 312.21(b), as amended (or its successor regulation), to permit the design of further Clinical Trials.

**1.1.101. "Phase III Clinical Trial**" means a pivotal Clinical Trial with a defined dose or a set of defined doses of a pharmaceutical product designed to ascertain efficacy and safety of such product, in a manner that is generally consistent with 21 CFR § 312.21(c), as amended (or its successor regulation), for the purpose of enabling the preparation and submission of an NDA.

# 1.1.102. "Pre-Clinical Development Candidate Designation" is defined in Section 6.4.

**1.1.103.** "**Pricing Approval**" means the later of (a) the approval, agreement, determination or governmental decision establishing the price for a Licensed Product that can be legally charged to consumers, as required in a given jurisdiction or country in connection with Commercialization of such Licensed Product in such jurisdiction or country and (b) the approval, agreement, determination or governmental decision establishing, the level of reimbursement for such Licensed Product that will be reimbursed by Governmental Authorities, as required in a given jurisdiction or country in connection with Commercialization of such Licensed Product in such jurisdiction or country.

1.1.104. "Product Bundle" is defined in the definition of Net Sales.

# 1.1.105. "Product Know-How" means Know-How

(a) that is Controlled by Merck or any Affiliate of Merck as of the Effective Date or at any time during the Term (including pursuant to Section 8.2.2, and including Know-How that is invented, conceived, or developed by either or both Parties, or its or their Affiliates or Third Parties acting on its or their behalf, in each case in the course of conducting its or their activities under this Agreement), and

(b) solely to the extent relating to or consisting of

(i) [\*\*],
(ii) [\*\*],
(iii) [\*\*],
(iv) [\*\*],
(v) [\*\*].

If any Know-How would otherwise constitute both Product Know-How and Joint Know-How, then such Know-How will be deemed to be Product Know-How. If any Know-How would otherwise constitute both Mersana Platform Know-How and Product Know-How, then such Know-How will be deemed to be Product Know-How.

1.1.106. "Product Patent Right" means a Patent Right that claims Product Know-How.

1.1.107. "Product Technology" means the Product Know-How and the Product Patent Rights.

1.1.108. "Product Trademarks" is defined in Section 8.6.1.

1.1.109. "Project Leader" is defined in Section 2.5.2.1.

**1.1.110. "Public Domain Cytotoxic Compound"** means any [\*\*], that is in the public domain as of the Effective Date or at any time during the Term other than by a breach by a Party under this Agreement.

1.1.111. "Publication" is defined in Section 7.5.

1.1.112. "Quarterly Report" is defined in Section 2.5.3.5.

**1.1.113.** "**Regulatory Approval**" means final regulatory approval (but excluding Pricing Approval) required to Commercialize a Licensed Product for a disease or condition in accordance with the Applicable Laws of a given country. In the United States, its territories and possessions, Regulatory Approval means approval of a New Drug Application ("**NDA**"), Biologics License Application ("**BLA**") or an equivalent by the FDA.

**1.1.114.** "**Regulatory Authority**" means, with respect to a country in the Territory, any national (e.g., the FDA), supranational (e.g., the European Commission, the Council of the European Union, or the European Medicines Agency), regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority involved in the granting of a Regulatory Approval or a Pricing Approval, for biopharmaceutical products in such country.

**1.1.115.** "**Regulatory Documentation**" means: all (a) applications (including all INDs), registrations, licenses, authorizations and approvals (including Regulatory Approvals and Pricing Approvals); (b) correspondence 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; (c) clinical and other data contained, referenced or otherwise relied upon in any of the foregoing; and (d) for clarity, any Drug Master File.

1.1.116. "Research Fees" is defined in Section 6.2.1.

**1.1.117.** "**Research Plan**" means, with respect to any Research Program, the written plan for such Research Program, as further described in Section 2.2.

1.1.118. "Research Program" means each research program conducted pursuant to Section 2.

**1.1.119.** "Research Program Materials" is defined in Section 2.2.1.3.

1.1.120. "Research Program Term" is defined in Section 2.3.

1.1.121. "Royalty Report" is defined in Section 6.10.1.1.

1.1.122. "Royalty Term" is defined in Section 6.3.3.

**1.1.123. "Strategic IP Plan"** means, for each Research Program, the plan mutually agreed between the Parties that sets out the agreed overall strategy that the Parties intend to follow for the protection by means of Patent Rights generated under this Agreement and such further Patent Rights as the Parties may agree on as part of such Strategic IP Plan. The Strategic IP Plan for each Research Program shall be established, agreed, updated, revised and executed as set out in Section 2.5.4.

1.1.124. "Study Materials" is defined in Section 2.2.1.3.

**1.1.125.** "Sublicensee" means a person or entity that is granted a sublicense under an Exclusive License by Merck in accordance with the terms of this Agreement.

1.1.126. "Supply Agreement" is defined in Section 4.3.2.

1.1.127. "Supply Fees" is defined in Section 6.2.1.

1.1.128. "Target Exclusivity Period" is defined in Section 2.4.4.1.

**1.1.129. "Tax"** or "**Taxes**" means any federal, state, local or foreign income, gross receipts, license, payroll, employment, excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not.

1.1.130. "Technology Access Fee" is defined in Section 6.1.

1.1.131. "Term" is defined in Section 11.1.

1.1.132. "Territory" means all countries in the world.

1.1.133. "Third Party" means a person or entity other than Merck, Mersana and their respective Affiliates.

1.1.134. "Third Party Action" is defined in Section 9.1.1.

1.1.135. "TUBE Agreement" is defined in <u>Schedule 1.1.94</u>.

**1.1.136.** "TUBE Toxins" means the [\*\*] pursuant to the TUBE Agreement.

1.1.137. "Valid Patent Claim" means with respect to a Patent Right in a country any claim of an

- (a) issued Patent Right that has not (i) expired, irretrievably lapsed or been abandoned, revoked, dedicated to the public or disclaimed or (ii) been found to be unpatentable, invalid or unenforceable by an unreversed and unappealable decision of a Governmental Authority in such country; or
- (b) application for a Patent Right that (i) has been pending for less than [\*\*] from the earliest claimed priority date and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing and (ii) has not been admitted to be invalid or unenforceable through reissue, reexamination, or disclaimer, and which is not subject to an interference claim.

In the event that a Patent Right issues from an application for a Patent Right described in clause (b) of this Section 1.1.137 that has been pending for more than [\*\*] from the earliest claimed priority date, the claims of such issued Patent Right will be deemed to be Valid Patent Claims from and after the date of issuance so long as it satisfies the requirements of clause (a) of this Section 1.1.137.

#### 1.2. Certain Rules of Interpretation in this Agreement and the Schedules and Exhibits.

**1.2.1.** Unless otherwise specified, all references to monetary amounts are to United States of America currency (United States Dollars);

**1.2.2.** The preamble to this Agreement and the descriptive headings of sections are inserted solely for convenience of reference and are not intended as complete or accurate descriptions of the content of this Agreement or of such sections;

**1.2.3.** Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders and the word "or" is used in the inclusive sense (and/or);

**1.2.4.** The words "include" and "including" have the inclusive meaning frequently identified with the phrases "without limitation" and "but not limited to";

1.2.5. The words "shall" and "will" have the same meaning;

**1.2.6.** Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. Unless otherwise specified, deadlines within which any payment is to be made or act is to be done within or following specified time period after a date will be calculated by excluding the day, Business Day, month or year of such date, as applicable, and including the day, Business Day, month or year of the date on which the period ends;

**1.2.7.** Whenever any payment is to be made or action to be taken under this Agreement is required to be made or taken on a day other than a Business Day, such payment will be made or action taken on the next Business Day following such day to make such payment or do such act; and

**1.2.8.** Unless otherwise specified, references in this Agreement to any section, exhibit or schedule mean references to such section, exhibit or schedule of this Agreement.

# 2. Research Program.

**2.1.** <u>Objective and Conduct of the Research Programs</u>. The Parties will conduct a number of Research Programs, each in accordance with a Research Plan, the terms of this Agreement and Applicable Law in good scientific manner. The purpose of each Research Program will be to identify, develop and evaluate ADCs to enable Merck to make a Pre-Clinical Development Candidate Designation and subsequently Exploit such ADCs under this Agreement. Each Party will use Commercially Reasonable Efforts to perform activities assigned to it under each Research Plan in accordance with the timelines set forth therein. Merck will promptly notify Mersana in the event that (a) Merck makes a Pre-Clinical Development Candidate Designation with respect to an ADC or a Licensed Product, or (b) Merck makes a determination to not make a Pre-Clinical Development Candidate Designation with respect to an ADC or a Licensed Product.

### 2.2. Research Plans.

**2.2.1.** <u>Research Plan Framework</u>. Each Research Plan will provide a framework for the applicable Research Program. Each Research Plan will include the following activities (all as will be more specifically set forth in the applicable Research Plan):

2.2.1.1. Merck will deliver to Mersana specified quantities of [\*\*].

2.2.1.2. Mersana will use Commercially Reasonable Efforts to [\*\*] set forth in the Research Plan.

2.2.1.3. Mersana will deliver to Merck [\*\*] as contemplated under the Research Plan or otherwise agreed to by the

Parties.

2.2.1.4. Non-GLP Toxicology Studies and GLP Toxicology Studies with respect to such ADC Materials will be

conducted by Mersana or Merck, as specified in the applicable Research Plan.

**2.2.1.5.** Each Research Plan will include a budget for Mersana's activities thereunder, including with respect to FTEs to be provided by Mersana and Research Fees to be included thereunder.

# 2.2.1.6. [\*\*] Antibodies

(a) In the event that a Research Program involves the use of a [\*\*].

(b) In the event that a Research Program involves the use of a [\*\*].

# 2.2.2. <u>Restrictions on use of Materials</u>.

**2.2.2.1.** Mersana (a) will not use the Merck Antibodies for any purpose other than exercising its rights and performing its obligations under the applicable Research Plan, (b) will only use the Merck Antibodies in compliance with all Applicable Laws, and (c) will not transfer the Merck Antibodies or grant any rights thereto to any Third Party without the express prior written consent of Merck. Merck will retain full ownership of, and all right, title and interest in and to, the Merck Antibodies. At the end of the applicable Research Program Term, or upon earlier termination of this Agreement, Mersana will at the instruction of Merck either destroy or return any remaining Merck Antibodies.

**2.2.2.** Prior to Merck making a Pre-Clinical Development Candidate Designation with respect to a Licensed Product, Merck (a) will not use the applicable Research Program Materials for any purpose other than exercising its rights and performing its obligations under this Agreement, (b) will only use the applicable Research Program Materials in compliance with all Applicable Laws, and (c) will not transfer the applicable Research Program Materials or grant any rights thereto to any Third Party without the express prior written consent of Mersana. Mersana will retain full ownership of, and all right, title, and interest in and to, the Research Program Materials, except that following the Pre-Clinical Development Candidate Designation of a Licensed Product. Upon the earliest of (i) Merck's election to not make a Pre-Clinical Development Candidate Designation with respect to a Licensed Product, (ii) a replacement of the Designated Target Antigen under Section 2.4.3, and (iii) termination of this Agreement, Merck will at the instruction of Mersana either destroy or return any remaining Research Program Materials from the applicable Research Program. After Merck makes a Pre-Clinical Development Candidate Designated Target for any purpose within the scope of the Exclusive License for such Designated Target.

**2.2.3.** <u>Research Plans</u>. The Research Plan for the [\*\*] Designated Target is attached as <u>Schedule 2.2.3-1</u>. Subsequent Research Plans agreed upon in accordance with Section 2.4.2.4 will be attached as additional sequentially numbered schedules (<u>Schedule 2.2.3-2</u>, <u>Schedule 2.2.3-3</u>, etc.).

**2.2.4.** <u>Changes to Research Plans</u>. Each Party may via the Joint Project Team propose changes to a Research Plan, which will be subject to review and approval by the Project Leaders, as provided in Section 2.5.2.

**2.2.5.** <u>Research Program Records</u>. Mersana will maintain, in good scientific manner, complete and accurate books and records pertaining to its activities under each Research Plan.

**2.3.** <u>Term of a Research Program</u>. The term of the [\*\*] Research Program, which covers the [\*\*]Designated Target, will commence upon the Effective Date, and the term of each subsequent Research Program will commence upon approval of a Research Plan under Section 2.4.2.4. Each Research Program will continue until [\*\*] (a) [\*\*]; (b) [\*\*]; (c) [\*\*]; (d) [\*\*]; and (e) [\*\*] (the term of a Research Program, each, a "**Research Program Term**"). If a Research Program Term ends pursuant to clause (c), (d) or (e) of this Section 2.3, then the Designated Target that is the subject of the applicable Research Program will no longer be deemed to be a Designated Target hereunder.

### 2.4. Availability of Targets; Approval of New Research Plans.

**2.4.1.** <u>Designated Targets</u>. Merck may designate up to six (6) Antigens as Designated Targets (together with any applicable replacement Designated Targets under Section 2.4.3) under this Agreement as follows:

2.4.1.1. The [\*\*] Designated Target is set forth on <u>Schedule 2.4.1-1</u>.

2.4.1.2. The [\*\*] Designated Target is set forth on <u>Schedule 2.4.1-2</u>.

**2.4.1.3.** Merck may designate [\*\*] Designated Target in accordance with this Section 2.4.1.3 at any time prior to the [\*\*]. Such Designated Targets that are designated in accordance with this Section 2.4.1.3 will be set forth on <u>Schedule 2.4.1-3</u> and <u>Schedule 2.4.1-4</u>, respectively.

**2.4.1.4.** Merck may designate a [\*\*] Designated Target in accordance with this Section 2.4.1.4 at any time following the [\*\*]. Such Designated Targets that are designated in accordance with this Section 2.4.1.4 will be set forth on <u>Schedule 2.4.1-5</u> and <u>Schedule 2.4.1-6</u>, respectively.

### 2.4.2. Gatekeeper Process.

**2.4.2.1.** In order to designate an Antigen as a new Designated Target under Section 2.4.1.3, Section 2.4.1.4 or Section 2.4.3, Merck will provide the Gatekeeper with a confidential written description of such Antigen, including to the extent available, the Name and UniProt/SwissProt number sequence for such proposed Antigen. Within [\*\*] Business Days following Gatekeeper's receipt of such written notice with respect to a particular proposed Antigen, Mersana will ensure that Gatekeeper will notify Merck in writing whether the proposed Antigen is Available for designation as a Designated Target. The Parties hereby acknowledge and agree that a proposed Antigen will be "**Available**" for designation by Merck as a Designated Target unless [\*\*].

**2.4.2.2.** For clarity, in the event that the Gatekeeper notifies Merck that a proposed Antigen is not Available pursuant to the procedures set forth in this Section 2.4.2, Merck will not have exhausted any of its rights to designate an Antigen as a new Designated Target hereunder within the applicable designation time period. Should an Antigen proposed by Merck be rejected by the Gatekeeper, the applicable nomination period for such Antigen shall be automatically extended by the time consumed by the unsuccessful nomination process.

**2.4.2.3.** The Parties acknowledge and agree that, as of the Effective Date, the first and second Designated Targets set forth on Schedule 2.4.1-1 and Schedule 2.4.1-2 are Available, and the procedures set forth in Section 2.4 will not apply to such Designated Targets, other than with respect to replacement of such Designated Targets in accordance with Section 2.4.3.

2.4.2.4. In the event that the Gatekeeper notifies Merck that a proposed Antigen is Available for designation as a Designated Target in accordance with Section 2.4.2, within [\*\*] Business Days following receipt of such notice, Merck will thereafter notify the Gatekeeper if it wishes to so designate such proposed Antigen (in which case, Merck will also promptly provide notice to Mersana that it has designated an Antigen to be a Designated Target). Upon such designation, Merck will disclose to Mersana the identity of the Designated Target, and the JPT will promptly meet to draft a Research Plan for such Designated Target and will use good faith efforts to agree on such Research Plan. Upon written agreement by the Project Leaders on a proposed Research Plan, such Antigen will be deemed a Designated Target hereunder (if applicable), such proposed Research Plan will be deemed to be a Research Plan hereunder, and the corresponding Research Program will commence. In addition to Section 2.4.4, the Parties agree that from receiving the notification of availability of an Antigen from the Gatekeeper until its designation as a Designated Target, such Antigen shall not be available for a collaboration between Mersana and a Third Party.

**2.4.3.** <u>Replacement of Designated Targets</u>. During the Research Program Term for a Research Program, in the event that the Project Leaders reasonably determine that it is [\*\*] in accordance with the applicable Research Plan using at least one of the Merck Antibodies provided thereunder, the Project Leaders will promptly notify Merck in writing thereof. Merck may, at any time within [\*\*] following receipt of such notice, designate a new Designated Target in accordance with Section 2.4.2 to

replace the original Designated Target without using an additional of the overall six (6) options to designate an Antigen as a new Designated Target pursuant to Section 2.4.1. The original Designated Target will no longer be deemed to be a Designated Target, and Merck will have no further right or license under this Agreement with respect to the original Designated Target.

# 2.4.4. Target Exclusivity.

**2.4.4.1.** During the Term on a Designated Target-by-Designated Target basis, Mersana will collaborate exclusively with Merck with respect to such Designated Target during the period commencing with the designation of an Antigen as a Designated Target by Merck pursuant to Section 2.4.2.4 and ending on the earliest of (a) [\*\*]; (b) [\*\*]; (c) [\*\*] or (d) [\*\*] (each such period, a "**Target Exclusivity Period**"). For purposes of this Section 2.4.4, "collaborate exclusively" means that Mersana will not, [\*\*]. The provisions of this Section 2.4.4.1 shall not apply to any Future Acquirer or any Affiliate of any Future Acquirer other than Mersana to the extent that any activities conducted by any such Future Acquirer or any such Affiliate with respect to such Designated Target do not make use of any information or intellectual property right that is deemed Controlled by Mersana pursuant to this Agreement.

- **2.4.4.2.** Upon the expiration or termination of a Target Exclusivity Period for a Designated Target:
  - (a) the Exclusive License to Merck pursuant to Section 3.2 with respect to such Designated Target shall automatically terminate, and
  - **(b)** Merck will (i) [\*\*] and (ii) [\*\*].

# 2.5. Alliance Managers; Governance of Research Program.

**2.5.1.** <u>Alliance Managers</u>. Promptly following the Effective Date, each Party will designate an alliance manager to be reasonably available to the other Party to facilitate communication, respond to questions and otherwise oversee that the Parties' activities hereunder are in line with this Agreement. Such alliance managers will regularly interact with each other on a frequency to be mutually agreed by the Parties and on an *ad hoc* basis if requested by the Joint Project Team or the Project Leaders. A Party may replace its alliance manager at any time by written notice to the other Party.

### 2.5.2. Project Leaders

**2.5.2.1.** Formation and Composition. Within [\*\*] Business Days after the Effective Date, each Party will appoint an individual from senior management of such Party to be a project leader (each, a "**Project Leader**") to oversee the Parties' activities under this Agreement. A Party may change its Project Leader at any time by written notice to the other Party. Such Project Leader may, but is not required to, serve as a representative of its respective Party on the JPT. The Parties may allow additional employees and consultants to attend meetings of the Project Leaders and may consult with additional employees and advisors prior to making a decision, subject to the confidentiality provisions of Section 7.

**2.5.2.2.** <u>Functions and Authority</u>. The Project Leaders will be responsible for supervising and managing the Research Programs. Their functions will be:

- (a) Overseeing and coordinating the progress, timelines, budget and results of the Research Programs;
- (b) Reviewing and approving each Research Plan (including the budget therein) and any proposed amendments to the Research Plans proposed pursuant to Section 2.2.4, *provided* that the Research Plan (including the budget therein) for the first and second Designated

Targets attached hereto as Schedule 2.2.3-1 shall be deemed approved by the Project Leaders;

- (c) Reviewing each Party's reports regarding its activities under each Research Plan;
- (d) Deciding whether it is scientifically or technically feasible to create an ADC Directed to the applicable Designated Target in accordance with each Research Plan;
- (e) Deciding whether an ADC meets the applicable Performance Specifications set forth in each Research Plan;
- (f) Approval of and any changes to the Strategic IP Plan proposed by the JIPC.
- (g) Resolving any disputes delegated to the Project Leaders by the JPT or the JIPC;
- (h) Overseeing the activities conducted pursuant to each Supply Agreement; and
- (i) Such other matters as the Parties may mutually agree in writing.

**2.5.2.3.** <u>Meetings</u>. During the Term, the Project Leaders will meet in person or by teleconference or videoconference at least once every Calendar Quarter during a Research Program Term. The Project Leaders also may choose to meet more frequently on an as needed basis. In advance of each meeting of the Project Leaders, the JPT will provide a Quarterly Report to the Project Leaders.

**2.5.2.4.** <u>Decisions.</u> The Project Leaders will take action by unanimous consent or by a written resolution signed by the Project Leaders. In the event the Project Leaders are unable to secure unanimous consent on any matter, [\*\*] shall make the final determination on any such matter which shall be binding on the Parties as though it had been made by a consensus of the Project Leaders; *provided* that [\*\*] shall <u>not</u> have the authority to make the final determination with respect to the following matters:

- (a) [\*\*];
- (b) amendments to any Research Plan that would require [\*\*], in which case such amendment will not be approved without [\*\*] consent, which consent may be withheld in [\*\*] reasonable discretion; and
- (c) amendments to any Research Plan that would require that [\*\*], in which case such amendment will not be approved without [\*\*] consent, which consent may be withheld in [\*\*] reasonable discretion.

**2.5.2.5.** <u>Minutes and Reports</u>. The Project Leaders will document their decisions regarding each Research Plan in the meeting minutes. Promptly after each meeting, one Project Leader will provide the other with a draft version of the meeting minutes for review and comment. Within [\*\*] Business Days of each meeting, the Project Leaders will provide the Parties and the JPT with a final agreed version of the meeting minutes.

**2.5.2.6.** Duration. The office of the Project Leaders will exist until the later of (a) last to expire Research Program Term, or (b) the completion of all activities pursuant to any Supply Agreement.

#### 2.5.3. Joint Project Team.

**2.5.3.1.** <u>Formation and Composition</u>. Within [\*\*] Business Days after the Effective Date, the Parties will establish a joint project team (the "Joint Project Team" or "JPT") composed of three (3) appointed representatives of each of Merck and Mersana. A Party may change one or more of its representatives on the JPT at any time or elect to have one of its members represented by a delegate at a meeting of the JPT. The JPT will be chaired by a Merck representative selected by Merck from one of the Merck's members of the JPT. The Parties may allow additional employees and consultants to attend meetings of the JPT subject to the confidentiality provisions of Section 7.

functions will be:

- 2.5.3.2. Functions and Authority. The JPT will be responsible for carrying out each Research Program. Its
  - (a) Drafting the Research Plans (including the budgets therein) for each Research Program and proposing such Research Plans for approval by the Project Leaders.
  - (b) Documenting the progress, timelines, budget and results of the Research Program;
  - (c) Proposing amendments to the Research Plan proposed pursuant to Section 2.2.4;
  - (d) Reporting its activities under each Research Plan;
  - (e) Evaluating whether it is scientifically or technically feasible to create an ADC Directed to the applicable Designated Target in accordance with each Research Plan and making a recommendation to the Project Leaders;
  - (f) Evaluating whether an ADC meets the applicable Performance Specifications set forth in each Research Plan and making a recommendation to the Project Leaders;
  - (g) Preparing Quarterly Reports based on reports to be provided by each Party of such Party's activities during the applicable Calendar Quarter;
  - (h) Documenting the activities conducted pursuant to each Supply Agreement;
  - (i) Determining the Estimated Pre-Payment for each Calendar Quarter during each Research Program Term (other than the first Calendar Quarter of the Term) pursuant to Section 6.2.2.1(b); and
  - (j) Such other matters as the Parties may mutually agree in writing.

**2.5.3.3.** <u>Meetings</u>. During the Term, the JPT will meet in person or by teleconference or videoconference at least [\*\*] during a Research Program Term, unless otherwise decided by the JPT. The JPT also may choose to meet more frequently on an as needed basis. The JPT shall meet in person at least [\*\*], unless otherwise decided by the JPT. At each meeting of the JPT, each Party will provide a report regarding the progress of its activities under each Research Plan.

**2.5.3.4.** <u>Decisions</u>. The JPT will take action by unanimous consent of the Parties, with each Party having [\*\*] vote, irrespective of the number of representatives actually in attendance at a meeting (but provided that at least one representative from each Party is in attendance), or by a written resolution signed by the designated representatives of each of the Parties. In the event the JPT is unable to secure unanimous consent on any matter the decision shall be escalated [\*\*]. For clarity, the JPT shall not have the authority to amend the Research Plan or this Agreement.

**2.5.3.5.** <u>Minutes and Reports</u>. The JPT will maintain accurate minutes of its meetings, including the status of the Research Programs and all proposed decisions and recommended actions or decisions taken. Promptly after each meeting, a member of the JPT designated by the JPT will provide the Parties with a draft version of the meeting minutes of each meeting for review and comment. Within [\*\*] Business Days of each meeting, the JPT chair will provide the Parties and the Project Leaders with a final version of the meeting minutes incorporating any such comments from the Parties, and such version will be recognized as having been accepted by the Parties. In advance of each quarterly meeting of the Project Leaders, the JPT will prepare a report for the Project Leaders detailing the progress of activities under each Research Plan, any decisions that are needed from the Project Leaders and any matters on which the JPT could not reach agreement (each a "Quarterly Report").

**2.5.3.6.** Duration. The JPT will be in existence until the later of (a) last to expire Research Program Term, or (b) the completion of all activities pursuant to any Supply Agreement.

**2.5.4.** Joint Intellectual Property Committee. As soon as practicable after the Effective Date, the Parties shall form a joint intellectual property committee (the "Joint Intellectual Property Committee" or "JIPC"). The JIPC shall comprise no more than [\*\*] members, and shall be composed of an equal number of representatives from each Party. The Parties may allow additional employees and consultants to attend meetings of the JIPC subject to the confidentiality provisions of Section 7.

- 2.5.4.1. Functions and Authority. During the Term the JIPC shall:
  - (a) for each Research Program, draft and propose a Strategic IP Plan (and any amendments thereto) to the Project Leaders, which Strategic IP Plan at a minimum needs to detail the countries of filing and a patent filing strategy, which strategy shall (1) be aligned between the Parties to secure the maximum protection of Product Technology and Mersana Platform Technology, (2) [\*\*] and (3) include that any proposed filing of a Mersana Platform Patent Right [\*\*];
  - (b) oversee the drafting, filing, prosecution and maintenance of all Patent Rights generated from the activities under this Agreement in accordance with the Strategic IP Plan and Section 8, which shall include overseeing Mersana's reasonable opportunity to comment on all [\*\*] Patent Right filings and Merck's obligation to reasonably consider in good faith Mersana's comments with respect thereto;
  - (c) as necessary, take day-to-day decisions relating to the drafting, filing, prosecution and maintenance of the resulting Patent Rights in accordance with the Strategic IP Plan and Section 8;
  - (d) report to the Project Leaders on the drafting, filing, prosecution and maintenance of such Patent Rights;
  - (e) propose to the Project Leaders any changes or additions to the Strategic IP Plan that the JIPC deems fit, and upon approval of said changes and additions, implement said changes and additions; and
  - (f) consider whether it is necessary to enter into any license agreements with a Third Party in respect of a Designated Target.

In the event of a conflict between the JIPC's authority under this Section 2.5.4.1 and a Party's rights under Section 8.3.3 or Section 8.3.4, as applicable, Mersana's and Merck's respective rights under Section 8.3.3 and Section 8.3.4 shall prevail.

**2.5.4.2.** <u>Meetings</u>. During the Term, the JIPC will meet in person or by teleconference or videoconference on a frequency to be determined by the JIPC.

**2.5.4.3.** <u>Decisions</u>. The JIPC will take action by unanimous consent of the Parties, with each Party having [\*\*] vote, irrespective of the number of representatives actually in attendance at a meeting (but provided that at least one representative from each Party is in attendance), or by a written resolution signed by the designated representatives of each of the Parties. In the event the JIPC is unable to secure unanimous consent on any matter the decision shall be escalated to [\*\*]. The JIPC shall however have no authority to amend any Strategic IP Plan or this Agreement.

**2.5.4.4.** <u>Minutes and Reports</u>. The JIPC will document their decisions regarding each Strategic IP Plan in the meeting minutes. Promptly after each meeting, one member of the JIPC will provide the others with a draft version of the meeting minutes for review and comment. Within [\*\*] Business Days of each meeting, the JIPC will provide the Parties and the Project Leaders with a final agreed version of the meeting minutes.

# 3. License Grants.

**3.1.** <u>Research License to Mersana</u>. Subject to the terms and conditions of this Agreement Merck will, and hereby does, grant to Mersana and its Affiliates, a non-exclusive, transferrable (only to the extent set forth in Section 13.2), sublicensable (only to the extent set forth below in this Section 3.1), worldwide, royalty-free right and research license to and under the Merck Technology, Product Technology and Merck's interest in the Joint Technology solely to conduct its activities under each Research Plan during the applicable Research Program Term. Such license includes the right to grant sublicenses through multiple tiers to Third Parties who conduct activities under the applicable Research Program on behalf, and under the direction of Mersana or its Affiliates, as applicable, subject to Merck's prior written consent, which consent may not be unreasonably withheld, delayed or conditioned; *provided*, that any such sublicensee is bound to applicable provisions of this Agreement, including obligations of confidentiality and assignment of inventions comparable in scope to those included herein.

**3.2.** Exclusive Licenses to Merck. With respect to each Designated Target, subject to the terms and conditions of this Agreement, Mersana will, and does hereby, grant to Merck an exclusive (even as to Mersana, except to the extent required for Mersana to perform its obligations under this Agreement), transferrable (only to the extent set forth in Section 13.2), sublicensable (only to the extent set forth in Section 3.3), royalty-bearing (a) right and license to and under the Mersana Technology, Mersana Platform Technology and Mersana's interest in the Joint Technology, and (b) right to access and reference to the Mersana Regulatory Documentation in accordance with Section 5, solely in connection with its exercise of its rights under clause (a) of this Section 3.2, in each case ((a) and (b)), to Exploit ADCs and Licensed Products, in each case, Directed to such Designated Target (including to conduct its activities under each Research Program as set forth in the applicable Research Plan), within the Field in the Territory (collectively (a) and (b) with respect to such Designated Target, an "Exclusive License"); provided, that (x) Mersana Platform Technology shall <u>not</u> include the rights granted [\*\*]. Each Exclusive License will continue (i) for the applicable Royalty Term, unless earlier terminated pursuant to Section 11 or Section 2.4.4.2(a), and (ii) thereafter, as provided in Section 11.5.2.2(b) and Section 11.5.4.

**3.3.** <u>Sublicensing</u>. Subject to Section 2.2.2.2(c), Merck will have the right to grant sublicenses under each Exclusive License through multiple tiers to any Affiliate or any Third Party, subject to [\*\*]. As a condition to granting any sublicense hereunder, Merck will require each Sublicensee to assign to Merck all Know-How and Patent Rights invented, conceived, or developed by or on behalf of any such Sublicensee, whether alone or with Merck or a Third Party, that would be Mersana Platform Technology if invented, conceived or developed by Merck (alone or with Merck). Merck will remain obligated for all of its obligations under this Agreement and, as between the Parties, will remain liable for all acts or omissions of its Sublicensees under any Exclusive License. Merck will promptly notify Mersana after granting any sublicense under an Exclusive License and will provide a copy of the agreement with such Sublicensee, which agreement may be redacted to remove information not relevant for the purposes of checking compliance with sublicense requirements hereunder. Merck will make all payments due to Mersana pursuant to this Agreement by reason of achievement of any milestones and royalties set forth herein by any Sublicensee.

**3.4.** <u>Compliance with the Mersana In-Licenses</u>. Merck and its Affiliates will comply with, and Merck shall cause its Sublicensees to comply with, all obligations, covenants and conditions of the

Original Mersana In-Licenses and any Future Mersana In-Licenses, and any amendments thereto (following written disclosure and notice of such amendments to Merck, provided that Mersana may not amend any Original Mersana In-Licenses or any Future Mersana In-Licenses except as specified in Section 10.3.1), that apply under each of the Original Mersana In-Licenses and any Future Mersana In-Licenses to Merck, its Affiliates or Sublicensees, as applicable.

#### 4. Development, Commercialization, Supply and Manufacturing.

**4.1.** <u>In General; Diligence</u>. Merck will have the sole right and responsibility, at its sole expense, for all aspects of the Exploitation of ADCs and Licensed Products, except with respect to those obligations of Mersana in support thereof as provided hereunder, including as set forth in Section 4.3 and Section 5.1. Merck will use Commercially Reasonable Efforts to (a) Develop and obtain Regulatory Approval for a Licensed Product Directed to such Designated Target [\*\*], and (b) Commercialize such Licensed Product in any country or jurisdiction in which Regulatory Approval and Pricing Approval is obtained for such Licensed Product. Merck will comply with all Applicable Laws (including Good Laboratory Practices, Good Clinical Practices, and Good Manufacturing Practices) in the Exploitation of such Licensed Products, and will require its Sublicensees to do the same.

**4.2.** <u>Funding and Progress Reports</u>. Merck will be solely responsible for funding all costs of the Exploitation of ADCs and Licensed Products pursuant to each Exclusive License. Merck will keep Mersana informed in a timely manner as to the progress of the Development of Licensed Products, including through the Quarterly Reports of the JPT as set forth in Section 2.5.3.5. Without limiting the generality of the foregoing, and after the disbanding of the JPT pursuant to Section 2.5.3.6, on a Licensed Product-by-Licensed Product basis, Merck will provide Mersana, through its alliance manager identified in accordance with Section 2.5.1, with written [\*\*] reports that provide a summary of Merck's [\*\*] activities related to Development and Commercialization of each Licensed Product and the status of Clinical Trials and applications for Regulatory Approval necessary for marketing such Licensed Product. Such reports will be deemed Merck's Confidential Information for the purposes of Section 7.

### 4.3. Technology Disclosure; Supply; Manufacturing.

**4.3.1.** <u>Technology Disclosure</u>. Following Merck making a Pre-Clinical Development Candidate Designation with respect to a Licensed Product, Mersana will disclose and make available to Merck such Mersana Know-How and Mersana Platform Know-How as is necessary or useful to enable Merck to use and reference the Mersana Technology, Mersana Platform Technology and Mersana Regulatory Documentation to practice the applicable Exclusive License on the terms, and subject to the conditions, of this Agreement, including for the Exploitation of ADCs and Licensed Products. [\*\*].

**4.3.2.** <u>Supply Agreements</u>. Commencing at such time that Non-GLP Toxicology Studies are commenced by or on behalf of Merck with respect to a Licensed Product, Merck and Mersana will commence negotiations in good faith to enter into a commercially reasonable supply agreement pursuant to which (a) Mersana will Manufacture and supply to Merck such Licensed Product in order for Merck to conduct GLP Toxicology Studies, if conducted by or on behalf of Merck (other than by Mersana) pursuant to the applicable Research Plan, and Phase I Clinical Trials, for such Licensed Product, and (b) Merck will Manufacture and supply to Mersana the Merck Antibodies and, as applicable, Merck Cytotoxic Compounds, necessary in order for Mersana to perform its obligations under clause (a) of this Section 4.3.2 (each such agreement, a "Supply Agreement"). Under each such Supply Agreement, (i) Mersana will supply the applicable Licensed Product to Merck at [\*\*], and (ii) Merck will supply such Merck Antibody and, as applicable, such Merck Cytotoxic Compound, to Mersana for use in Manufacturing such Licensed Product [\*\*].

**4.3.3.** <u>Transfer of Production Processes</u>. For Clinical Trials following the Phase I Clinical Trials for a Licensed Product, Merck will be responsible for all Manufacturing and supply of Licensed Products. At such times as Merck will request, Mersana will (a) disclose to Merck the names of Mersana's existing, back-up or alternative suppliers of and vendors with respect to Mersana Cytotoxic Compounds, Public Domain Cytotoxic Compounds and ADCs (and any intermediate or component thereof), and (b) continue to provide access to the Mersana Know-How and Mersana Platform Know-How as set forth in Section 4.3.1 in order to timely enable the production of Licensed Products prior to

such Clinical Trials by Merck and/or up to two (2) independent contract manufacturing organizations selected by Merck. Merck will compensate Mersana for such assistance in accordance with Section 6.2.

**4.4.** <u>Booking of Sales</u>; <u>Distribution</u>; <u>Recalls</u>. Merck will have the sole right to invoice and book sales, establish all terms of sale (including pricing and discounts) and warehouse and distribute the Licensed Products in the Territory and perform or cause to be performed all related services. As between the Parties, Merck or its subcontrators and/or Sublicensees will handle all returns, recalls or withdrawals, order processing, invoicing, collection, distribution and inventory management with respect to the Licensed Products in the Territory. Merck will notify Mersana within a reasonable period after commencing any recall of any Licensed Product wherein such recall may be related to Mersana Technology, Mersana Platform Technology or Mersana's Manufacture and supply of such Licensed Product to Merck.

### 5. Regulatory Matters.

#### 5.1. Regulatory Assistance.

**5.1.1.** <u>Merck Rights and Obligations</u>. As between the Parties, Merck will (a) be solely responsible for, and will solely own, all applications for Regulatory Approval and Pricing Approval with respect to a Licensed Product and (b) have the sole right and responsibility to (i) file all INDs and make all other filings with the Regulatory Authorities, and to otherwise seek all Regulatory Approvals and Pricing Approvals for Licensed Products, in the Territory, as well as to conduct all correspondence and communications with Regulatory Authorities regarding such matters and (ii) report all adverse events to Regulatory Authorities if and to the extent required by Applicable Law. Promptly following Merck making a Pre-Clinical Development Candidate Designation with respect to a Licensed Product, Mersana will, and does hereby, assign to Merck or its designated Affiliate or Sublicensee all of its right, title and interest in and to all Regulatory Documentation solely relating to any applicable ADC or such Licensed Product.

**5.1.2.** <u>Mersana Cooperation</u>. At Merck's reasonable request and sole expense, Mersana will consult and cooperate with Merck in and provide all other reasonable assistance preparing filings and submissions necessary to obtain and maintain Regulatory Approval for each Licensed Product. Such assistance may include (a) providing Mersana Regulatory Documentation to the extent it is able to do so without violating the terms of an agreement with a Third Party and which Mersana Regulatory Documentation may be redacted to remove information not relevant for the purposes hereunder, (b) providing other technical information in Mersana's Control that is necessary or useful for Merck in connection with any application for Regulatory Approval or Pricing Approval for the Licensed Product, and (c) providing rights of reference and necessary instruments effectuating such rights to the extent such rights of reference may be granted by Mersana without violating any agreement between Mersana and a Third Party and are necessary or useful in Merck's respective filings relating to a Licensed Product. Merck will compensate Mersana for such assistance in accordance with Section 6.2.

**5.2.** <u>Regulatory Participation</u>. Merck will keep Mersana reasonably informed regarding the status and progress of seeking Regulatory Approval for each Licensed Product, including:

**5.2.1.** <u>Access to Applications</u>. Providing Mersana with access to any applications for Regulatory Approval proposed to be made to or with a Regulatory Authority with respect to a Licensed Product reasonably in advance of filing such applications; and

**5.2.2.** <u>Correspondence</u>. Providing Mersana with a copy of all material, substantive written correspondence from a Regulatory Authority regarding the status and progress of seeking Regulatory Approval for a Licensed Product to the extent such correspondence is related to the Mersana Technology or the Mersana Platform Technology.

#### 6. Fees, Milestones, and Royalties.

**6.1.** <u>Technology Access Fee</u>. After the Effective Date, within [\*\*] days after receipt of the corresponding invoice from Mersana, Merck will pay to Mersana, a one-time, non-refundable, non-

creditable, upfront fee of Twelve Million Dollars (\$12,000,000.00) (the "**Technology Access Fee**"). Payment of the Technology Access Fee shall be subject to any withholding Tax obligations set forth in Section 6.9.1.

### 6.2. Research Fees.

**6.2.1.** <u>Research Fees</u>. Merck will pay Mersana at the annual fully loaded FTE Rate, for each FTE who performs Development, consultation or support work under the applicable Research Plan or this Agreement (including pursuant to Section 4.3.1, Section 4.3.3, and Section 5.1.2), which FTE Rate shall include the cost of routine lab supplies and materials used by such FTEs in such Development, consultation or support work (the "**FTE Fees**"). Merck shall also pay Mersana for all non-routine supplies and materials used by Mersana in the performance of activities under the applicable Research Plan and amounts paid to Third Parties (including consultants, vendors and suppliers) performing activities on behalf of Mersana under the Research Plan (including out-of-pocket costs pursuant to Section 4.3.1, Section 4.3.3, and Section 5.1.2), in each case, at the actual and verifiable out-of-pocket costs to Mersana therefor (the "**Supply Fees**"); *provided* that any such Supply Fees are included in the budget that is included within the applicable Research Plan approved pursuant to Section 2.5.2.2(b). The FTE Fees and the Supply Fees are collectively referred to herein as the "**Research Fees**."

#### 6.2.2. Payment Process.

### 6.2.2.1. Pre-Payments.

- (a) <u>First Calendar Quarter</u>. Following the Effective Date, Merck will make an initial pre-payment of [\*\*] within [\*\*] Business Days after receipt of the corresponding invoice from Mersana to cover [\*\*] percent [\*\*] of the estimated Research Fees for the first Calendar Quarter of the [\*\*] Research Programs.
- (b) <u>Subsequent Calendar Quarters</u>. At the latest [\*\*] days prior to the end of each Calendar Quarter during the Research Program Term for each Research Program, the JPT will develop a good faith estimate of the Research Fees to be incurred during the subsequent Calendar Quarter in such Research Program in accordance with the applicable Research Plan ([\*\*] percent [\*\*] of such estimate, an "Estimated Pre-Payment"). Merck will pay to Mersana within [\*\*] days after the receipt of the corresponding invoice the Estimated Pre-Payment for such Calendar Quarter minus any Overage retained by Mersana.

**6.2.2.2.** <u>Reconciliation</u>. Within [\*\*] days after the end of each Calendar Quarter during each Research Program Term, Mersana will provide Merck with a reasonably detailed invoice including information concerning the Research Fees actually incurred during such Calendar Quarter. If such Research Fees exceed amounts pre-paid by Merck for such Calendar Quarter (including any amounts carried forward from previous

Calendar Quarters pursuant to the next sentence), they will be paid by Merck within [\*\*] days following receipt of the applicable invoice. Any amounts pre-paid pursuant to Section 6.2.2.1 with respect to a Research Program for a Calendar Quarter, that exceed the Research Fees actually incurred during such Calendar Quarter (such excess amount, the "**Overage**"), will be carried forward for pre-payment for the subsequent Calendar Quarter in addition to any additional payment required by Section 6.2.2.1 necessary to make the full Estimated Pre-Payment. Any Overage retained by Mersana and not credited hereunder before the end of a Research Program Term for a Research Program will be refunded to Merck within [\*\*] days following the end of such Research Program Term or the earlier termination of this Agreement.

#### 6.3. Royalties Payable by Merck.

**6.3.1.** <u>Royalties</u>. Merck will pay to Mersana royalties on annual aggregate Net Sales of all Licensed Products at the following rates as set forth below, whereby it is understood that a higher

royalty rate shall only be payable for that portion of Net Sales that exceeds the threshold of sales that determines such higher royalty rate:

Worldwide annual aggregate Net Sales of all Licensed Products	Royalty rate
[**]	[**]
[**]	[**]
[**]	[**]

**6.3.2.** <u>Royalty Example</u>. For avoidance of doubt, the incremental royalty rates set forth in Section 6.3.1 will only apply to that portion of the Net Sales that falls within the indicated range of sales. By way of example only if, during a Calendar Year, Net Sales of all Licensed Products were equal to [\*\*] million, the royalty payable by Merck would be calculated by adding (a) the royalty due on Net Sales with respect to the first [\*\*] million at the first level percentage of [\*\*] percent [\*\*] and (b) the royalty due on Net Sales with respect to the next [\*\*] million at the second level percentage of [\*\*] percent [\*\*]. The obligation to pay royalties will be imposed only once with respect to the same unit of Licensed Product sold by Merck, its Affiliates or Sublicensees.

**6.3.3.** <u>Royalty Term</u>. Merck's obligation to pay royalties under Section 6.3.1 will commence on the First Commercial Sale of a Licensed Product and continue on a country-by-country and Licensed Product-by-Licensed Product basis until the later to occur of (a) the last to expire Valid Patent Claim of any Mersana Patent Right or Mersana Platform Patent Right covering or claiming the Exploitation of such Licensed Product in such country or (b) ten (10) years following the date of First Commercial Sale of such Licensed Product in such country (the "Royalty Term").

# 6.3.4. Royalty Adjustments.

**6.3.4.1.** <u>No Mersana Patent Right Coverage</u>. On a country-by-country and Licensed Product-by-Licensed Product basis, at such time that there is no Valid Patent Claim of any Mersana Patent Right, or Mersana Platform Patent Right covering or claiming the Exploitation of such Licensed Product in such country, the amount of payment owed pursuant to Section 6.3.1 with respect to Net Sales of such Licensed Product will be [\*\*] percent [\*\*] of the amount that would otherwise be due pursuant to Section 6.3.1.

# 6.3.4.2. Third Party Agreements.

- (a) Merck will be entitled to deduct from the amount due to Mersana under Section 6.3.1 with respect to Net Sales of a Licensed Product in a particular country in the Territory an amount equal to [\*\*] percent [\*\*] of any amounts incurred in the license of Third Party rights [\*\*].
- (b) Mersana will promptly notify Merck of any Future Mersana In-License. If Merck wishes to include the rights granted to Mersana under such Future Mersana In-license within the scope of an Exclusive License, it will notify Mersana within [\*\*] days after receiving notice of such agreement from Mersana and the Parties will negotiate the economic terms thereof in good faith for a period of [\*\*] days thereafter. If the Parties reach agreement on such economic terms, such Third Party agreement will be deemed to be a Future Mersana In-License. If under such agreement, Merck is responsible for paying royalties owed by Mersana under any such Future Mersana In-License to the extent due as a result of Exploitation of a

Licensed Product in the Territory by Merck or its Affiliates or Sublicensees, Merck will be entitled to deduct from the amount due to Mersana under Section 6.3.1 with respect to Net Sales of a Licensed Product in a particular country in the Territory an amount equal to [\*\*] percent [\*\*] of any amounts paid by Merck under such Future Mersana In-License based upon the sales of, or to the extent incurred with respect to the Exploitation of, such Licensed Product in such country.

**6.3.4.3.** <u>Competing Product</u>. If, in a country of the Territory, a Licensed Product is [\*\*] covered by one or more [\*\*] claims of any [\*\*] Patent Right or [\*\*] Patent Right, which, but for the licenses granted under this Agreement, would be infringed by the Commercialization of such Licensed Product, and the Commercialization of a Licensed Product in such country is not covered by any [\*\*] Patent Right, and where a Competing Product with respect to such Licensed Product [\*\*], Merck may reduce the royalties that would otherwise be due pursuant to Section 6.3.1 based on Net Sales in such country by [\*\*] percent [\*\*]; *provided* however, that such royalties shall only be reduced until the earlier of when (a) [\*\*] Mersana takes action to stop Commercialization of such Competing Product ([\*\*]); or (b) such Competing Product is withdrawn from the market in said country.

**6.3.4.4.** <u>Limitations on Royalty Adjustments</u>. Notwithstanding anything to the contrary, in no event will the royalty rates for payments to Mersana be reduced pursuant to Section 6.3.4.1, Section 6.3.4.2, and Section 6.3.4.3 below [\*\*] percent [\*\*] of the royalty payments otherwise due pursuant to Section 6.3.1.

**6.4.** <u>Development Milestone Payments</u>. Merck shall promptly notify Mersana after the first occurrence of each event set forth in the table below with respect to each Designated Target or Licensed Product, as applicable, to achieve such event and pay to Mersana the following milestone payments within [\*\*] days following the receipt of the corresponding invoice from Mersana:

Row	Development Milestone	Payment
1	Delivery by Mersana of an ADC directed to each Designated Target that meets the Performance Specifications set forth in the applicable Research Plan	\$500,000
2	[**]	[**]
3	[**]	[**]
4	[**]	[**]
5	[**]	[**]
6	Dosing of the first patient in the first Phase III Clinical Trial for the Licensed Product	[**]
7	Regulatory Approval for the Licensed Product in a first indication in the US by the applicable Regulatory Authority	[**]
8	Regulatory Approval of the Licensed Product for a first indication in any country in the European Union by the applicable Regulatory Authority	[**]
9	Regulatory Approval of the Licensed Product for a first indication in Japan by the applicable Regulatory Authority	[**]
10	Regulatory Approval of the Licensed Product for a second indication in the United States by the applicable Regulatory Authority	[**]
11	Regulatory Approval of the Licensed Product for a third indication in the United States by the applicable Regulatory Authority	[**]

# 6.5. Sales Milestone Payments.

**6.5.1.** <u>Sales Milestones</u>. With respect to each Licensed Product, Merck shall notify Mersana within [\*\*] days after the end of the Calendar Quarter in which the annual aggregate Net Sales of such Licensed Product in the Territory first reach the following thresholds and will pay to Mersana the following sales milestone payments within [\*\*] days after receipt of the corresponding invoice from Mersana:

Annual Net Sales of a Licensed Product	Payment
Greater than [**]	[**]
Greater than [**]	[**]
Greater than [**]	[**]

**6.5.2.** <u>Sales Milestones Payment Limitations</u>. Each sales milestone payment is separate and may only be earned once for each Licensed Product, irrespective of the number of times such thresholds are achieved for such Licensed Product, but if more than one Net Sales threshold is reached in the same Calendar Year, all corresponding sales milestone payments will be payable during such Calendar Year. For example, if annual Net Sales of a Licensed Product [\*\*].

**6.6.** <u>Payment Terms</u>. Royalties shown to have accrued by each Royalty Report provided for under Section 6.10 will be due on the date such Royalty Report is due pursuant to Section 6.10.1.1.

**6.7.** <u>Payment Method</u>. All payments by Merck to Mersana under this Agreement will be paid in United States Dollars, and all such payments will be made by bank wire transfer in immediately available funds to the bank account designated by Mersana in writing; *provided*, that such account information is provided to Merck at least [\*\*] days prior to any such payment becoming due hereunder.

**6.8.** Late Payments. All payments under this Agreement shall earn interest from the date due until paid at a per annum rate equal to the lesser of (a) the maximum rate permissible under Applicable Law and (b) [\*\*] percent [\*\*] above the monthly Reuters 01 EURIBOR, measured at 2 p.m. Frankfurt/Germany time on the date payment is due. Interest will be calculated on a 365/360 basis.

# 6.9. <u>Taxes</u>

**6.9.1.** <u>Withholding Taxes</u>. Except as otherwise provided below, all amounts due from Merck to Mersana under this Agreement are gross amounts. Merck will be entitled to deduct the amount of any withholding Taxes payable or required by Applicable Law to be withheld by Merck, its Affiliates or Sublicensees, to the extent Merck, its Affiliates or Sublicensees pay such withheld amounts to the appropriate Governmental Authority on behalf of Mersana. Merck will use Commercially Reasonable Efforts to minimize any such Taxes, levies or charges required to be withheld on behalf of Mersana by Merck, its Affiliates or Sublicensees. Merck promptly will deliver to Mersana proof of payment of all such Taxes, levies and other charges, together with copies of all communications from or with such Governmental Authority with respect thereto, and other supporting documentation as may be required by the Governmental Authority, and will cooperate with Mersana in seeking any related Tax exemption or credits that may be available to Mersana with respect thereto.

# 6.9.2. Value Added Tax (VAT).

**6.9.2.1.** All remuneration amounts paid by Merck to Mersana are net amounts. It is the common understanding of the Parties that the transactions under this Agreement are subject to the reverse-charge-mechanism under the German VAT Code. Mersana will refer to the reverse-charge-mechanism in its proper invoices and will not add VAT to the net amounts in the invoices. Merck will pay this VAT according to the German VAT Code.

**6.9.2.2.** In case the transactions under this Agreement are subject to VAT (or similar GST or sales Taxes) within the United States, VAT shall be added to the net amounts and be paid by Merck to Mersana. Mersana shall remit such VAT to the proper Tax authorities and shall cooperate with Merck in any way reasonably requested by Merck, to obtain available reductions, credits or refunds of any VAT amount attributable to the transactions under this Agreement unless otherwise stated by local

law. In that case Merck is entitled to receive a proper invoice where any VAT amount is shown separately.

#### 6.10. Royalty Reports and Accounting

### 6.10.1. Royalty Reports, Payments and Exchange Rates.

**6.10.1.1. Royalty Reports and Payments**. Within [\*\*] days after the end of each Calendar Quarter during which Licensed Products have been sold, Merck shall deliver to Mersana, together with the applicable royalty payment due, a written report (each, a "**Royalty Report**"). Each such Royalty Report shall be deemed "Confidential Information" of Merck subject to the obligations of Section 7 and shall include on a Licensed Product-by-Licensed Product and a country-by-country basis in reasonable detail:

- (a) the Net Sales of Licensed Products in the Territory and the royalties payable in United States Dollars;
- (b) the month and Calendar Year of the First Commercial Sale of each Licensed Product in each country in the Territory for which royalties are due hereunder, if it has occurred during the corresponding Calendar Quarter; and
- (c) the exchange rates (as determined pursuant to Section 6.10.1.2) used in determining the royalty amount expressed in United States Dollars.

**6.10.1.2. Exchange Rates**. With respect to sales not denominated in United States Dollars, Merck shall convert each applicable quarterly sales in foreign currency into United States Dollars by using the then-current and reasonable standard exchange rate methodology applied to its external reporting. Based on the resulting sales in United States Dollars, the then applicable royalties shall be calculated. The Parties may vary the method of payment set forth herein at any time upon mutual agreement, and any change shall be consistent with the Applicable Law at the place of payment or remittance.

#### 6.10.2. <u>Audits</u>.

**6.10.2.1.** Upon the written request of Mersana and with at least [\*\*] days prior written notice, but not more than once in any Calendar Year, Merck will permit an independent certified public accounting firm of internationally recognized standing, selected by Mersana and reasonably acceptable to Merck, at Mersana's sole cost and expense (except as set forth in this Section 6.10.2), to have access during normal business hours to such of the records of Merck as required to be maintained under this Agreement to verify the accuracy of the Royalty Reports due hereunder. Such accountants may audit records relating to Royalty Reports made for any year ending not more than [\*\*] months prior to the date of such request. The accounting firm will disclose to Mersana only whether the Royalty Reports were correct or not, and the specific details concerning any discrepancies and such information will be shared at the same time with Merck. No other information obtained by such accountants will be shared with Mersana.

**6.10.2.2.** If such accounting firm concludes that any royalties were owed but not paid to Mersana, Merck will pay the additional royalties within [\*\*] days following the date Mersana delivers to Merck such accounting firm's written report so concluding, together with the interest payment required by Section 6.8. The fees charged by such accounting firm will be paid by Mersana; *provided*, that if the audit discloses that the royalties payable by Merck for the audited period are more than [\*\*] percent [\*\*] of the royalties actually paid for such period, then Merck will pay the reasonable fees and expenses charged by such accounting firm. If such accounting firm concludes that the royalties paid were more than what was owed during such period, Mersana will refund the overpayments within [\*\*] days following the date Mersana receives such accounting firm's written report so concluding.



**6.10.2.3.** Upon the written request of Merck and with at [\*\*] days prior written notice, but not more than once in any Calendar Year, Mersana will permit an independent certified public accounting firm of internationally recognized standing, selected by Merck and reasonably acceptable to Mersana, at Merck's sole cost and expense, to have access during normal business hours to such of the records of Mersana as required to be maintained under this Agreement to verify the accuracy of the Research Fees and fees incurred by the Exploitation of Future Mersana In-licenses due hereunder. Such accountants may audit such records made for any year ending not more than [\*\*] months prior to the date of such request. The accounting firm will disclose to Merck only whether the Research Fees or fees incurred by the Exploitation of Future Mersana In-licenses were correct or not, and the specific details concerning any discrepancies and such information will be shared at the same time with Mersana. No other information obtained by such accountants will be shared with Merck.

**6.10.2.4.** If such accounting firm concludes that any Research Fees or other reimbursements were paid but not owed to Mersana, Mersana will refund or reimburse Merck such overpaid amounts within [\*\*] days following the date Merck delivers to Mersana such accounting firm's written report so concluding, together with the interest payment required by Section 6.8. The fees charged by such accounting firm will be paid by Merck; *provided*, that if the audit discloses that the Research Fees or other reimbursements payable by Merck for the audited period are less than [\*\*] percent [\*\*] of such amounts actually paid for such period, then Mersana will pay the reasonable fees and expenses charged by such accounting firm. If such accounting firm concludes that the Research Fees or fees incurred by the Exploitation of Future Mersana In-licenses paid were less than what was owed during such period, Merck will pay the underpayments within [\*\*] days following the date Merck receives such accounting firm's written report so concluding.

**6.10.3.** <u>Confidential Financial Information</u>. Each Party will treat all financial information of the other Party subject to review under this Section 6 or under any sublicense agreement of the other Party as Confidential Information of such other Party as set forth in Section 7, and will cause its accounting firm to retain all such financial information in confidence under terms substantially similar to those set forth in Section 7 and with respect to each inspection, the independent accounting firm will be obliged to execute for each Party's benefit a reasonable confidentiality agreement prior to commencing any such inspection.

### 7. Confidentiality.

**7.1.** <u>Non-Disclosure Obligations</u>. Except as otherwise provided in this Section 7 during the Term and for a period of [\*\*] years thereafter, each Party and their respective Affiliates will maintain in confidence, and use only for purposes as expressly authorized and contemplated by this Agreement, all Confidential Information of the other Party. The terms of this Agreement and Confidential Information consisting of Joint Know-How will be Confidential Information of both Parties (and both Parties will be deemed the receiving Party with respect thereto). Each Party will use at least the same standard of care as it uses (but not less than reasonable care) to protect its own Confidential Information for purposes as expressly authorized and contemplated by this Agreement and clinical investigators only make use of the other Party's Confidential Information for purposes as expressly authorized and contemplated by this Agreement and do not disclose or make any unauthorized use of such Confidential Information.

#### 7.2. Permitted Disclosures.

**7.2.1.** Exceptions. The provisions of Section 7.1 will not apply to information, documents or materials that the receiving Party can conclusively establish:

7.2.1.1. have become published or otherwise entered the public domain or become generally available to the public other than by breach of this Agreement by the receiving Party or its Affiliates;

7.2.1.2. are permitted to be disclosed by prior consent of the other Party;

**7.2.1.3.** have become known to the receiving Party by a Third Party, provided such Confidential Information was not obtained by such Third Party directly or indirectly from the disclosing Party on a confidential basis;

**7.2.1.4.** prior to disclosure under this Agreement, were already in the possession of the receiving Party, its Affiliates or Sublicensees; or

**7.2.1.5.** have been independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information;

**7.2.2.** <u>Limitations on Exceptions</u>. The exceptions described in Section 7.2.1.4 and Section 7.2.1.5 will not apply with respect to Confidential Information constituting (a) Mersana Platform Know-How that was originally invented, conceived or developed by Merck or (b) Product Know-How originally invented, conceived or developed by Mersana.

**7.2.3.** Other Permitted Disclosures. Each Party may also disclose Confidential Information as set forth below in this Section 7.2.3. Notwithstanding the disclosures permitted under this Section 7.2.3, any Confidential Information so disclosed will remain subject to the confidentiality obligations of Section 7.1, unless and until any exceptions described in Section 7.2.1 will apply. Either Party may disclose Confidential Information to the extent such disclosure is made:

**7.2.3.1.** in response to a valid order of a court of competent jurisdiction or other Governmental Authority or Regulatory Authority 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 (including the rules and regulations of any stock exchange or trading market on which the disclosing Party's (or its parent's) securities are traded); *provided*, that the receiving Party where reasonably practicable will 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 or requirement be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; *provided, further*, that the Confidential Information disclosed in response to such court or governmental order or Applicable Law will be limited to that information which is legally required to be disclosed in response to such court or governmental order or Applicable Law (including the rules and regulations of any stock exchange or trading market on which the disclosing Party's (or its parent's) securities are traded);

**7.2.3.2.** solely to the extent reasonably necessary in a patent application claiming Product Patent Rights or Mersana Platform Patent Rights made hereunder to be filed with the United States Patent and Trademark Office or any similar foreign agency; *provided*, that the Party filing the patent will provide at least [\*\*] days prior written notice of such disclosure to the other Party and take reasonable and lawful actions to avoid or minimize the degree of disclosure;

**7.2.3.3.** by Merck, to a Regulatory Authority, as reasonably required or useful in connection with any filing, submission or communication with respect to any ADC or Licensed Product; *provided*, that reasonable measures will be taken to assure confidential treatment of such information, to the extent such protection is available;

**7.2.3.4.** to a Sublicensee as permitted hereunder; *provided*, that such Sublicensee is then subject to obligations of confidentiality and limitations on use of such Confidential Information substantially similar to those contained herein and Merck otherwise complies with Section 3.3; and

**7.2.3.5.** by Mersana to actual or potential strategic partners, investors or acquirers; *provided*, that such disclosures will be limited to the terms of this Agreement and pre-clinical data and results, in each case arising out of a Research Program and that are presented in a manner that does not divulge or otherwise make available (a) the identity of any Designated Target, (b) the identity of any ADC or any Merck Antibody used in the Research Program, or (c) the identity of Merck or any of its Affiliates or Sublicensees; *provided*, further, that, in each case, such Third Party recipient is then subject

to obligations of confidentiality and limitations on use of such Confidential Information substantially similar to those contained herein.

**7.3.** <u>Press Releases and Other Disclosures to Third Parties</u>. Neither Mersana nor Merck will, without the prior consent of the other, issue any press release or make any other public announcement or furnish any statement to any person or entity (other than either Party's respective Affiliates) concerning the existence of this Agreement, its terms and the transactions contemplated hereby, except for (a) an initial press release mutually agreed upon by the Parties and substantially in the form attached hereto as <u>Schedule 7.3</u>, (b) disclosures made in compliance with Section 7.1, Section 7.2 and Section 7.4, (c) disclosures made to attorneys, consultants, and accountants retained to represent the Parties in connection with the negotiation and consummation of the transactions contemplated hereby, and (d) press releases by Merck, in its sole discretion, regarding Merck's activities under this Agreement with respect to a Licensed Product following Merck making a Pre-Clinical Development Candidate Designation with respect thereto, with Mersana being provided a courtesy copy of such press release. In addition, if so required, first approval by a Party of the contents of a press release or public disclosure will constitute permission of a Party to use such same contents subsequently, without submission of the press release or public disclosure to a Party for approval.

**7.4.** Use of Name. Except as expressly provided herein, neither Party will mention or otherwise use the name, logo or trademark of the other Party or any of its Affiliates or any of its or their Sublicensees (or any abbreviation or adaptation thereof) (including any Product Trademark) in any publication, press release, marketing and promotional material or other form of publicity without the prior written consent of such other Party. The restrictions imposed by this Section 7.4 will not prohibit either Party from making any disclosure identifying the other Party (a) to the extent required in connection with its exercise of its rights or obligations under this Agreement or (b) that is required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted).

**7.5.** Publications Regarding Results of the Research Program. Neither Party may publish, present or announce results of the Research Programs or Development of ADCs or Licensed Products hereunder either orally or in writing (a "Publication") without complying with the provisions of this Section 7.5. A Party wishing to make a Publication will provide the other Party with a copy of the proposed Publication. The other Party will have [\*\*] days from receipt of a proposed Publication to provide comments or proposed changes to the publishing Party. The publishing Party will take into account the comments or proposed changes made by the other Party on any Publication and will agree to designate employees or others acting on behalf of the other Party as co-authors on any Publication describing results to which such persons have contributed in accordance with standards applicable to authorship of scientific publications. If the other Party reasonably determines that the Publication should be filed prior to any such disclosure, submission of the concerned Publication to Third Parties will be delayed for such period as may be reasonably necessary for deleting any such Confidential Information or of the other Party (if the other Party has requested deletion thereof from the proposed Publication), or the drafting and filing of a patent application covering or claiming such invention, provided such additional period will not exceed [\*\*] days from the date the publishing Party first provided the proposed Publication to the other Party. Notwithstanding anything to the contrary in the foregoing, with respect to any Publications by investigators, such materials will be subject to review by Mersana under this Section 7.5 only to the extent that Merck has the right to review such Publications, and Merck will use Commercially Reasonable Efforts to obtain such right.

**7.6.** <u>Return of Confidential Information</u>. Upon the earlier of (a) the effective date of the termination of this Agreement for any reason or (b) the expiration or termination of the Target Exclusivity Period with respect to a Designated Target, in each case (of (a) and (b)) with respect to Confidential Information to which such non-requesting Party does not retain rights under the surviving provisions of this Agreement each Party will, upon and in accordance with the other Party's request in writing, either: (i) promptly destroy all copies of such Confidential Information in the possession or control of the non-requesting Party and confirm 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 will be permitted to retain such Confidential Information (A) to the extent necessary or useful for purposes of performing any continuing obligations or exercising any ongoing rights hereunder and, in any event, a single copy of such Confidential Information for archival purposes and (B) 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, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information will continue to be subject to the terms of this Agreement for the period set forth in Section 7.1.

# 8. Inventions and Patents.

**8.1.** <u>Disclosure of Inventions</u>. Merck will promptly disclose to Mersana any Joint Technology, Mersana Platform Technology or Product Technology that Merck invents, conceives, develops or reduces to practice. Mersana will promptly disclose to Merck any Joint Technology or Product Technology that Mersana invents, conceives, develops or reduces to practice.

### 8.2. Ownership of Intellectual Property.

**8.2.1.** <u>Mersana Rights</u>. The Parties acknowledge and agree that Mersana is and will be the sole and exclusive owner of all right, title and interest in and to any Mersana Technology and any Mersana Platform Technology.

**8.2.2.** <u>Merck Rights</u>. The Parties acknowledge and agree that Merck is and will be the sole and exclusive owner or licensee of all right, title and interest in and to any Merck Technology and any Product Technology.

**8.2.3.** Joint Technology. The Parties acknowledge and agree that the Parties will each own an equal, undivided interest in Joint Technology. Each Party will have the right to Exploit the Joint Technology without a duty of seeking consent of or accounting to the other Party; *provided*, that neither Party will have the right to disclose (except as provided in Section 7) or license (except as may be permitted under Section 3) any Joint Technology without the prior written consent of the other Party.

**8.2.4.** <u>Other Intellectual Property</u>. Except as set forth above in this Section 8.2, all Know-How and Patent Rights will be owned by the Party that invented, conceived or developed such Know-How or Patent Rights, and the determination of which Party invented, conceived or developed such Know-How or Patent Rights will be made in accordance with Applicable Law in the United States.

**8.2.5.** <u>Assignment of Rights</u>. Each Party will and hereby does assign to the other Party, and will cause each of its officers, directors, employees, Affiliates, Sublicensees (in the case of Merck), subcontractors and agents to assign to the other Party any right, title and interest in and to Patent Rights and Know-How, without additional compensation, as is necessary to fully effect the sole and joint ownership of Mersana Platform Technology, Product Technology, and Joint Technology provided for Section 8.2.1, Section 8.2.2 and Section 8.2.3.

### 8.3. Patent Prosecution and Maintenance.

**8.3.1.** <u>Mersana Patent Rights</u>. Mersana will have the sole right and authority, but not the obligation, to prepare, file, prosecute and maintain the Mersana Patent Rights on a worldwide basis and to be responsible for any related interference, re-issuance, re-examination and opposition proceedings, in each case, at Mersana's sole expense.

**8.3.2.** <u>Merck Patent Rights</u>. Merck will have the sole right and authority, but not the obligation, to prepare, file, prosecute and maintain the Merck Patent Rights on a worldwide basis, and to be responsible for any related interference, re-issuance, re-examination and opposition proceedings, in each case, at Merck's sole expense.

**8.3.3.** <u>Mersana Platform Patent Rights</u>. Subject to Section 8.3.6, Mersana will have the sole right and authority, but not the obligation, to prepare, file, prosecute and maintain the Mersana Platform Patent Rights on a worldwide basis and to be responsible for any related interference, re-issuance, re-examination and opposition proceedings, in each case, at Mersana's sole expense.

**8.3.4.** <u>Product Patent Rights</u>. Subject to Section 8.3.6 and Section 2.4.4.2(b), Merck will have the sole right and authority, but not the obligation, to prepare, file, prosecute and maintain the Product Patent Rights covering or claiming such Licensed Product on a worldwide basis and to be responsible for any related interference, re-issuance, re-examination and opposition proceedings, in each case, at Merck's sole expense.

**8.3.5.** Joint Patent Rights. Mersana will have the first right and authority, but not the obligation, to prepare, file, prosecute and maintain the Joint Patent Rights on a worldwide basis and to be responsible for any related interference, re-issuance, re-examination and opposition proceedings. Mersana will keep Merck reasonably informed and provide reasonable opportunity for Merck to comment with respect to all material steps with regard to the filing, prosecution and maintenance of Joint Patent Rights and will reasonably consider such comments in good faith. The Parties will [\*\*] the costs associated with filing, prosecution, and maintenance of such Joint Patent Rights; *provided*, that Merck will have the right, on written notice to Mersana to elect not to bear such costs with respect to a Joint Patent Right, in which case Merck will, and does hereby, assign its right, title and interest in and to such Joint Patent Right to Mersana. If Mersana decides not to continue prosecuting any Joint Patent Rights, then Mersana will promptly so notify Merck in writing (which written notice will be at least [\*\*] days before any relevant deadline prior to taking any extension for such Joint Patent Right), in which case, Mersana will, and does hereby, assign its right, title and interest in and to such Joint Patent Right), in which case, Mersana will, and does hereby, assign its right, to Merck. Thereafter, Merck will have the right, but not the obligation, to prosecute or maintain such Joint Patent Right, and to be responsible for any related interference, re-issuance, re-examination and opposition proceedings, at Merck's sole expense.

#### 8.3.6. Cooperation.

**8.3.6.1.** The Parties will at all times fully cooperate with each other in order to reasonably implement the foregoing provisions of this Section 8.3. Such cooperation may include each Party's execution of necessary legal documents, coordinating filing or prosecution of applications to avoid potential issues during prosecution (including novelty, enablement, estoppel and double patenting and execution of amendments), and the assistance of each Party's relevant personnel. Each Party will use reasonable efforts to avoid creating potential issues in prosecution of the patent applications covering or claiming Mersana Patent Rights, Mersana Platform Patent Rights, Merck Patent Rights or Joint Patent Rights via the JIPC.

**8.3.6.2.** Notwithstanding anything to the contrary in this Agreement, it is agreed between the Parties that Merck shall have the right to making any filing in a country with respect to a Product Patent Right beyond the date that is four weeks prior to IND filing or application for Regulatory Approval.

**8.3.7.** <u>Patent Term Extension and Supplementary Protection Certificate</u>. As between the Parties, [\*\*] will have the sole right to make decisions regarding, and to apply for, patent term extensions in the Territory, including in the United States with respect to extensions pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable (collectively, the "Extensions"), for the [\*\*] Patent Rights and [\*\*] Patent Rights, in each case including whether or not to do so. [\*\*] will provide prompt and reasonable assistance with respect thereto, as requested by [\*\*], including by taking such action as is required under any Applicable Law to obtain such extension or supplementary protection certificate. As between the Parties, [\*\*] will have the sole right to make decisions regarding, and to apply for, Extensions for the [\*\*] Patent Rights, [\*\*] Patent Rights, and [\*\*].

**8.3.8.** <u>Common Ownership Under Joint Research Agreements</u>. Notwithstanding anything to the contrary in this Section 8, neither Party will have the right to make an election under 35

U.S.C. 103(c) when exercising its rights under this Section 8 without the prior written consent of the other Party. With respect to any such permitted election, the Parties will coordinate their activities with respect to any submissions, filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined in 35 U.S.C. 100(h).

### 8.4. Enforcement of Patent Rights.

**8.4.1.** <u>Notification of Infringement</u>. In the event either Party becomes aware of an infringement by a Third Party of a Mersana Patent Right, Mersana Platform Patent Right, Merck Patent Right, Product Patent Right or Joint Patent Right it will promptly notify the other Party. In no event will a Party make an argument or settle a dispute that would render a claim in a Joint Patent Right or, in the case of Merck, a Mersana Platform Patent Right or Mersana Patent Right, or, in the case of Mersana, a Product Patent Right or Merck Patent Right, to be invalid or unenforceable without the other Party's prior written consent.

**8.4.2.** <u>Mersana Patent Rights</u>; <u>Mersana Platform Patent Rights</u>. Mersana will have the sole right, at its sole expense, but not the obligation, to determine the appropriate course of action to enforce the Mersana Patent Rights and the Mersana Platform Patent Rights or otherwise to abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce the Mersana Patent Rights and the Mersana Patent Rights, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to the Mersana Patent Rights and the Mersana Platform Patent Rights. Merck shall cooperate with and assist Mersana in all reasonable respects with any such litigation, enforcement action, or settlement. Upon the reasonable request of Mersana, Merck shall join such litigation, enforcement action, or settlement and shall be represented using counsel of its own choice, at Mersana's expense.

**8.4.3.** <u>Merck Patent Rights</u>. Merck will have the sole right, at its sole expense, but not the obligation, to determine the appropriate course of action to enforce Merck Patent Rights, or otherwise to abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce the Merck Patent Rights, to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to the Merck Patent Rights. Mersana shall cooperate with and assist Merck in all reasonable respects with any such litigation, enforcement action, or settlement. Upon the reasonable request of Merck, Mersana shall join such litigation, enforcement and shall be represented using counsel of its own choice, at Merck's expense.

**8.4.4.** [\*\*]. [\*\*] will have the sole right, at its sole expense, to determine the appropriate course of action to enforce [\*\*], or otherwise to abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce the [\*\*], to control any litigation or other enforcement action and to enter into, or permit, the settlement of any such litigation or other enforcement action with respect to the [\*\*]. [\*\*] will fully cooperate with [\*\*], at [\*\*] request and expense, in any action to enforce the [\*\*]. All monies recovered upon the final judgment or settlement of any such suit to enforce any such [\*\*] will be allocated first to [\*\*] to the extent necessary to compensate it for its expenses in its enforcement, second to [\*\*] to the extent necessary to compensate it for its expenses in cooperating with [\*\*] in its enforcement, and finally any remaining amounts will be split between the Parties so that Mersana retains [\*\*] percent [\*\*] and Merck retains [\*\*] percent [\*\*] of such amounts.

**8.4.5.** Joint Patent Rights. The Parties shall discuss and mutually agree on an appropriate course of action in the event of any infringement by a Third Party of any Joint Patent Right.

**8.5.** <u>In-Licensed Patent Rights</u>. Notwithstanding anything to the contrary in this Agreement, with respect to any Mersana Patent Rights or Mersana Platform Patent Rights that are subject to the Original Mersana In-Licenses or any Future Mersana In-Licenses, the rights and obligations of the Parties under Section 8.3 and 8.4 will be subject to Mersana's licensors' rights to participate in and control prosecution, maintenance and enforcement of such Mersana Patent Rights and Mersana Platform Patent Rights, and to receive a share of damages recovered in such action, in accordance with the terms and conditions of the applicable Original Mersana In-License or Future Mersana In-License.

### 8.6. Trademarks.

**8.6.1.** Merck will be responsible for the selection, registration, maintenance and defense of all trademarks for use in connection with the sale or marketing of the Licensed Products in the Territory (collectively, "**Product Trademarks**") at Merck's own cost and expense, and Merck will own such Product Trademarks.

**8.6.2.** Mersana will not, and will not permit its Affiliates to, attack, dispute or contest the validity of or ownership of any Product Trademark anywhere in the Territory or any registrations issued or issuing with respect thereto that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of any Product Trademark. Mersana will not, and will not permit its Affiliates to, (a) use in their respective businesses, any trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of any product Trademark, misleading or deceptive with respect to or that dilutes any (or any part) of any Product Trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of any Product Trademark and (b) do any act that endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to any Product Trademark.

**8.6.3.** Merck will not, and will not permit its Affiliates to, attack, dispute or contest the validity of or ownership of any trademark owned or Controlled by Mersana that is used in connection with the sale or marketing of products arising out of Exploitation of the Mersana Technology or Mersana Platform Technology ("**Mersana Trademarks**"), anywhere in the Territory or any registrations issued or issuing with respect thereto that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of any Mersana Trademark. Merck will not, and will not permit its Affiliates to, (a) use in their respective businesses, any trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (b) do any act that endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to any Mersana Trademark.

#### 9. Infringement or Other Actions Brought by Third Parties.

#### 9.1. Third Party Actions.

**9.1.1.** Notice of Third Party Actions. Each Party will immediately disclose to the other Party in writing any warning letter or other notice of infringement or misappropriation received by a Party, or any action, suit or proceeding brought against a Party alleging infringement of a Patent Right or misappropriation of intellectual property of any Third Party with regard to any aspect of the conduct by either Party, its Affiliates or Sublicensees pursuant to this Agreement or a Research Program (each, a "Third Party Action").

**9.1.2.** <u>Consultation; Settlement</u>. The Parties will reasonably consult and cooperate with each other in all such actions or proceedings. No Party will admit the invalidity or unenforceability of any Patent Right Controlled by the other Party without the other Party's prior written consent.

### 9.1.3. Practice of Product Technology; Exploitation of a Licensed Product.

**9.1.3.1.** [\*\*], at its own expense and through counsel of its choosing, will have the first right, but not the obligation to defend against or settle any Third Party Action in the Territory alleging that the Exploitation of any Licensed Product or the practice of Product Technology infringes or misappropriates a Third Party's intellectual property rights. [\*\*] will have the sole and exclusive right to select counsel for such Third Party Action.

**9.1.3.2.** In the event that any Third Party Action in the Territory involves an allegation that (a) the Exploitation of any Licensed Product or the practice of Product Technology infringes or misappropriates a Third Party's intellectual property rights, **and** (b) the practice of the Mersana Technology or the Mersana Platform Technology infringes or misappropriates such Third Party's intellectual property rights, and if [\*\*] declines to defend or fails to assert its intention to defend or to settle such a Third Party Action under Section 9.1.3.1 within [\*\*] days following the receipt or provision of notice under Section 9.1.1, then [\*\*], at its own expense and through counsel of its choosing,

will have the right, but not the obligation to defend against any such Third Party Action. [\*\*] will have the sole and exclusive right to select counsel for such Third Party Action.

**9.1.3.3.** In case the practice of the Mersana Technology or the Mersana Platform Technology by Merck, in each case as such Mersana Technology or Mersana Platform Technology exists as of the Effective Date, infringes or misappropriates a Third Party's intellectual property rights, all settlement costs (excluding any amounts paid under any license entered into in connection with the settlement of any such suit) and the payment of any damages to the Third Party shall be borne solely by Mersana, inclusive of cases where Merck defends or settles the claim according to Section 9.1.3.1 and Section 9.1.3.2; *provided* that any amounts paid by Mersana pursuant to this Section 9.1.3.3 shall not exceed the lesser of (a) [\*\*] and (b) [\*\*].

**9.1.4.** <u>Practice of Mersana Technology or Mersana Platform Technology</u>. Except as provided in Section 9.1.3.1 and Section 9.1.3.2, Mersana, at its own expense and through counsel of its choosing, will have the sole right, but not the obligation to defend against any Third Party Action in the Territory alleging that the practice of the Mersana Technology or the Mersana Platform Technology infringes or misappropriates a Third Party's intellectual property rights. Mersana will have the sole and exclusive right to select counsel for such Third Party Action.

**9.1.5.** <u>Practice of Merck Technology</u>. Except as provided in Section 9.1.3 or Section 9.1.4, Merck, at its own expense and through counsel of its choosing, will have the sole right, but not the obligation to defend against any Third Party Action in the Territory alleging that the practice of the Merck Technology infringes or misappropriates a Third Party's intellectual property rights. Merck will have the sole and exclusive right to select counsel for such Third Party Action.

### 10. Representations, Warranties and Covenants.

**10.1.** <u>Mutual Representations and Warranties</u>. Each Party hereby represents and warrants, as of the Effective Date, and covenants (as applicable) to the other Party as follows:

**10.1.1.** <u>Corporate Existence and Power</u>. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the licenses granted by it hereunder.

**10.1.2.** <u>Authority and Binding Agreement</u>. As of the Effective Date, (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; (c) this Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms; and (d) its execution of and performance under this Agreement will not violate or breach any obligation or restriction (including any confidentiality or non-competition obligation or any exclusivity restriction) to which such Party is legally bound by contract, judicial order or otherwise.

**10.1.3.** <u>No Conflict</u>. It is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement. It has the full right to grant the licenses or sublicenses (as applicable) granted herein and such grant will not result in the misappropriation of any Third Party intellectual property or violation of such Third Party's rights with respect thereto. During the Term, it will not enter into any agreement, contract, commitment or other arrangement that could reasonably be expected to conflict with the rights granted to the other Party hereunder or otherwise prevent the other Party from exercising the rights granted to such other Party hereunder. Neither Party will misappropriate any trade secret of a Third Party in connection with the performance of its activities hereunder.

**10.1.4.** <u>No Debarment</u>. It will not use, during the Term, any employee or consultant who has been debarred by any Regulatory Authority, or, to the best of such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority.

**10.1.5.** <u>Government Authorizations</u>. It will maintain throughout the Term all permits, licenses, registrations, and other forms of authorizations and approvals from any Governmental Authority, necessary or required to be obtained or maintained by such Party in order for such Party to execute and deliver this Agreement and to perform its obligations hereunder in a manner which complies with all Applicable Laws.

**10.2.** <u>Additional Representations and Warranties of Mersana</u>. Mersana hereby represents and warrants, as of the Effective Date, to Merck as follows:

**10.2.1.** <u>Non-Infringement of Mersana Patent Rights or Mersana Platform</u> <u>Patent Rights by Third Parties</u>. To Mersana's knowledge, there are no activities by Third Parties that would constitute infringement of the Mersana Patent Rights or Mersana Platform Patent Rights within the Territory.

**10.2.2.** <u>Ownership</u>. Mersana Controls the Mersana Technology and Mersana Platform Technology free and clear of all liens (excluding licenses that do not conflict with the rights granted to Merck hereunder).

**10.2.3.** <u>Validity and Enforceability</u>. Mersana has complied in all material respects with all Applicable Laws with respect to the filing, prosecution and maintenance of those Mersana Patent Rights and Mersana Platform Patent Rights owned by Mersana or otherwise of which Mersana has control of such filing, prosecution and maintenance (the "Mersana Prosecution Patent Rights") and, to Mersana's knowledge, the filing, prosecution and maintenance of all other Mersana Patent Rights and Mersana Platform Patent Rights has been in compliance in all material respects with all Applicable Laws with respect thereto. Mersana has paid all maintenance and annuity fees with respect to the Mersana Prosecution Patent Rights due and, to Mersana's knowledge, all maintenance and annuity fees with respect to all other Mersana Patent Rights and Mersana Platform Patent Rights or threatened with respect to the Mersana Prosecution Patent Rights or, to Mersana's knowledge, with respect to any other Mersana Patent Rights.

**10.2.4.** <u>No Action or Claim</u>. There (a) are no actual, pending or, to Mersana's knowledge, alleged or threatened, adverse actions, suits, claims, interferences, re-examinations, oppositions, inventorship challenges or formal governmental investigations involving the Mersana Technology or Mersana Platform Technology by or against Mersana or any of its Affiliates, in each case that are in or before any Governmental Authority, and (b) are no actual, pending or, to Mersana's knowledge, alleged or threatened, adverse actions, suits, claims, interferences, re-examinations, oppositions, inventorship challenges or formal governmental investigations involving the Mersana Technology or Mersana Platform Technology, in each case that are in or before any Governmental Authority, which if adversely determined would have a material effect upon the ability of Mersana to use or provide the Mersana Technology or Mersana Platform Technology in connection with the activities to be conducted hereunder, or to fulfill its obligations pursuant to the terms of this Agreement.

**10.2.5.** <u>Completeness</u>. <u>Schedule 1.1.78</u> includes a complete and correct list, in all material respects, of all Mersana Patent Rights, and <u>Schedule 1.1.80</u> includes a complete and correct list, in all material respects, of all Mersana Platform Patent Rights.

**10.2.6.** <u>Mersana In-Licenses</u>. <u>Schedule 1.1.94</u> sets forth a true and complete list of all Original Mersana In-Licenses.</u> Mersana has, prior to the Effective Date, provided Merck with access to true and complete copies of each of the agreements listed in <u>Schedule 1.1.94</u> and any prior agreements where surviving obligations restrict or have an adverse material impact on either Party with respect to the Mersana Technology or Mersana Platform Technology. As of the Effective Date, (a) the licenses in the Original Mersana In-Licenses are sublicensable; (b) the Original Mersana In-Licenses are in full force and effect, have been duly maintained and have not been cancelled, expired or abandoned; (c) Mersana is not

aware of any challenges to or violation of the rights granted thereunder by any Third Party; (d) Mersana is not in breach under any of the Original Mersana In-Licenses, nor, to Mersana's knowledge, is any counterparty thereto; and (e) Mersana has not received any notice of breach under any of the Original Mersana In-Licenses.

**10.2.7.** <u>Manufacturing Agreements</u>. There are no exclusivity provisions or any other restrictions in any agreement between Mersana or its Affiliates, on the one hand, and any Third Party manufacturer of the ADCs (including any intermediate or component thereof), on the other hand, that would limit Merck's ability to have the ADCs or Licensed Product (including any intermediate or component thereof) Manufactured.

**10.2.8.** <u>Compliance with Applicable Law</u>. The Development of Mersana Technology and the Mersana Platform Technology has been conducted by Mersana and its Affiliates and its and their subcontractors, in compliance with all Applicable Law in all material respects. Neither Mersana nor any of its Affiliates, nor any of their respective officers, employees or agents, has made an untrue statement of a material fact or fraudulent statement to any Regulatory Authority or failed to disclose a material fact required to be disclosed to any Regulatory Authority.

### 10.3. Additional Covenants of Mersana.

**10.3.1.** <u>Derogation of Rights</u>. Mersana will not enter into any agreement with respect to or otherwise assign, transfer, license, convey or otherwise encumbered its right, title or interest in or to (a) the Mersana Technology, Mersana Platform Technology or Mersana Regulatory Documentation (including by granting any covenant not to sue with respect thereto) or (b) any Patent Right or other intellectual property or proprietary right that would be Mersana Technology, Mersana Platform Technology or Mersana Regulatory Documentation, but for such assignment, transfer, license, conveyance or encumbrance, in each case of (a) and (b), that is inconsistent with or would otherwise diminish the rights and licenses granted to Merck under this Agreement. Mersana will maintain and perform its obligations under the Original Mersana In-Licenses and maintain such Original Mersana In-Licenses in full force and effect during the Term and will not amend any Original Mersana In-Licenses in a manner that adversely affects Merck's rights hereunder, without having first obtained Merck's express prior written consent. Furthermore, Mersana will maintain and perform its obligations under the Future Mersana In-Licenses in full force and effect during the Term and will not amend any Original Mersana In-Licenses in full force and effect during the Set obtained Merck's express prior written consent. Furthermore, Mersana will maintain and perform its obligations under the Future Mersana In-Licenses in full force and effect during the Term and will not amend any Future Mersana In-Licenses in a manner that adversely affects Merck's rights hereunder, without having first obtained Merck's express prior written consent.

**10.3.2.** <u>Conformance of Materials</u>. All ADC Materials and Study Materials provided by or on behalf of Mersana hereunder will be Manufactured in conformance with Applicable Law and this Agreement.

**10.4.** <u>Performance by Affiliates</u>. The Parties recognize that each may perform some or all of its obligations under this Agreement through Affiliates; *provided*, that each Party will remain responsible and be a guarantor of the performance by its Affiliates and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

**10.5. <u>DISCLAIMER OF WARRANTIES</u>**. 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 OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENT RIGHTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

# 11. Term and Termination.

**11.1.** <u>Term</u>. Unless earlier terminated pursuant to this Section 11, the term of this Agreement (the "Term") will commence on the Effective Date and will remain in full force and effect until (a) the

expiration of all Research Program Terms, if Merck has not elected to make a Pre-Clinical Development Candidate Designation with respect to an ADC or Licensed Product for any Research Program, or (b) the date of expiration of the last to expire Royalty Term, if Merck elects to make a Pre-Clinical Development Candidate Designation with respect to an ADC or Licensed Product for any Research Program.

**11.2.** <u>Termination by Merck</u>. Merck will have the right, at any time, to terminate this Agreement in its entirety, or with respect to an Exclusive License only, by providing not less than sixty (60) days' prior written notice to Mersana of such termination. Any such termination of an Exclusive License will not affect the continuation of any other Exclusive License or this Agreement.

**11.3.** <u>Termination for Cause</u>. Either Party may (but is not required to and without limitation of any other right or remedy such Party may have) terminate this Agreement for material breach by the other Party (the "Breaching Party") of this Agreement if the Breaching Party has not cured such breach within [\*\*] days after notice from the non-Breaching Party thereof (such period, the "Notice Period") specifying the breach and such non-Breaching Party's claim of right to terminate this Agreement, other than (a) with respect to a breach of a payment obligation, in which case the Notice Period will be [\*\*] days, and (b) with respect to a breach that cannot be cured within the Notice Period and the Breaching Party commences actions to cure such breach within the Notice Period, in which case the Notice Period will be tolled (i.e., suspended) (provided, that the Breaching Party thereafter diligently continues such actions); *provided*, that if either Party initiates a dispute resolution procedure under Section 13.6 as permitted under this Agreement to resolve the dispute for which termination is being sought within [\*\*] days following the end of the Notice Period and is diligently pursuing such procedure, the Notice Period will be tolled (i.e., suspended) and the termination will become effective only if such breach remains uncured for [\*\*] days after the final resolution of the dispute through such dispute resolution procedure, including pursuant to Section 13.6.4 (or, if the breach cannot be cured within such [\*\*] day period, if the Breaching Party commences actions to cure such breach within such period and thereafter diligently continues such actions).

**11.4.** <u>License Survival Upon Insolvency</u>. All licenses (and to the extent applicable, rights) granted under or pursuant to this Agreement are, and will otherwise be deemed to be, for purposes of Section 365(n) of 11 U.S.C. Section 101, et. seq. ("**Bankruptcy Code**"), licenses of rights to "intellectual property" as defined under the Paragraph 101(35A) of the Bankruptcy Code. The Parties agree that the non-bankrupt Party will retain and may fully exercise all of its rights and elections under Applicable Law. The Parties further agree that, in the event of the commencement of bankruptcy proceeding by or against a bankrupt Party, the other Party will be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property which at that date is known to be useful or necessary for a Research Program or the Exploitation of ADCs or Licensed Products throughout the Territory and all embodiments of such intellectual property; and the same, if not already in the other Party's possession, will be promptly delivered to the other Party (a) upon any such commencement of a bankrupt Party (or trustee on behalf of the bankrupt Party) elects within [\*\*] days to continue to perform all of its obligations under this Agreement or (b) if not delivered under (a) above, upon rejection of this Agreement by or on behalf of the bankrupt Party, upon written request therefore by the other Party.

#### 11.5. Effect of Expiration and Termination.

**11.5.1.** <u>General Effects</u>. Except where explicitly provided within this Agreement, expiration or termination of this Agreement or any Exclusive License, as applicable, for any reason, will not affect any obligations, including payment of any royalties or other sums which have accrued as of the date of termination or expiration. Notwithstanding the foregoing, but subject to Section 11.5.2.2(b) and Section 11.5.4, upon expiration or termination of this Agreement in its entirety, all licenses granted by either Party to the other Party hereunder, including all Exclusive Licenses, and all sublicenses granted by either Party thereunder, will immediately terminate; *provided*, that in the event of a termination with respect to one Exclusive License, only such Exclusive License will terminate.

#### 11.5.2. Effect of Termination by Merck for Convenience or by Mersana for Cause.

**11.5.2.1.** If Merck terminates this Agreement in its entirety pursuant to Section 11.2 or Mersana terminates this Agreement in its entirety pursuant to Section 11.3, all Exclusive Licenses granted by Mersana to Merck (and then in effect) will automatically be terminated and Merck will immediately cease Commercialization of any Licensed Product in the Territory for which, and for so long as, there remains any Valid Patent Claim of any Mersana Patent Right, or Mersana Platform Patent Right covering or claiming the Exploitation of such Licensed Product.

**11.5.2.2.** If Merck terminates an Exclusive License pursuant to Section 11.2 with respect to a Licensed Product or Mersana terminates an Exclusive License pursuant to Section 11.3, all Exclusive Licenses granted by Mersana to Merck (and then in effect) with respect to such Licensed Product will automatically be terminated and Merck will immediately cease Commercialization of such Licensed Product in the Territory if, and for so long as, there remains any Valid Patent Claim of any Mersana Patent Right, or Mersana Platform Patent Right covering or claiming the Exploitation of such Licensed Product.

#### 11.5.3. Effect of Termination Right by Merck for Cause.

**11.5.3.1.** In the event that Merck is entitled to terminate this Agreement in its entirety pursuant to Section 11.3 due to a material breach by Mersana, Merck may elect instead to maintain this Agreement in effect, except that Merck's obligations to make payments to Mersana pursuant to Section 6.3, Section 6.4 and Section 6.5 will be reduced to fifty percent (50%) of the amount otherwise payable thereunder; **provided** that if such material breach is a breach of Section 2.4.4.1 and such breach results in (including by granting any right or license in breach of Section 2.4.4.1) a Third Party Commercializing a Competing Product in any country in the Territory, Merck shall have no obligation to make payments to Mersana pursuant to Section 6.3, Section 6.4 or Section 6.5.

**11.5.3.2.** If Merck terminates this Agreement in its entirety pursuant to Section 11.3 for an uncured and material breach of Mersana's obligation set forth in Section 2.1, Merck's sole and exclusive remedy shall be for Mersana to pay Merck Twelve Million Dollars (\$12,000,000).

**11.5.4.** License to Merck Upon Royalty Term Expiration. Upon the date of expiration of each Royalty Term with respect to a Licensed Product in a country, the Exclusive License granted with respect to such Licensed Product in such country will automatically be converted into a royalty-free, fully-paid, perpetual, worldwide, nonexclusive, freely transferable and sublicensable license to use the Mersana Technology and Mersana Platform Technology to Exploit such Licensed Product, with no further obligation to Mersana.

**11.5.5.** <u>Survival</u>. The following provisions will survive expiration or termination of this Agreement: Section 1 (Definitions), Section 2.2.2 (Restrictions on use of Materials), Section 6.8 (Late Payments), Section 6.10 (Royalty Reports and Accounting), Section 7 (Confidentiality), Section 8.2 (Ownership of Intellectual Property), Section 8.3.5 (Joint Patent Rights), Section 10.5 (Disclaimer of Warranties), Section 11.4 (License Survival Upon Insolvency), Section 11.5 (Effect of Expiration and Termination), Section 12 (Indemnity; Limitation of Liability; Insurance), and Section 13 (Miscellaneous).

### 12. Indemnity; Limitation of Liability; Insurance.

### 12.1. Indemnity.

**12.1.1.** <u>Mersana Indemnity</u>. Mersana will defend, indemnify and hold harmless Merck, its Affiliates and its and their respective directors, officers, employees and agents from and against all liabilities, losses, damages, and expenses, including reasonable attorneys' fees and costs, (each, a "Liability") resulting from all Third Party claims, suits, actions, terminations or demands (each, a "Claim") to the extent such Claims are incurred, relate to, are in connection with or arise out of (a) the breach or non-fulfillment of this Agreement by Mersana, or (b) the negligence, recklessness or willful misconduct of Mersana in connection with the performance of its obligations hereunder, except in each case, to the extent such Liabilities resulted from any action for which Merck must indemnify Mersana under Section 12.1.2.

**12.1.2.** <u>Merck Indemnity</u>. Merck will defend, indemnify and hold harmless Mersana, its Affiliates and its and their respective directors, officers, employees and agents from and against all Liabilities resulting from all Claims to the extent such Claims are incurred, relateto or arise out of (a) the breach or non-fulfillment of this Agreement by Merck, (b) the negligence, recklessness or willful misconduct of Merck in connection with the performance of its obligations hereunder, or (c) the Exploitation of Licensed Products by Merck, its Affiliates or Sublicensees, except, in each case, to the extent such Liabilities resulted from any action for which Mersana must indemnify Merck under Section 12.1.1.

**12.2.** <u>Procedure</u>. A Party (the "Indemnitee") that intends to claim indemnification under this Section 12.2 will promptly provide notice to the other Party (the "Indemnitor") of any Claim in respect of which the Indemnitee intends to claim such indemnification, which notice will include a reasonable identification of the alleged facts giving rise to such Liability, and the Indemnitor will have the right to participate in, and, to the extent the Indemnitor so desires, jointly with any other Indemnitor similarly noticed, to control the defense thereof with counsel selected by the Indemnitor. However, notwithstanding the foregoing, the Indemnitee will have the right to participate in, but not control, the defense of any Claim, and request separate counsel, with the fees and expenses to be paid by the Indemnitee, unless (a) representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other Party represented by such counsel in such proceedings or (b) the Indemnitor. The Indemnitee will, and will cause each of its Affiliates and its and their respective directors, officers, employees and agents, as applicable, to, cooperate in the defense or prosecution thereof and will furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals and otherwise provide reasonable access to such Indemnitor will reimburse the Indemnitor in each case as may be reasonably requested in connection therewith; *provided*, that the Indemnitor will claim, and the Indemnite for its reasonable and verifiable out-of-pocket expenses in connection therewith. The Indemnitor will reimburse the Indemnitee for its reasonable and verifiable out-of-pocket expenses in connection therewith. The Indemnitor will reimburse the Indemnitee for its reasonable for or be bound by any settlement of a Claim that imposes an obligation on it, without the prior w

**12.3.** <u>Limitation of Liability</u>. EXCEPT (A) IN THE EVENT OF THE WILLFUL MISCONDUCT OR FRAUD OF A PARTY OR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER SECTION 7, (B) AS PROVIDED UNDER SECTION 13.12 AND (C) 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 SECTION 12, NEITHER PARTY NOR ANY OF ITS AFFILIATES OR SUBLICENSEES WILL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR FOR LOST PROFITS SUFFERED BY THE OTHER PARTY AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES.

**12.4.** <u>Insurance</u>. During the Term, each Party shall obtain and maintain, at its sole cost and expense, product liability insurance (including any self-insured arrangements) in amounts, that are reasonable and customary in the pharmaceutical and biotechnology industry for companies engaged in comparable activities in their respective jurisdiction. It is understood and agreed that this insurance shall not be construed to limit either Party's liability with respect to its indemnification obligations hereunder. Each Party will, except to the extent self insured, provide to the other Party upon request a certificate evidencing the insurance such Party is required to obtain and keep in force under this Section 12.4.

### 13. Miscellaneous.

**13.1.** Force Majeure. No Party (or any of its Affiliates) will be held liable or responsible to the other Party (or any of its Affiliates) hereunder, or be deemed to have defaulted under or breached this Agreement, for failure or delay by such Party in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party (or any of its Affiliates), including fire, floods, embargoes, war, acts of war (whether war be

declared or not), insurrections, riots, civil commotions, acts of God, earthquakes, or omissions or delays in acting by any Governmental Authority (each, an "**Event of Force Majeure**"); *provided*, that the affected Party will exert all reasonable efforts to eliminate, cure or overcome any such Event of Force Majeure and to resume performance of its obligations promptly. Notwithstanding the foregoing, to the extent that an Event of Force Majeure continues for a period in excess of [\*\*] months, the affected Party will promptly notify in writing the other Party of such Event of Force Majeure and within [\*\*] months of the other Party's receipt of such notice, the Parties will negotiate in good faith either (a) a resolution of the Event of Force Majeure, if possible, (b) an extension by mutual agreement of the time period to resolve, eliminate, cure or overcome such Event of Force Majeure, (c) an amendment of this Agreement to the extent reasonably possible, or (d) an early termination of this Agreement.

**13.2.** Assignment. This Agreement may not be assigned or otherwise transferred, nor, except as expressly provided hereunder, may any right or obligations hereunder be assigned or transferred to any Third Party by either Party without the consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, either Party may, without such consent but with notification and subject to the terms and conditions of this Section 13.2, assign this Agreement and its rights and obligations hereunder to any of its Affiliates or (a) in connection with a Change in Control of such Party or (b) to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of such Party's business to which this Agreement relates. Any permitted assignee will assume all rights and obligations of its assignor under this Agreement. Any attempted assignment of this Agreement not in accordance with this Section 13.2 will be void and of no effect.

**13.3.** <u>Severability</u>. Should one or more provisions of this Agreement be or become invalid, the Parties will substitute, by mutual consent, valid provisions for such invalid provisions, which in their economic effect, are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement based on such valid provisions. In case such alternative provisions cannot be agreed upon, the invalidity of one or several provisions of this Agreement will not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid provisions.

**13.4.** <u>Notices</u>. Any consent, notice or report required or permitted to be given or made under this Agreement by one Party to the other Party will be in writing, delivered personally or by facsimile (and promptly confirmed by personal delivery, first class air mail or courier), first class air mail or courier, postage prepaid (where applicable), addressed to such other Party at its address indicated below, or to such other address as the addressee will have last furnished in writing to the addresser in accordance with this Section 13.4 and (except as otherwise provided in this Agreement) will be effective upon receipt by the addressee. This Section 13.4 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.

#### If to Mersana:

Mersana Therapeutics, Inc. 840 Memorial Drive Cambridge, MA 02139 Attention: Legal Department Telephone: (617) 498-0020 Fax: (617) 498-0109

If to Merck:

Merck KGaA Frankfurter Strasse 250 64293 Darmstadt Germany Attn.: Alliance Management Facsimile: +49 6151 72 91 9885 In case of legal notifications with a copy to

Merck KGaA Frankfurter Strasse 250 64293 Darmstadt Germany

Attention: Legal Department Facsimile: +49 61 51 72 23 73

### 13.5. Applicable Law; Jurisdiction.

**13.5.1.** <u>Applicable Law</u>. Subject to Section 8.2.4, this Agreement will be governed by and construed in accordance with the laws of England and Wales, without regard to the conflict of law principles thereof that may dictate application of the laws of any other jurisdiction.

**13.5.2.** Jurisdiction. The Parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction over any disputes between the Parties for which relief is sought under this Agreement and each of the Parties hereto irrevocably: (a) submits to such exclusive jurisdiction for such purpose; (b) waives any objection which it may have at any time to the laying of venue of any proceedings brought in such courts; (c) waives any claim that such proceedings have been brought in an inconvenient forum and (d) further waives the right to object with respect to such proceedings that any such court does not have jurisdiction over such Party. Notwithstanding anything in this Section 13.5.2 or elsewhere in this Agreement to the contrary, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any Patent Rights shall be submitted to a court of competent jurisdiction in the country or region in which such Patent Rights were granted or arose.

**13.6.** <u>Dispute Resolution</u>. The Parties agree that if any dispute or disagreement arises between Merck on the one hand and Mersana on the other in respect of this Agreement, subject to Section 13.12, they will follow the following procedure in an attempt to resolve the dispute or disagreement.

**13.6.1.** The Party claiming that such a dispute exists will give notice in writing ("**Notice of Dispute**") to the other Party of the nature of the dispute.

**13.6.2.** Within [\*\*] Business Days following receipt of a Notice of Dispute, a nominee or nominees of Merck and a nominee or nominees of Mersana will meet in person at a mutually agreed upon time and location and exchange written summaries reflecting, in reasonable detail, the nature and extent of the dispute, and at this meeting they will use their reasonable endeavors to resolve the dispute.

**13.6.3.** If, within a further period of [\*\*] Business Days, the dispute has not been resolved, the Chief Executive Officer (or equivalent) of Mersana and the Chief Executive Officer of Merck Serono (or equivalent) of Merck will meet at a mutually agreed upon time and location for the purpose of resolving such dispute.

**13.6.4.** In the event of an unresolved dispute between the Parties, such dispute will, at either Party's election and subject to Section 13.5.1, be submitted for resolution by a court of competent jurisdiction.

**13.6.5.** In the event of a dispute regarding any payments owing under this Agreement, all undisputed amounts will be paid promptly when due and the balance, if any, promptly after resolution of the dispute.

13.7. Entire Agreement. This Agreement contains the entire understanding of the Parties with respect to the specific subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made with respect to the specific subject matter hereof are expressly superseded by this Agreement, including confidentiality agreements between the Parties and any of their Affiliates, which are hereby terminated effective as of the Effective Date; *provided*, that such agreements

will continue to govern the treatment of information disclosed by the Parties prior to the Effective Date in accordance with their respective terms. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties.

**13.8.** <u>Independent Contractors</u>. Mersana and Merck each acknowledge that they are independent contractors and that the relationship between the Parties will not constitute a partnership, joint venture, agency or any type of fiduciary relationship. Neither Mersana nor Merck will have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other Party, without the prior written consent of the other Party to do so.

**13.9.** <u>Waiver and Non-Exclusion of Remedies</u>. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party will not be deemed a waiver of any other right hereunder or of any other breach or failure by said 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.

**13.10.** <u>Further Assurances</u>. Each Party will execute such additional documents as are necessary to effect the purposes of this Agreement.

**13.11.** <u>No Third Party Rights</u>. Except as provided in Section 12, a person who is not a party to this Agreement may not enforce or enjoy the benefit of any term of this Agreement under the Contracts (Rights of Third Parties) Act 1999. Notwithstanding any term of this Agreement, no consent of any Third Party is required for any variation, amendment or waiver (including any release or compromise of any liability) or termination of this Agreement.

**13.12.** Equitable Relief. Nothing contained in this Agreement will deny any Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of prospective irreparable harm.

**13.13.** <u>Counterparts</u>. This Agreement may be executed in two (2) or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Counterparts may be signed or delivered by facsimile or electronically scanned signature page.

(The remainder of this page has been intentionally left blank. The signature page follows.)

IN WITNESS WHEREOF, the Parties have executed this Agreement to be effective as of the Effective Date.

## MERSANA THERAPEUTICS, INC.

By:	/s/ Eva Jack
Name:	Eva Jack
Title:	Chief Business Officer
MERCK	KGaA
By:	/s/ Susan Herbert
Name:	ppa. Susan Herbert
Title:	Executive Vice President Global Business Development

Title:	Executive Vice President Global Business Development
By:	/s/ i.V. Dr. Simone Heitz
Name:	i.V. Dr. Simone Heitz
Title:	Associate General Counsel

# Signature Page to Collaboration and Commercial License Agreement

# <u>SCHEDULE 1.1.76(a)</u>

# MERSANA CYTOTOXIC COMPOUNDS

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# SCHEDULE 1.1.76(b)

# TUBE Toxins(1)

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(1) [\*\*].

# **SCHEDULE 1.1.78**

MERSANA PATENT RIGHTS as of the Effective Date

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# **SCHEDULE 1.1.80**

## MERSANA PLATFORM PATENT RIGHTS as of the Effective Date

## **In-Licensed Mersana Platform Patent Rights**

Row	Title	Inventor(s)	Assignee	Patent No.	Serial No	Priority	Filing Date	<b>Issue Date</b>	Status
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
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[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

(2) [\*\*].

Row	Title	Inventor(s)	Assignee	Patent No.	Serial No	Priority	Filing Date	Issue Date	Status
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
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(3) [\*\*].

Row	Title	Inventor(s)	Assignee	Patent No.	Serial No	Priority	Filing Date	Issue Date	Status
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
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## Mersana Platform Patent Rights owned by Mersana

Row	Title	Inventors	Patent No	Serial No	Priority	Filing Date	<b>Issue Date</b>	Status
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
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Row	Title	Inventors	Patent No	Serial No	Priority	Filing Date	Issue Date	Status
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Row	Title	Inventors	Patent No	Serial No	Priority	Filing Date	Issue Date	Status
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Row	Title	Inventors	Patent No	Serial No	Priority	Filing Date	Issue Date	Status
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Row	Title	Inventors	Patent No	Serial No	Priority	Filing Date	Issue Date	Status
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Row	Title	Inventors	Patent No	Serial No	Priority	Filing Date	Issue Date	Status
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Row	Title	Inventors	Patent No	Serial No	Priority	Filing Date	Issue Date	Status
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Row	Title	Inventors	Patent No	Serial No	Priority	Filing Date	Issue Date	Status
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Row	Title	Inventors	Patent No	Serial No	Priority	Filing Date	<b>Issue Date</b>	Status
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Row	Title	Inventors	Patent No	Serial No	Priority	Filing Date	Issue Date	Status
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## SCHEDULE 1.1.94

### **ORIGINAL MERSANA IN-LICENSES**

- License Agreement between Mersana Therapeutics, Inc. and TUBE Pharmaceuticals GmbH dated September 22, 2011, as amended on December 21, 2012 (the "**TUBE Agreement**")(4)
- Second Restated and Amended License Agreement between Mersana Therapeutics, Inc. and The General Hospital Corporation dated October 19, 2005, as amended on July 27, 2012, and on September 19, 2012 (the "MGH Agreement")(5)

# SCHEDULE 2.2.3

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# SCHEDULE 2.4.1

## DESIGNATED TARGETS

#	Target	Definition	OMIM	SwissProt
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]

## SCHEDULE 7.3

### PRESS RELEASE



DRAFT-NOT FOR RELEASE

## Mersana and Merck KGaA of Darmstadt, Germany to Develop Next-Generation Antibody-Drug Conjugates

- Collaboration and license agreement allows the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, to expand its oncology drug portfolio
- Mersana Therapeutics' Fleximer® technology to be leveraged to create multiple antibody-drug conjugates

Cambridge, Mass., June 24, 2014 — Mersana Therapeutics, Inc., and the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, which operates as EMD Serono in the United States and Canada, announced today an agreement to collaboratively develop next-generation antibody-drug conjugates (ADCs). ADCs are composed of an antibody linked to cytotoxic drugs, whereby the antibody specifically targets and delivers the cytotoxic drug to cancer cells, which could lead to higher drug levels at the tumor site.

Mersana and the biopharmaceutical division of Merck KGaA will leverage Mersana's Fleximer® technology to generate ADCs for multiple undisclosed targets. Both parties have agreed to test a variety of ADCs by utilizing Mersana's platform technologies, and several cytotoxic agents as conjugates.

"This new collaboration provides an exciting opportunity to expand our oncology drug discovery and development portfolio into the evolving ADC space," said Dr. Andree Blaukat, head of the Translational Innovation Platform Oncology at Merck Serono, the biopharmaceutical division of Merck KGaA, Darmstadt, Germany. "We have a long standing commitment to improving oncology care, and we aim to deliver the best benefit possible to patients. Partnering with Mersana allows us to incorporate cutting edge research and technical excellence to enrich our pipeline."

"We look forward to working with Merck in Darmstadt, Germany, to apply our proprietary platform technologies to rapidly develop and demonstrate preclinical proof-of-concept of several customized, novel Fleximer-ADC candidates," said Timothy B. Lowinger, Ph.D., Mersana's Chief Scientific Officer.

Under the agreement, Merck KGaA will provide monoclonal antibodies to Mersana who will generate the Fleximer-ADCs and conduct drug discovery and preclinical development activities. Merck KGaA will be responsible for clinical development and commercialization of any products under an exclusive license from Mersana. In addition to an upfront payment, Mersana is eligible to receive milestones plus royalties on worldwide net sales of products.

## About Fleximer® Antibody-Drug Conjugate Technology

Mersana's next-generation Fleximer® antibody-drug conjugate (ADC) technology is based on the Company's proprietary biodegradable polymer system, known as Fleximer, and a wide variety of linkers that allow for the attachment of an extensive range of anti-tumor payloads to Fleximer. As an example, once loaded with drug(s), Fleximer is then attached through a stable linker that is different from the drug linker(s) to the antibody or antibody alternative to create a Fleximer-ADC.

Mersana's novel linker systems are designed to be stable in the blood stream and to release the potent payloads once inside the targeted cancer cell. Mersana's Fleximer-ADC technology provides several key advantages over currently available approaches, including: the ability to deliver diverse payloads; the opportunity to significantly increase drug loading per antibody; and the potential use with antibody fragments and alternative targeting moieties, in addition to monoclonal antibodies. Mersana's proprietary payload platforms include Dolaflexin<sup>TM</sup>, an auristatin derivative; Vindeflexin<sup>TM</sup>, a vindesine derivative; and Cytoflexin<sup>TM</sup>, a tubulysin derivative.

## **About Mersana Therapeutics**

Mersana Therapeutics engineers antibody drug conjugates (ADCs) that maximize the potential of new and established therapeutic classes. Mersana is developing, with select pharmaceutical partners, a portfolio of next-generation Fleximer® ADCs with superior properties not found with current ADC technologies, . The company is also advancing its own pipeline of Fleximer-ADCs with best-in-class potential to address unmet needs and improve patient outcomes in multiple oncology indications. www.mersana.com

#### About EMD Serono, Inc.

EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, is a leader in the US biopharmaceutical arena, integrating cutting-edge science with unparalleled patient support systems to improve people's lives. The company has strong market positions in neurodegenerative diseases, endocrinology and in reproductive health. In addition, EMD Serono is growing its expertise and presence in the area of oncology, with more than 15 projects currently in development. With a clear focus on the patient and a leadership presence in the biopharmaceutical industry, EMD Serono's US footprint continues to grow, with approximately 1,000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

For more information, please visit www.emdserono.com.

### About Merck KGaA, Darmstadt, Germany

Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in the pharmaceutical and chemical sectors. Its subsidiaries in Canada and the United States operate under the umbrella brand EMD. Around 38,000 employees work in 66 countries to improve the quality of life for patients, to further the success of customers and to help meet global challenges. The company generated total revenues of  $\notin 11.1$  billion in 2013 with its four divisions: Biopharmaceuticals, Consumer Health, Performance Materials and Life Science Tools. Merck KGaA of Darmstadt, Germany is the world's oldest pharmaceutical and chemical company — since 1668, the name has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70 percent interest, the founding family remains the majority owner of the company to this day.

#### **Media Contacts**

For Mersana: MacDougall Biomedical Communications Kari Watson kwatson@macbiocom.com +1 781 235 3060

For Merck KGaA: Dr. Andrea Marquart +49 6151 72-6517

###

News Release June 24, 2014 Your Contact Dr. Andrea Marquart Phone +49 6151 72-6517

#### Merck Serono and Mersana to Develop Next-Generation Antibody-Drug Conjugates

Collaboration and license agreement allows Merck Serono to expand its oncology drug portfolio

Mersana Therapeutics' Fleximer technology to be leveraged to create multiple antibody-drug conjugates

Darmstadt, Germany, June 24, 2014 — Merck Serono, the biopharmaceutical division of Merck, and Mersana Therapeutics, Inc., Cambridge, Mass., U.S., announced today an agreement to collaboratively develop next-generation antibody-drug conjugates (ADCs). ADCs are composed of an antibody linked to cytotoxic drugs, whereby the antibody part specifically targets and delivers the cytotoxic drug to cancer cells which could lead to higher drug levels at the tumor site.

Mersana and Merck Serono will leverage Mersana's Fleximer® technology to generate ADCs for multiple undisclosed targets. Both parties have agreed to test a variety of ADCs by utilizing Mersana's platform technologies, and several cytotoxic agents as conjugates. This agreement further underlines Merck Serono's approach to employ a collaborative research and development model, creating strategic partnerships to drive innovation, being consciously agnostic of the source of potential novel assets, and technologies.

"This new collaboration provides an exciting opportunity to expand our oncology drug discovery and development portfolio into the evolving ADC space," said Dr. Andree Blaukat, head of the Translational Innovation Platform Oncology at Merck Serono. "At Merck Serono, we have a long standing commitment to improving oncology care, and we aim to deliver the best benefit possible to patients. Partnering with Mersana allows us to incorporate cutting edge research and technical excellence to enrich our pipeline."

"We look forward to working with Merck Serono to apply our proprietary platform technologies to rapidly develop and demonstrate preclinical proof-ofconcept of several customized, novel Fleximer-ADC candidates," said Timothy B. Lowinger, Ph.D., Mersana's Chief Scientific Officer.

Under the agreement, Merck Serono will provide monoclonal antibodies to Mersana who will generate the Fleximer-ADCs and conduct drug discovery and preclinical development activities.

Merck Serono will be responsible for clinical development and commercialization of any products under an exclusive license from Mersana. In addition to an upfront payment, Mersana is eligible to receive milestones plus royalties on worldwide net sales of products. Further financial details are not being disclosed.

#### About Fleximer Antibody-Drug Conjugate Technology

Mersana's next-generation Fleximer® antibody-drug conjugate (ADC) technology is based on the Company's proprietary biodegradable polymer system, known as Fleximer, and a wide variety of linkers that allow for the attachment of an extensive range of anti-tumor payloads to Fleximer. As an example, once loaded with drug(s), Fleximer is then attached through a stable linker that is different from the drug linker(s), to an antibody or antibody alternative to create a Fleximer-ADC.

Mersana's novel linker systems are designed to be stable in the blood stream and to release the potent payloads once inside the targeted cancer cell. Mersana's Fleximer-ADC technology provides several key advantages over currently available approaches, including: the ability to deliver diverse payloads; the opportunity to significantly increase drug loading per antibody; and the potential use with antibody fragments and alternative targeting moieties in addition to monoclonal antibodies. Mersana's proprietary payload platforms include Dolaflexin<sup>TM</sup>, an auristatin derivative; Vindeflexin<sup>TM</sup>, a vindesine derivative; and Cytoflexin<sup>TM</sup>, a tubulysin derivative.

#### **About Mersana Therapeutics**

Mersana Therapeutics engineers antibody drug conjugates (ADCs) that maximize the potential of new and established therapeutic classes. Mersana is developing, with select pharmaceutical partners, a portfolio of next-generation Fleximer® ADC) with superior properties not found with current ADC technologies. The company is

also advancing its own pipeline of Fleximer-ADCs with best-in-class potential to address unmet needs and improve patient outcomes in multiple oncology indications. www.mersana.com

#### **About Merck Serono**

Merck Serono is the biopharmaceutical division of Merck. With headquarters in Darmstadt, Germany, Merck Serono offers leading brands in 150 countries to help patients with cancer, multiple sclerosis, infertility, endocrine and metabolic disorders as well as cardiovascular diseases. In the United States and Canada, EMD Serono operates as a separately incorporated subsidiary of Merck Serono.

Merck Serono discovers, develops, manufactures and markets prescription medicines of both chemical and biological origin in specialist indications. We have an enduring commitment to deliver novel therapies in our core focus areas of neurology, oncology, immuno-oncology and immunology.

For more information, please visit www.merckserono.com.

All Merck Press Releases are distributed by e-mail at the same time they become available on the Merck Website. Please go to www.merckgroup.com/subscribe to register online, change your selection or discontinue this service.

Merck is a leading company for innovative and top-quality high-tech products in the pharmaceutical and chemical sectors. With its four divisions Merck Serono, Consumer Health, Performance Materials and Merck Millipore, Merck generated total revenues of  $\in 11.1$  billion in 2013. Around 38,000 Merck employees work in 66 countries to improve the quality of life for patients, to further the success of customers and to help meet global challenges. Merck is the world's oldest pharmaceutical and chemical company — since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70 percent interest, the founding family remains the majority owner of the company to this day. Merck, Darmstadt, Germany is holding the global rights to the Merck name and brand. The only exceptions are Canada and the United States, where the company is known as EMD.

# EXHIBIT 1.1.98

## PERFORMANCE SPECIFICATIONS

Parameter	Analysis	Methods
[**]	[**] [**] [**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
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[**]	[**]	[**]
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Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

## **AMENDMENT 1**

### ТО

### COLLABORATION AND COMMERCIAL LICENSE AGREEMENT

This Amendment 1 to Collaboration and Commercial License Agreement ("Amendment") is entered into as of the 1st day of June, 2016 (the "Amendment Effective Date") by and between Mersana Therapeutics, Inc., a Delaware corporation, having its principal place of business at 840 Memorial Drive Cambridge, MA 02139 (hereinafter referred to as "Mersana") and Merck KGaA, a corporation with general partners having its principal place of business at Frankfurter Str. 250, 64293 Darmstadt, Germany (hereinafter referred to as "Merck," and together with Mersana, the "Parties"). This Amendment amends that certain Collaboration and Commercial License Agreement by and between Mersana and Merck dated June 23, 2014 (the "Original Agreement," and together with this Amendment, the "Agreement"). Capitalized terms used but not defined in this Amendment will have the definition set forth in the Original Agreement.

### RECITALS

WHEREAS, the Parties wish to amend the Original Agreement as set forth in this Amendment.

**NOW, THEREFORE**, in consideration of the mutual covenants and obligations set forth herein, the Parties hereto, intending to be legally bound, agree as follows:

### ARTICLE 1 — AMENDMENTS

**1.1** <u>Confidential Information</u>. Section 1.1.22 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"1.1.22. "Confidential Information" of a Party, means information relating to the business, operations or products of a Party or any of its Affiliates, including any Know-How, that such Party, any of its Affiliates or any Third Party acting on its behalf discloses to the other Party or any of its Affiliates under this Agreement, or information of a Party that otherwise becomes known to the other Party by virtue of this Agreement; *provided*, that notwithstanding anything to the contrary, (a) Confidential Information constituting Mersana Know-How, Mersana Platform Know-How or Mersana Regulatory Documentation will be Confidential Information of Mersana (and Mersana will be deemed the disclosing Party and Merck the receiving Party with respect thereto) and (b) Confidential Information of Merck (and Merck will be deemed the disclosing Party and Mersana the receiving Party with respect thereto)."

1.2 <u>Research Plans</u>. Section 2.2.3 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"**2.2.3.** <u>Research Plans</u>. The Research Plan for [\*\*] Designated Target is attached as <u>Schedule 2.2.3-1</u>. Subsequent Research Plans agreed upon in accordance with Section 2.4.2.4 or Section 2.4.1.5, as applicable, will be attached as additional sequentially numbered schedules (<u>Schedule 2.2.3-2</u>, <u>Schedule 2.2.3-3</u>, etc.)."

**1.3** <u>Term of a Research Program</u>. Section 2.3 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

**"2.3.** <u>Term of a Research Program</u>. The term of the first Research Program, which covers the [\*\*] Designated Target, will commence upon the Effective Date, and the term of each subsequent Research Program will commence upon approval of a Research Plan under Section 2.4.2.4 or

Section 2.4.1.5, as applicable. Each Research Program will continue until [\*\*] (a) [\*\*]; (b) [\*\*]; (c) such date as Merck notifies Mersana of Merck's election to [\*\*]; (d) [\*\*]; and (e) [\*\*] (the term of a Research Program, each, a "**Research Program Term**"). If a Research Program Term ends pursuant to clause (c), (d) or (e) of this Section 2.3, then the Designated Target that is the subject of the applicable Research Program will no longer be deemed to be a Designated Target hereunder."

**1.4** [\*\*] **Designated Target**. Section 2.4.1.4 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"**2.4.1.4.** Merck may designate a [\*\*] Designated Target in accordance with this Section 2.4.1.4 and Section 2.4.2 at any time following the [\*\*]. Such Designated Target that is designated in accordance with this Section 2.4.1.4 and Section 2.4.2 will be set forth on <u>Schedule 2.4.1-5</u>."

**1.5** [\*\*] <u>Designated Target</u>. The following new Section 2.4.1.5 is hereby inserted immediately following Section 2.4.1.4 of the Original Agreement.

"2.4.1.5. Merck may designate the [\*\*] Designated Target in accordance with this Section 2.4.1.5 at any time following the [\*\*] pursuant to Section 2.4.5.3 by delivering written notice of such designation to Mersana. Upon such designation, Merck will disclose to Mersana the identity of the [\*\*], and the JPT will promptly meet to draft a Research Plan for the [\*\*] and will use good faith efforts to agree on such Research Plan. Upon written agreement by the Project Leaders on a proposed Research Plan, the [\*\*] will be deemed a Designated Target hereunder, such proposed Research Plan will be deemed to be a Research Plan hereunder, and the corresponding Research Program will commence. Such Designated Target that is designated in accordance with this Section 2.4.1.5 will be set forth on <u>Schedule 2.4.1-6</u>. For clarity, if Merck does not make a timely designation of a [\*\*] under Section 2.4.5.1, it shall have no right to designate the [\*\*] Designated Target."

**1.6** <u>Gatekeeper Process</u>. Section 2.4.2 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

## "2.4.2. Gatekeeper Process.

**2.4.2.1.** In order to designate an Antigen as a new Designated Target under Section 2.4.1.3, Section 2.4.1.4 or Section 2.4.3 or as the [\*\*] under Section 2.4.5.1 or Section 2.4.5.2, Merck will provide the Gatekeeper with a confidential written description of such Antigen, including to the extent available, the Name and UniProt/SwissProt number sequence for such proposed Antigen. Within [\*\*] Business Days following Gatekeeper's receipt of such written notice with respect to a particular proposed Antigen, Mersana will ensure that Gatekeeper will notify Merck in writing whether the proposed Antigen is Available for designation as a Designated Target or the [\*\*], as applicable. The Parties hereby acknowledge and agree that a proposed Antigen will be "Available" for designation by Merck as a Designated Target or the [\*\*] Target, as applicable, unless [\*\*].

**2.4.2.2.** For clarity, in the event that the Gatekeeper notifies Merck that a proposed Antigen is not Available pursuant to the procedures set forth in this Section 2.4.2, Merck will not have exhausted any of its rights to designate an Antigen as a new Designated Target or the [\*\*] Target, as applicable, hereunder within the applicable designation time period. Should an Antigen proposed by Merck be rejected by the Gatekeeper, the applicable nomination period for such Antigen shall be automatically extended by the time consumed by the unsuccessful nomination process.

**2.4.2.3.** The Parties acknowledge and agree that, as of the Effective Date, the first and second Designated Targets set forth on Schedule 2.4.1-1 and Schedule 2.4.1-2 are Available, and the

procedures set forth in Section 2.4 will not apply to such Designated Targets, other than with respect to replacement of such Designated Targets in accordance with Section 2.4.3.

**2.4.2.4.** In the event that the Gatekeeper notifies Merck that a proposed Antigen is Available for designation as a Designated Target or the [\*\*] Target, as applicable, in accordance with Section 2.4.2, within [\*\*] Business Days following receipt of such notice, Merck will thereafter notify the Gatekeeper if it wishes to so designate such proposed Antigen (in which case, Merck will also promptly provide notice to Mersana that it has designated an Antigen to be a Designated Target [\*\*], as applicable). Upon such designation if such designation is for a Designated Target, Merck will disclose to Mersana the identity of the Designated Target, and the JPT will promptly meet to draft a Research Plan for such Designated Target and will use good faith efforts to agree on such Research Plan. Upon written agreement by the Project Leaders on a proposed Research Plan, such Antigen will be deemed a Designated Target hereunder (if applicable), such proposed Research Plan will be deemed to be a Research Plan hereunder, and the corresponding Research Program will commence. Upon such designation if such designation is for the [\*\*], such Antigen will be deemed the [\*\*] hereunder. In addition to Section 2.4.4, the Parties agree that from receiving the notification of availability of an Antigen from the Gatekeeper until its designation as a Designated Target [\*\*], as applicable, such Antigen shall not be available for a collaboration between Mersana and a Third Party."

1.7 <u>Target Exclusivity</u>. Section 2.4.4.1 of the Original Agreement is hereby deleted in its entirety and replaced with the following.

"2.4.4.1. During the Term on a Designated Target-by-Designated Target basis, Mersana will collaborate exclusively with Merck with respect to such Designated Target during the period commencing with the designation of an Antigen as a Designated Target by Merck pursuant to Section 2.4.2.4 or Section 2.4.1.5, as applicable, and ending on the earliest of (a) [\*\*]; (b) [\*\*]; (c) [\*\*] (d) [\*\*] (each such period, a "Target Exclusivity Period"). For purposes of this Section 2.4.4, "collaborate exclusively" means that Mersana will not, [\*\*]. The provisions of this Section 2.4.4.1 shall not apply to any Future Acquirer or any Affiliate of any Future Acquirer other than Mersana to the extent that any activities conducted by any such Future Acquirer or any such Affiliate with respect to such Designated Target do not make use of any information or intellectual property right that is deemed Controlled by Mersana pursuant to this Agreement."

**1.8** [\*\*] <u>Target</u>. The following new Section 2.4.5 is hereby inserted immediately following Section 2.4.4 of the Original Agreement.

## "2.4.5. [\*\*] Target.

**2.4.5.1.** Merck may designate an Antigen as a [\*\*] **Target**") in accordance with this Section 2.4.1.5 and Section 2.4.2 at any time prior to the [\*\*] anniversary of the Effective Date.

**2.4.5.2.** Following the designation of the initial [\*\*] Target and prior to the earlier of (i) [\*\*] and (ii) [\*\*], Merck may designate a new [\*\*] Target in accordance with Section 2.4.2 to replace the original [\*\*] Target, *provided* that Merck may only replace the [\*\*] Target [\*\*]. Following such designation, the original [\*\*] Target will no longer be deemed to be the [\*\*] Target, and Merck will have no further rights under this Agreement with respect to the original [\*\*] Target.

**2.4.5.3.** Following Merck's designation of an Antigen as the Reserved Target and prior to Merck's designation of the Reserved Target as a Designated Target, if a Third Party exercising its rights under an agreement with [\*\*], the Gatekeeper shall promptly provide notice to Merck of [\*\*] (an "Acceleration Notice") and Merck may elect to designate the [\*\*] Designated Target in accordance with Section 2.4.1.5 within [\*\*] Business Days of receipt of the Acceleration Notice from the Gatekeeper. If Merck fails to make such designation within [\*\*] Business Days, it shall have no further rights to the [\*\*] Target and shall no longer have a right to designate the [\*\*] Designated Target in accordance with Section 2.4.1.5."

## ARTICLE 2 — ACKNOWLEDGEMENT OF PRIOR DESIGNATIONS

**2.1** <u>Prior Designated Targets</u>. The Parties hereby acknowledge and agree that the [\*\*] Designated Targets have been designated in accordance with the Prior Agreement prior to the Amendment Effective Date and that this Amendment shall have no effect on such prior designations.

### ARTICLE 3 — MISCELLANEOUS

**3.1 <u>Effectiveness</u>**. Except as set forth in this Amendment, all terms and conditions of the Original Agreement are hereby ratified and shall remain in full force and effect. Amendments made pursuant to this Amendment shall be effective as of the Amendment Effective Date.

**3.2** <u>Conflicts</u>. In the event of a conflict between a provision of the Original Agreement and a provision of this Amendment, the provisions of this Amendment will control to the extent of such conflict.

**3.3** <u>Counterparts</u>. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be signed or delivered by facsimile or electronically scanned signature page.

(The remainder of this page has been intentionally left blank. The signature page follows.)

IN WITNESS WHEREOF, the Parties have executed this Amendment to be effective as of the Amendment Effective Date.

# MERSANA THERAPEUTICS, INC.

By:	/s/ Eva Jack
Name:	Eva Jack
Title:	Chief Business Officer

# MERCK KGaA

By:	/s/ Axel Hoffmann	
Name:	Axel Hoffmann	
Title:	Director Alliance Management Global	
Business Development & Alliance Management		

By:	/s/ Marco Rau
Name:	Dr. Marco Rau, LL.M.
Title:	Senior Counsel

Signature Page to Amendment 1 to Collaboration and Commercial License Agreement

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

### AMENDMENT 2 TO COLLABORATION AND COMMERCIAL LICENSE AGREEMENT

This Amendment 2 to Collaboration and Commercial License Agreement ("Amendment") is entered into as of the 12th day of August, 2016 (the "Amendment 2 Effective Date") by and between Mersana Therapeutics, Inc., a Delaware corporation, having its principal place of business at 840 Memorial Drive Cambridge, MA 02139 (hereinafter referred to as "Mersana") and Merck KGaA, a corporation with general partners having its principal place of business at Frankfurter Str. 250, 64293 Darmstadt, Germany (hereinafter referred to as "Merck," and together with Mersana, the "Parties"). This Amendment amends that certain Collaboration and Commercial License Agreement by and between Mersana and Merck dated June 23, 2014, as amended on June 1, 2016 (the "Original Agreement," and together with this Amendment, the "Agreement"). Capitalized terms used but not defined in this Amendment will have the definition set forth in the Original Agreement.

## RECITALS

WHEREAS, the Parties wish to designate [\*\*] Designated Target; and

WHEREAS, the Parties wish to amend the Original Agreement as set forth in this Amendment.

**NOW, THEREFORE**, in consideration of the mutual covenants and obligations set forth herein, the Parties hereto, intending to be legally bound, agree as follows:

## ARTICLE 1 — AMENDMENTS

1.1 <u>New Definitions</u>. The following new definitions are hereby added to Article 1 of the Agreement in alphabetical order:

(a) "Amendment 2 Effective Date" means August 12, 2016.

(b) "[\*\*] Designated Target" is defined in Section 2.4.1.4.

1.2 <u>Research Plans</u>. Section 2.2.3 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

**"2.2.3**. <u>Research Plans</u>. The Research Plan for [\*\*] Designated Target is attached as Schedule 2.2.3 #1. Subsequent Research Plans agreed upon in accordance with Section 2.4.1.4, Section 2.4.1.5 or Section 2.4.2.4, as applicable, will be attached as additional sequentially numbered schedules (Schedule 2.2.3 #2, Schedule 2.2.3 #3, etc.)."

**1.3** <u>Term of a Research Program</u>. Section 2.3 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"2.3. <u>Term of a Research Program</u>. The term of the first Research Program, which covers the [\*\*] Designated Target, will commence upon the Effective Date, and the term of each subsequent Research Program will commence upon approval of a Research Plan under Section 2.4.1.4, Section 2.4.1.5 or Section 2.4.2.4, as applicable. Each Research Program will continue until [\*\*] (a) [\*\*]; (b) [\*\*]; (c) [\*\*]; (d) [\*\*]; and (e) [\*\*] (the term of a Research Program, each, a "**Research Program Term**"). If a Research Program Term ends pursuant to clause (c), (d) or (e) of this Section 2.3, then the Designated Target that is the subject of the applicable Research Program will no longer be deemed to be a Designated Target hereunder."

**1.4** [\*\*] Designated Target. Section 2.4.1.4 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"2.4.1.4. The [\*\*] Designated Target is set forth on <u>Schedule 2.4.1#5</u> (the [\*\*] **Designated Target**"). Following the Amendment 2 Effective Date, the JPT will promptly meet to draft a Research Plan for the [\*\*] Designated Target and will use good faith efforts to agree on such Research Plan. Upon written agreement by the Project Leaders on a proposed Research Plan for the [\*\*] Designated Target, such proposed Research Plan will be deemed to be a Research Plan hereunder, and the Research Program for the [\*\*] Designated Target will commence."

1.5 <u>Gatekeeper Process</u>. The reference to "Section 2.4.1.4" in the first sentence of Section 2.4.2 of the Original Agreement is hereby deleted.

**1.6** <u>Target Exclusivity</u>. Section 2.4.4.1 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"2.4.4.1. During the Term on a Designated Target-by-Designated Target basis, Mersana will collaborate exclusively with Merck with respect to such Designated Target during the period commencing with (i) [\*\*], (ii) [\*\*], (iii) [\*\*] pursuant to Section 2.4.1.5, and ending [\*\*] (a) [\*\*]; (b) [\*\*]; (c) [\*\*] or (d) [\*\*] (each such period, a "Target Exclusivity Period"). For purposes of this Section 2.4.4, "collaborate exclusively" means that Mersana will not, [\*\*]. The provisions of this Section 2.4.4.1 shall not apply to any Future Acquirer or any Affiliate of any Future Acquirer other than Mersana to the extent that any activities conducted by any such Future Acquirer or any such Affiliate with respect to such Designated Target do not make use of any information or intellectual property right that is deemed Controlled by Mersana pursuant to this Agreement."

**1.7** [\*\*] <u>Restrictions</u>. The following new Section 2.4.4.3 is hereby inserted immediately following Section 2.4.4.2 of the Original Agreement:

"2.4.4.3. During the Target Exclusivity Period for the [\*\*] Designated Target, Mersana will not, either directly or indirectly, [\*\*]. The provisions of this Section 2.4.4.3 shall not apply to any Future Acquirer or any Affiliate of any Future Acquirer other than Mersana to the extent that any activities conducted by any such Future Acquirer or any such Affiliate with respect to [\*\*] do not make use of any information or intellectual property right that is deemed Controlled by Mersana pursuant to this Agreement."

1.8 Exclusive License. Section 3.2 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

**"3.2.** <u>Exclusive Licenses to Merck</u>. With respect to each Designated Target, subject to the terms and conditions of this Agreement, Mersana will, and does hereby, grant to Merck an exclusive (even as to Mersana, except to the extent required for Mersana to perform its obligations under this Agreement), transferrable (only to the extent set forth in Section 13.2), sublicensable (only to the extent set forth in Section 3.3), royalty-bearing (a) right and license to and under the Mersana Technology, Mersana Platform Technology and Mersana's interest in the Joint Technology, and (b) right to access and reference to the Mersana Regulatory Documentation in accordance with Section 5, solely in connection with its exercise of its rights under clause (a) of this Section 3.2, in each case ((a) and (b)), to Exploit ADCs and Licensed Products, in each case, Directed to such Designated Target (including to conduct its activities under each Research Program as set forth in the applicable Research Plan), within the Field in the Territory (collectively (a) and (b) with respect to such Designated Target, an "Exclusive License"). Each Exclusive License will continue (i) for the applicable Royalty Term, unless earlier terminated pursuant to Section 11 or Section 2.4.4.2(a), and (ii) thereafter, as provided in Section 11.5.3.1 and Section 11.5.4. Notwithstanding anything to the contrary, with respect to the [\*\*] Designated Target, the rights granted to Merck in the Exclusive License shall be solely for the Exploitation of ADCs and Licensed Products, in each case, Directed to the [\*\*]."

**1.9** <u>Schedule of Designated Targets</u>. <u>Schedule 2.4.1</u> of the Original Agreement is hereby deleted in its entirety and replaced with <u>Exhibit A</u> attached hereto.

**1.10** <u>Original Mersana In-Licenses</u>. The Parties acknowledge and agree that the TUBE Agreement and MGH Agreement have been terminated prior to the Amendment Effective Date. All references to the TUBE Agreement, MGH Agreement and Original Mersana In-Licenses in the Original Agreement are hereby deleted.

## ARTICLE 2 — ACKNOWLEDGEMENT OF PRIOR DESIGNATIONS

**2.1** <u>Prior Designated Targets</u>. The Parties hereby acknowledge and agree that the [\*\*] Designated Targets have been designated in accordance with the Original Agreement prior to the Amendment Effective Date and that this Amendment shall have no effect on such prior designations.

# ARTICLE 3 — MISCELLANEOUS

**3.1** <u>Effectiveness</u>. Except as set forth in this Amendment, all terms and conditions of the Original Agreement are hereby ratified and shall remain in full force and effect. Amendments made pursuant to this Amendment shall be effective as of the Amendment Effective Date.

**3.2** <u>Conflicts</u>. In the event of a conflict between a provision of the Original Agreement and a provision of this Amendment, the provisions of this Amendment will control to the extent of such conflict.

**3.3** <u>Counterparts</u>. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be signed or delivered by facsimile or electronically scanned signature page.

(The remainder of this page has been intentionally left blank. The signature page follows.)

IN WITNESS WHEREOF, the Parties have executed this Amendment to be effective as of the Amendment Effective Date. MERSANA THERAPEUTICS, INC.

MEKSA	INA THERAPEUTICS, INC.
By:	/s/ Eva M. Jack
Name:	Eva Jack
Title:	Chief Business Officer
MERCK	K KGaA
By:	/s/ Axel Hoffmann
Name:	Axel Hoffmann
Title:	Director Alliance Management Global
Business	Development & Alliance Management
By:	/s/ Marco Rau
Name:	Dr. Marco Rau, LL.M.
Title:	Senior Counsel

Signature Page to Amendment 2 to Collaboration and Commercial License Agreement

#### Exhibit A <u>SCHEDULE 2.4.1</u> DESIGNATED TARGETS

#	Target	Definition	OMIM	SwissProt
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

#### AMENDMENT 3 TO COLLABORATION AND COMMERCIAL LICENSE AGREEMENT

This Amendment 3 to Collaboration and Commercial License Agreement ("Amendment 3") is entered into as of the 28th day of February, 2017 (the "Amendment 3 Effective Date") by and between Mersana Therapeutics, Inc., a Delaware corporation, having its principal place of business at 840 Memorial Drive Cambridge, MA 02139 (hereinafter referred to as "Mersana") and Merck KGaA, a corporation with general partners having its principal place of business at Frankfurter Str. 250, 64293 Darmstadt, Germany (hereinafter referred to as "Merck," and together with Mersana, the "Parties"). This Amendment 3 amends that certain Collaboration and Commercial License Agreement by and between Mersana and Merck dated June 23, 2014, as amended on June 1, 2016 ("Amendment 1") and on August 12, 2016 ("Amendment 2") (together the "Original Agreement," and together with this Amendment 3, the "Agreement"). Capitalized terms used but not defined in this Amendment 3 will have the definition set forth in the Original Agreement.

#### RECITALS

WHEREAS, the Parties wish to amend the Original Agreement as set forth in this Amendment 3;

WHEREAS, Merck has previously designated [\*\*] as the Reserved Target in accordance with the terms of the Original Agreement; and

**NOW, THEREFORE**, in consideration of the mutual covenants and obligations set forth herein, the Parties hereto, intending to be legally bound, agree as follows:

## ARTICLE 1 — AMENDMENTS

1.1 <u>New Definitions</u>. The following new definitions are hereby added to Article 1 of the Original Agreement in alphabetical order:

- (a) "Amendment 3 Effective Date" means February 28, 2017.
- (b) "[\*\*] Designated Target Initial Research Period" is defined in Section 2.6.

**1.2** <u>Designation of [\*\*]</u> <u>Designated Target</u>. Notwithstanding Section 2.4.1.5 of the Original Agreement, Merck hereby designates the Reserved Target as the [\*\*] Designated Target and Mersana hereby agrees to such designation. <u>Schedule 2.4.1</u> of the Original Agreement is hereby deleted in its entirety and replaced with <u>Exhibit A</u> attached hereto.

**1.3** <u>Research Plan and Research Program for the [\*\*] Designated Target</u>. Notwithstanding Sections 2.4.1.5 and 2.2.3 of the Original Agreement, the Research Plan for the [\*\*] Designated Target is attached hereto as <u>Exhibit B</u> and is hereby approved by the Parties. Notwithstanding Section 2.3 of the Original Agreement, the Research Program for [\*\*] Designated Target shall commence as of the Amendment 3 Effective Date.

**1.4 <u>Replacement of [\*\*] Designated Target</u>**. Section 2.4.3 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"2.4.3. <u>Replacement of Designated Targets</u>. During the Research Program Term for a Research Program, in the event that the Project Leaders reasonably determine that it is [\*\*] in accordance with the applicable Research Plan using at least one of the Merck Antibodies provided thereunder, the Project Leaders will promptly notify Merck in writing thereof. Merck may, at any time within [\*\*] following receipt of such notice, designate a new Designated Target in

accordance with Section 2.4.2 to replace the original Designated Target without using an additional of the overall [\*\*] options to designate an Antigen as a new Designated Target pursuant to Section 2.4.1. The original Designated Target will no longer be deemed to be a Designated Target, and Merck will have no further right or license under this Agreement with respect to the original Designated Target. Within [\*\*] after the expiration of the [\*\*] Designated Target Initial Research Period, Merck may designate a new Designated Target in accordance with Section 2.4.2 to replace the original [\*\*] Designated Target and after such designation the original [\*\*] Designated Target, and Merck will no longer be deemed to be a Designated Target, and Merck will have no further right or license under this Agreement with respect to the original [\*\*] Designated Target.

**1.5** <u>Initial [\*\*] Designated Target Research</u>. The following new Section 2.6 is hereby inserted immediately following Section 2.5.4.4 of the Original Agreement.

"2.6. <u>Initial [\*\*] Designated Target Research</u>. Following the Amendment 3 Effective Date, Mersana shall prepare and deliver ADCs Directed to the sixth Designated Target as set forth under "Initial ADC Preparation and Delivery" in the Research Plan for the sixth Designated Target. During the [\*\*] period following delivery of such ADCs to Merck in accordance with the Research Plan (the "[\*\*] Designated Target Initial Research Period"), Merck shall conduct the activities set forth under "Initial In Vitro Assessment" in the Research Plan and shall promptly provide Mersana with all data resulting from such activities."

#### ARTICLE 2 — ACKNOWLEDGEMENT OF PRIOR DESIGNATIONS

**2.1** <u>Prior Designated Targets</u>. The Parties hereby acknowledge and agree that the first, second, third, fourth and fifth Designated Targets have been designated in accordance with the Original Agreement prior to the Amendment 3 Effective Date and that this Amendment 3 shall have no effect on such prior designations.

#### ARTICLE 3 — MISCELLANEOUS

**3.1** Effectiveness. Except as set forth in this Amendment 3, all terms and conditions of the Original Agreement are hereby ratified and shall remain in full force and effect. Amendments made pursuant to this Amendment 3 shall be effective as of the Amendment 3 Effective Date.

**3.2** <u>Conflicts</u>. In the event of a conflict between a provision of the Original Agreement and a provision of this Amendment 3, the provisions of this Amendment 3 will control to the extent of such conflict.

**3.3** <u>Counterparts</u>. This Amendment 3 may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be signed or delivered by facsimile or electronically scanned signature page.

(The remainder of this page has been intentionally left blank. The signature page follows.)

2

IN WITNESS WHEREOF, the Parties have executed this Amendment 3 to be effective as of the Amendment 3 Effective Date. MERSANA THERAPEUTICS. INC.

MERSA	NA IIIERAI EUTICS, INC.
By:	/s/ Eva M. Jack
Name:	Eva M. Jack
Title:	Chief Business Officer
MERCK	KGaA
By:	/s/ i.V. Axel Hoffmann
Name:	Axel Hoffman
Title:	Director Alliance Management Global Business Development & Alliance Management
By:	/s/ i.V. Tobias Greven
Name:	Tobias Greven
Title:	Head of BD Legal Healthcare

Signature Page to Amendment 3 to Collaboration and Commercial License Agreement

### Exhibit A

# SCHEDULE 2.4.1

# **DESIGNATED TARGETS**

#	Target	Definition	OMIM	SwissProt
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]		[**]
[**]	[**]	[**]		[**]
[**]	[**]	[**]		[**]

## Exhibit B

# **Research Plan for Sixth Designated Target**

# **SCHEDULE 2.2.3-5**

# PROPOSED RESEARCH PLAN FOR [\*\*] ([\*\*] Designated Target)

Description of Work Flow Steps

[\*\*]

# EXHIBIT 1.1.98

# **PERFORMANCE SPECIFICATIONS for** [\*\*] (Sixth Designated Target)

Parameter	Analysis	Methods
	[**]	
[**]	[**] [**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

# LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

### between

# MERSANA THERAPEUTICS, INC.

and

# **RECEPTA BIOPHARMA S.A.**

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### LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This License, Development and Commercialization Agreement ("Agreement"), effective as of July 9, 2015 ("Effective Date"), is by and between Mersana Therapeutics, Inc. ("Mersana"), with offices at 840 Memorial Dr., Cambridge, MA 02139, USA and Recepta Biopharma, S.A. ("Recepta"), with offices at Rua Tabapuã, 1123 conj 36, Itaim Bibi, São Paulo, SP, CEP 04533 - 014, Brazil. Mersana and Recepta may be referred to in this Agreement individually as a "Party" or together as the "Parties."

#### BACKGROUND

WHEREAS, Mersana controls certain intellectual property rights relating to antibody-drug conjugates, including rights to its proprietary Fleximer® technology;

WHEREAS, Recepta controls certain patents, patent applications, proprietary know-how, scientific and technical information relating to the Antibody (as defined below), all of which Recepta controls from Brazil;

**WHEREAS**, subject to the terms and conditions of this Agreement, Mersana wishes to obtain, and Recepta is willing to grant, an exclusive license to certain intellectual property rights for the development, use, manufacture and commercialization of therapeutic products for the treatment of human cancers; and

**WHEREAS**, subject to the terms and conditions of this Agreement, Recepta desires to obtain the exclusive right in Brazil to commercialize products developed by Mersana pursuant to the aforementioned license.

**NOW, THEREFORE**, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

# AGREEMENT

**1. DEFINITIONS**. For purposes of this Agreement, the following capitalized terms, whether used in the singular or plural, shall have the following meanings:

1.1 "Additional Development Activities" shall have the meaning assigned thereto in Section 3.1.2.

1.2 "Affiliate" means any Person that, directly or indirectly, controls, is controlled by or is under common control with a Party for so long as such control exists, where "control" means the direct or indirect ownership of at least fifty percent (50%) of the voting securities of an entity (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in particular jurisdiction), or such other relationship as results in the power to control the management and policies of an entity. References herein to a Party's "controlled Affiliates" shall mean any Person that is directly or indirectly controlled, within the meaning of this definition, by such Party.

1.3 "Antibody" means Recepta's proprietary monoclonal antibody sequence that [\*\*].

1.4 "ANVISA" means the Brazilian National Sanitary Surveillance Agency or any successor agency thereto.

1.5 "Applicable Law" means any law, statute, rule or regulation issued by a Governmental Authority or Regulatory Authority and any judicial, governmental or administrative order, judgment, decree, or ruling, in each case as applicable to the subject matter of this Agreement and the Parties and having a binding effect on the applicable Person.

1.6 "BLA" means a Biologics License Application or any amendments thereto submitted to the FDA, or any equivalent application in the United States that replaces such application.

1.7 "BLA Acceptance" means the written notification by the FDA that the BLA has met all the criteria for filing acceptance.

1.8 "BLA Approval" means approval by the FDA for marketing and sale of a Licensed Product in the United States, including any applicable final labeling approval, whether by virtue of any accelerated approvals, such as through Breakthrough Therapy Designation, or otherwise.

1.9 "Breakthrough Therapy Designation" means a drug designated by the FDA as a Breakthrough Therapy pursuant to Section 902 of the Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012), as it may be amended from time to time, and the regulations promulgated thereunder.

1.10 "Business Day" means, (i) when used in relation to any obligation or notice to be given by Mersana, any day that is not a Saturday or Sunday or a day on which banks in New York, New York are authorized or required to be closed, or (ii) when used in relation to any obligation or notice to be given by Recepta, any day that is not a Saturday or Sunday or a day on which banks in São Paulo, Brazil are authorized or required to be closed, or (iii) when used in relation to any other matter, any day that is not a Saturday or Sunday or a day on which banks in either New York, New York or São Paulo, Brazil are authorized or required to be closed.

1.11 "Cessation Date" shall the meaning assigned thereto in Section 10.3.2(a).

1.12 "Claim" means any charge, complaint, action, suit, proceeding, hearing, investigation, claim or demand.

1.13 "Clinical Trials" means a clinical trial in human subjects that has been approved by a Regulatory Authority and an institutional review board or ethics committee, and is designed to measure the safety and/or efficacy of a Licensed Product. Clinical Trials shall include Phase I Clinical Trials, Phase II Clinical Trials, Phase III Clinical Trials and any pre-clinical or post-Regulatory Approval studies undertaken in relation to any Licensed Product.

1.14 "Combination Product" means a product that consists of an antibody drug conjugate and other active compounds or active ingredients sold as a single formulation or any combination of a Licensed Product sold together with another product that is not a Licensed Product ("Other Product") for a single invoiced price. Notwithstanding the foregoing, Other Products shall not include any Linker, drug delivery vehicle, cytotoxic compound or other therapeutically active ingredient conjugated or otherwise linked to the Antibody, adjuvant, excipient or diagnostic compound.

1.15 "Commercialization" or "Commercialize" means engaging in any and all activities directed to (i) in the case of either Party's activities, obtaining pricing and reimbursement approvals, marketing, promoting, distributing, offering for sale, selling, importing, or commercially exploiting a product and (ii) in the case of Mersana's activities (in

addition to the activities listed under the foregoing clause (i)) exporting a product and conducting post-Regulatory Approval studies.

1.16 "Confidential Information" shall have the meaning assigned thereto in Section 6.1.

1.17 "Control" or "Controlled" when used in reference to any intellectual property or intellectual property right of either Party or its Affiliates, including Patents and Know-How of such Party or such Affiliates, means the legal authority or right of such Party or such Affiliates to: (i) grant, or procure the grant of, a license or sublicense, to the extent provided for herein, of the intellectual property, intellectual property right, material, Know-How or information to the other Party; and/or (ii) in relation to material, Know-How or information to the other Party, and in each case without (1) breaching the terms of any agreement with a Third Party, (2) misappropriating the material, Know-How or information of a Third Party or (3) paying any additional consideration to any Third Party.

1.18 "Cover" or "Covering" means, (i) with respect to any Patent, that at least one Valid Claim of such Patent would be infringed by the product, method, use, or device, as applicable, and (ii) with respect to any other intellectual property right that the product, method, use or device would infringe or misappropriate such rights unless a license were granted.

1.19 "Development" or "Develop" means engaging in preclinical and clinical drug development activities, including, but not limited to, discovery, test method development, stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, analytical method validation, manufacturing process validation, cleaning validation, post-approval changes, quality assurance/quality control, statistical analysis, report writing, preclinical studies, Clinical Trials, regulatory filing submission and approval and regulatory affairs.

1.20 "Diligent Efforts" means, with respect to a Party's obligations or tasks under this Agreement, the carrying out of such obligations or tasks with a level of effort and resources as would normally be devoted by a biotechnology company of similar size, resources and experience in connection with the research, development, manufacture or commercialization of a product (or product under development) owned by it, or to which it has exclusive rights,

which is of similar market potential, profit potential or strategic value, based on the conditions then prevailing, taking into account, among other things, patient safety, efficacy and the costs and timeframes necessary to achieve Regulatory Approval in the relevant territory. The foregoing efforts shall at least be consistent with those that the applicable Party would normally devote to a product (or product under development) of similar market potential, profit potential or strategic value resulting from its own research efforts, based on the conditions then prevailing. In determining the appropriate level of efforts required to be devoted to its tasks and obligations under this Agreement, in no event shall a Party take into account the market potential, profit potential or strategic value of any product (or product under development) (other than the Licensed Products) to which it or any of its controlled Affiliates has any right or interest that targets the same protein as the Antibody, such that the market potential and strategic value of any such other product (or product under development) to which the applicable Party or any of its controlled Affiliates has any right or interest that targets the same protein as the Antibody. Without limiting the foregoing, Diligent Efforts in all cases requires at least that the applicable Party (i) promptly assigns responsibility for such obligations to specific employee(s) who monitor progress on an ongoing basis; (ii) sets and consistently seeks to achieve specific and meaningful objectives for carrying out such

obligations; and (iii) consistently makes and implements decisions and allocates resources designed to advance progress with respect to such objectives; provided, however, that the foregoing clauses (i) through (iii) shall not apply to any activity in respect of the Development, manufacturing or Commercialization of Licensed Products that a Party, acting reasonably and in good faith, has suspended or delayed (a) due to medical necessity to protect patients enrolled in a Clinical Trial or for other safety or efficacy reasons, or (b) in order to comply with Applicable Laws. Diligent Efforts will be determined on a country-by-country basis.

1.21 "Disclosing Party" shall have the meaning assigned thereto in Section 6.1.

1.22 "Effective Date" shall have the meaning assigned thereto in the first paragraph of this Agreement.

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

1.24 "FD&C Act" means the United States Federal Food, Drug & Cosmetic Act, as amended, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

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

1.26 "Field" means the diagnosis, prophylaxis and/or treatment of human cancers.

1.27 "First Commercial Sale" means, with respect to any Licensed Product and with respect to any country of the Territory, the first transfer or disposition for value of a Licensed Product by either Party or its Affiliates or sublicensees to a Third Party following, if

required by Applicable Law, Regulatory Approval and Pricing Approval of such Licensed Product and, when Regulatory Approval and Pricing Approval are not required by Applicable Law for the Licensed Product, the first sale, transfer or disposition for value of a Licensed Product in that country by either Party or its Affiliates or sublicensees to a Third Party; *provided*, that sales for clinical study purposes or compassionate, named patient (paid or unpaid) or similar use will not constitute a First Commercial Sale.

1.28 "Fleximer®" means Mersana's biodegradable polymer platform, poly(hydroxymethylene)hydroxymethyl formal, in any of its forms and sizes and varieties, including any improvements or enhancements thereto or adaptations or subsequent versions thereof.

1.29 "Force Majeure Event" shall have the meaning assigned thereto in Section 11.6.

1.30 "General Improvement" means any discovery (whether patentable or not) (i) which is invented during the Term by Mersana or its Affiliates or sublicensees as a result of Development or other activities undertaken by it or its Affiliates or sublicensees within the scope of this Agreement in respect of a Licensed Product and (ii) which relates to the Antibody and one or more other antibodies. For the avoidance of doubt, General Improvement does not include any discovery which is invented by any of Mersana's Affiliates (a) prior to or after the Term of the Agreement or (b) during the Term but is not actually used by Mersana's Affiliate or Mersana at any time during the Term in the Development, Commercialization or commercial manufacturing of, or incorporated in, any Licensed Product or the Antibody.

1.31 "Good Manufacturing Practices" or "GMP" means, with respect to the United States, the minimum thencurrent good manufacturing practices for methods, facilities, and controls to be used for the manufacture, processing, packing, or holding of a drug to assure that it meets the requirements of the FD&C Act for safety and has the identity and strength and meets the quality and purity characteristics, specified in 21 C.F.R. Parts 210 and 211, as may be amended, and, with respect to any other country or jurisdiction, the regulations in such other country or jurisdiction having a comparable purpose.

1.32 "Governmental Authority" means an applicable multi- or supra-national, federal, state, local, municipal or other government authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.33 "ICC" means the International Chamber of Commerce.

1.34 "IND" means (i) in the United States, an Investigational New Drug Application, as defined in the FD&C Act, that is required to be filed with the FDA before conducting a Clinical Trial (including all supplements and amendments that may be filed with respect to the foregoing); and (ii) any foreign counterpart of the foregoing.

1.35 "Indemnified Party" shall have the meaning assigned thereto in Section 8.3.1.

1.36 "Indemnifying Party" shall have the meaning assigned thereto in Section 8.3.1.

1.37 "Initiation" means, with respect to a Clinical Trial, the date of the dosing of the first subject.

1.38 "Know-How" means proprietary technical information, processes, formulae, data, inventions (whether or not patentable), methods, knowledge, discoveries, trade secrets and other information that are not generally known, including any tangible embodiments of the foregoing.

1.39 "Licensed Products" means (i) with respect to products manufactured, Developed or Commercialized by Mersana and/or any of its Affiliates or sublicensees, any product that (a) contains the [\*\*], and (b) the Development, manufacture, use or Commercialization of which utilizes any Recepta Know-How or, [\*\*] or (ii) with respect to products Commercialized by Recepta or any of its Affiliates or sublicensees, any formulation of a product described in clause (i) above which results from the Development activities carried out by Mersana and/or any of its Affiliates or sublicensees pursuant to this Agreement.

1.40 "LICR" means the Ludwig Institute for Cancer Research and any successor entity thereto.

1.41 "LICR License" means that certain Research, Development and License Agreement between LICR and Recepta, dated October 10, 2006, [\*\*].

1.42 "Linker" shall have the meaning assigned thereto in the definition of Mersana Platform Know-How.

1.43 "Losses" means any and all damages (including, but not limited to, all loss of profits, diminution in value, and incidental, indirect, consequential, special, reliance, exemplary, punitive, statutory and treble damages), awards, deficiencies, settlement amounts, defaults,

assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses and expenses (including, but not limited to, court costs, interest and reasonable fees of attorneys, accountants and other experts) incurred by or awarded to Third Parties and required to be paid to Third Parties with respect to a Claim by reason of any judgment, order, decree, stipulation or injunction, or any settlement entered into in accordance with the provisions of this Agreement, together with all documented outof-pocket costs and expenses incurred in contesting any Third Party Claim or complying with any judgments, orders, decrees, stipulations and injunctions that arise from or relate to a Third Party Claim.

1.44 "Major Market" means the following countries: [\*\*].

1.45 "MAA" means a Marketing Authorization Approval issued by the EMA.

1.46 "Mersana" shall have the meaning assigned thereto in the preamble.

1.47 "Mersana Annual Net Sales" means Mersana's, its Affiliates' and its sublicensees' aggregate worldwide Net Sales of all Licensed Products in a given calendar year during the Royalty Term.

1.48 "Mersana Cytotoxic Compound" means [\*\*] that Mersana or any of its Affiliates Controls as of the Effective Date or at any time during the Term.

1.49 "Mersana Know-How" means Know-How, other than Recepta Know-How, that is (i) owned or Controlled by Mersana or any Affiliate of Mersana as of the Effective Date or at any time during the Term and (ii) necessary or useful to manufacture, Develop or Commercialize Licensed Products; *provided*, *however*, that in no event will any Specific Improvements constitute Mersana Know-How.

1.50 "Mersana Platform Know-How" means Mersana Know-How to the extent relating to or consisting of (i) a Mersana Cytotoxic Compound, (ii) [\*\*], (iii) the conjugation of a Mersana Cytotoxic Compound to a Linker, (iv) the conjugation of a pharmaceutical compound to a Linker, (v) [\*\*] or (vi) [\*\*]; *provided, however*, that in no event will any Specific Improvements constitute Mersana Platform Know-How.

1.51 "Mersana Patents" means all Patents that are owned or Controlled by Mersana or any of its controlled Affiliates as of the Effective Date, or which become owned or Controlled by it or any of its controlled Affiliates during the Term, that, but for the license granted to Recepta under Section 2.1.2, would be infringed by Recepta's performance of its obligations or exercise of its rights under this Agreement; *provided, however*, that the Mersana Patents shall not include the Recepta Patents.

1.52 "Mersana Platform Patents" means all Mersana Patents that Cover any Mersana Platform Know-How.

1.53 "Mersana Product Patents" means all Mersana Patents other than Mersana Platform Patents.

1.54 "Mersana Promotional Materials" shall have the meaning set forth in Section 2.3.1.

1.55 "Mersana Technology" means the Mersana Patents and the Mersana Know-How.

1.56 "MHLW" means the Ministry of Health, Labour and Welfare in Japan, and any successor agency thereto.

1.57 "Net Sales" means the gross amounts invoiced or otherwise billed by a Party, its Affiliates or a Party's sublicensees for sales of Licensed Products to Third Party purchasers of such Licensed Products, *less the following deductions* with respect to such sales to the extent that such amounts are either included in the billing as a line item as part of the gross amount invoiced, or otherwise documented to be specifically attributable to actual sales of such Licensed Products:

(a) trade discounts, including trade, cash and quantity discounts or rebates, credits or refunds (including inventory management fees, discounts or credits);

(b) allowances or credits actually granted upon claims, returns or rejections of Licensed Products, including recalls, regardless of the Party requesting such recall;

(c) bad debts; *provided* that the amount of any bad debts deducted pursuant to this exception and actually collected in a subsequent calendar quarter shall be included in Net Sales for such subsequent calendar quarter;

(d) charges included in the gross sales price for freight, insurance, transportation, postage, handling and any other charges relating to the sale, transportation, delivery or return of such Licensed Product;

(e) customs duties, sales, excise and use taxes and any other governmental charges (including value added tax) actually paid in connection with the transportation, distribution, use or sale of such Licensed Product (but excluding what are commonly known as income taxes);

(f) rebates and chargebacks or retroactive price reductions made to federal, state or local governments (or their agencies), or any Third Party payor, administrator or contractor, including managed health organizations; and

(g) non-recurring cash consideration given to Third Parties for the direct costs incurred by such Third Parties for establishing the infrastructure necessary for such Third Parties to import or distribute any Licensed Product in any country in the Territory where a Party does not have such infrastructure in place (specifically excluding any commission paid to sales personnel, sales representatives and sales agents who are employees or consultants of the selling Party or its Affiliates or any of their sublicensees).

All of the foregoing deductions from the gross invoiced sales prices of Licensed Products will be determined in accordance with IFRS or GAAP, or such other accounting standard utilized by the Party or its Affiliate or sublicensee, as consistently applied by the applicable Party or its Affiliate or sublicensee, as applicable, with respect to external reporting. In the event that a Party, its Affiliates or any of its sublicensees makes any adjustments to such deductions after the associated Net Sales have been reported pursuant to this Agreement, the adjustments will be reported and reconciled in the next report and payment of any royalties due.

For clarification, sale of Licensed Products by a Party, its Affiliates or any of its sublicensees to another of these entities for resale by such entity to a Third Party shall not be deemed a sale for purposes of this definition of "Net Sales" unless such entity is the end customer of the Licensed Product sold. Further, use, supply or donation of Licensed Products by a Party, its Affiliates or any of its sublicensees for no profit (i) in connection with patient assistance programs, (ii) for charitable or promotional purposes, (iii) for preclinical, clinical, regulatory or governmental

purposes, or compassionate use or other similar programs, or (iv) for tests or studies reasonably necessary to comply with any Applicable Law, regulation or request by a Regulatory Authority shall not, in each case, be deemed sales of such Licensed Products for purposes of this definition of "Net Sales."

1.58 "Other Product" shall have the meaning assigned thereto in the definition of Combination Product.

1.59 "Party" or "Parties" shall have the meaning assigned thereto in the first paragraph of this Agreement.

1.60 "Patent" means any and all national, regional or international (i) issued patents and pending patent applications (including provisional patent applications), (ii) patent applications filed either from the foregoing or from an application claiming priority in whole or in part to the foregoing, including all provisional applications, converted provisionals, substitutions, continuations, continuations-in-part, divisions, renewals and continued prosecution applications, and all patents granted thereon, (iii) patents-of-addition, revalidations, reissues, reexaminations and extensions, adjustments or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof, (iv) inventor's certificates, utility models, innovation patents and design patents, (v) other forms of government-issued rights substantially similar to any of the foregoing, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing and (vi) United States and foreign counterparts of any of the foregoing.

1.61 "Patent Challenge" shall have the meaning assigned thereto in Section 9.2.

1.62 "Person" means any natural person, corporation, general partnership, limited partnership, limited liability company, proprietorship or other *de jure* entity organized under Applicable Laws of any jurisdiction.

1.63 "Phase I Clinical Trial" means a Clinical Trial that provides for the first introduction into humans of a product with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of such product, in a manner that is generally consistent with 21 CFR § 312.21(a), as amended (or its successor regulation).

1.64 "Phase II Clinical Trial" means a Clinical Trial, the principal purpose of which is to make a preliminary determination as to whether a product is safe for its intended use and to obtain sufficient information about such product's efficacy, in a manner that is generally consistent with 21 CFR § 312.21(b), as amended (or its successor regulation), to permit the design of further Clinical Trials.

1.65 "Phase III Clinical Trials" means a pivotal Clinical Trial with a defined dose or a set of defined doses of a therapeutic product designed to ascertain efficacy and safety of such product, in a manner that is generally consistent with 21 CFR § 312.21(c), as amended (or its successor regulation), for the purpose of enabling the preparation and submission of a BLA or a foreign equivalent thereof.

1.66 "Pricing Approval" means, in any country or jurisdiction where a Governmental Authority is required, pursuant to Applicable Law, to approve or determine pricing or pricing reimbursement for medicinal products sold in such country or jurisdiction, the later of (i) the approval, agreement, determination or governmental decision establishing the

price for the applicable Licensed Product that can be legally charged to consumers, as required by Applicable Law in such jurisdiction or country in connection with Commercialization of such Licensed Product in such jurisdiction or country and (ii) the approval, agreement, determination or governmental decision establishing the level of reimbursement for the applicable Licensed Product that will be reimbursed by Governmental Authorities, as required by Applicable Law in such jurisdiction or country in connection with Commercialization of such Licensed Product in such jurisdiction or country in connection with Commercialization of such Licensed Product in such jurisdiction or country in connection with Commercialization of such Licensed Product in such jurisdiction or country.

1.67 "Product Bundle" shall have the meaning set forth in Section 5.7.

1.68 "Promotional Materials" shall have the meaning set forth in Section 2.3.1.

1.69 "Receiving Party" shall have the meaning assigned thereto in Section 6.1.

1.70 "Recepta" shall have the meaning assigned thereto in the preamble.

1.71 "Recepta Annual Net Sales" means Recepta's and its Affiliates' and its sublicensees' (for clarity, excluding Mersana and its sublicensees) aggregate worldwide Net Sales of all Licensed Products in a given calendar year during the Royalty Term.

1.72 "Recepta Know-How" means all Know-How that is (i) owned or Controlled by Recepta or any Affiliate of Recepta as of the Effective Date or at any time during the Term and (ii) necessary or useful for the Development, manufacture and Commercialization of Licensed Products in the Field in the Territory, including, but not limited to, all data and records (including preclinical and process-related data) that are owned or Controlled by Recepta or its Affiliate and related to the Antibody in existence as of the Effective Date.

1.73 "Recepta Patents" means the Patents listed in Exhibit 1 hereto and (i) patent applications filed either from the foregoing or from an application claiming priority to the foregoing, including all provisional applications, converted provisionals, substitutions, continuations, continuations-in-part, divisions, renewals and continued prosecution applications, and all patents granted thereon, (iii) patents-of-addition, revalidations, reissues, reexaminations and extensions, adjustments or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof, (iv) inventor's certificates, utility models, innovation patents and design patents, (v) other forms of government-issued rights substantially similar to any of the foregoing, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing and (vi) United States and foreign counterparts of any of the foregoing, in each case (clauses (i) through (vi)), that are owned or Controlled by Recepta or any of its controlled Affiliates as of the Effective Date or at any time during the Term.

1.74 "Recepta Promotional Materials" shall have the meaning assigned thereto in Section 2.3.1.

1.75 "Recepta Technology" means the Recepta Patents, Recepta Know-How and Specific Improvements, collectively.

1.76 "Recepta Territory" means Brazil.

1.77 "Recepta Trademarks" shall have the meaning assigned thereto in Section 2.3.2.

1.78 "Regulatory Approval" means, with respect to a particular country, final regulatory approval (but excluding Pricing Approval) required to commercially sell a Licensed Product for a disease or condition in accordance with the Applicable Laws of such country. In the United States, its territories and possessions, Regulatory Approval means BLA Approval. In the European Union and for any country that is a member of the European Union, Regulatory Approval means issuance of an MAA or an equivalent by the EMA.

1.79 "Regulatory Authority" means, with respect to a country in the Territory, any national (e.g., the FDA), supranational (e.g., the European Commission, the Council of the European Union, or the European Medicines Agency), regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority involved in the granting of a Regulatory Approval or a Pricing Approval, for biopharmaceutical products in such country.

1.80 "Responsible Party" shall have the meaning assigned thereto in Section 9.3.

1.81 "ROW Promotional Materials" shall have the meaning assigned thereto in Section 2.3.1.

1.82 "ROW Trademarks" shall have the meaning assigned thereto in Section 2.3.2.

1.83 "Royalty Term" means, (i) when used in relation to a particular country and a particular Licensed Product, a period starting on the Effective Date and expiring upon the later of (a)(1) with respect to products Commercialized by Mersana or any of its Affiliates or sublicensees, the expiry of the last-to-expire Recepta Patent which has at least one Valid Claim Covering such Licensed Product in such country (including the term of any applicable SPC) or (2) with respect to products Commercialized by Recepta or any of its Affiliates or sublicensees, the expiry of the last-to-expire Mersana Patent which has at least one Valid Claim Covering such Licensed Product in the Recepta Territory (including the term of any applicable SPC) and (b) ten (10) years from the date of First Commercial Sale of such Licensed Product in such country, (ii) when used in relation to a particular country, the last to expire Royalty Term, within the meaning of the foregoing clause (i), in such country and (iii) when used other than in relation to a particular Licensed Product or country, the last to expire Royalty Term, within the meaning of the foregoing clause (ii), in the Territory or in the Recepta Territory, as applicable.

1.84 "SPC" means a right based upon a Patent to exclude others from making, having made, using, offering to sell, selling, importing or exporting a Licensed Product, such as a Supplementary Protection Certificate.

1.85 "Specific Improvement" means any discovery (whether patentable or not) (a) which is invented during the Term by Mersana or its Affiliates or sublicensees as a result of Development or other activities undertaken by it or its Affiliate or sublicensee in respect of a Licensed Product and (b) which relates solely and specifically to the Antibody. For the avoidance of doubt, "Specific Improvement" specifically excludes General Improvements and any other discoveries relating directly to the Mersana Technology, including all patent applications and any patents resulting therefrom.

1.86 "Supply Agreement" shall have the meaning assigned thereto in Section 3.3.2.

1.87 "Term" shall have the meaning assigned thereto in Section 10.1.

1.88 "Territory" means all the countries and territories of the world.

1.89 "Third Party" means a Person who is not a Party or an Affiliate of a Party.

1.90 "Third Party Claim" shall have the meaning assigned thereto in Section 8.3.1.

1.91 "Third Party IP" shall have the meaning assigned thereto in Section 5.4.2.

1.92 "Third Party Licenses" means, collectively (i) the LICR License, (ii) that certain Agreement, dated [\*\*], as amended and (iii) that certain [\*\*], as amended.

1.93 "Third Party Payment" shall have the meaning assigned thereto in Section 5.4.2.

1.94 "Three-Party Agreement" means that certain Agreement Regarding LICR Technology between Recepta, LICR and Mersana of even date herewith.

1.95 "United States" means the United States of America and its territories and possessions.

1.96 "Valid Claim" means with respect to a Patent in a country any claim of an (i) issued Patent that has not (a) expired, irretrievably lapsed or been abandoned, revoked, dedicated to the public or disclaimed or (b) been found to be unpatentable, invalid or unenforceable by an unreversed and unappealable decision of a Governmental Authority in such country or (ii) application for a Patent that (a) has been pending for less than [\*\*] years from the earliest claimed priority date and is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing and (b) has not been admitted to be invalid or unenforceable through reissue, reexamination, or disclaimer.

#### 2. LICENSE GRANTS AND OWNERSHIP.

#### 2.1 License Grants.

2.1.1 License to Mersana. Subject to the terms and conditions of this Agreement, including Section 2.1.2 and Section 2.6, Recepta hereby grants to Mersana, and Mersana accepts, an exclusive, royalty-bearing, non-transferable (except as expressly set forth in Section 2.2.1 and Section 11.10) license or sublicense, as applicable, under Recepta's rights in the Recepta Technology, to make, have made, use, register, sell, offer to sell, import, export, exploit, research, improve, Develop and Commercialize Licensed Products in the Field in the Territory.

2.1.2 License Back to Recepta. Subject to the terms and conditions of this Agreement, Mersana hereby grants to Recepta, and Recepta accepts, an exclusive (including as to Mersana), royalty-bearing, non-transferable (except as expressly set forth in Section 2.2.2 and Section 11.10) license, under Mersana's rights in the Recepta Technology, the Mersana Know-How and the Mersana Patents, to import, promote, offer for sale, and sell (including through multiple tiers of distribution) and otherwise Commercialize Licensed Products in the Recepta Territory and to otherwise carry out its obligations and exercise its rights under this Agreement, in accordance with and subject to the terms hereof.

#### 2.2 Sublicensing and Subcontracting.

2.2.1 <u>Mersana's Right to Sublicense and Subcontract</u>. Mersana may sublicense or subcontract its rights hereunder to research, Develop, manufacture or Commercialize Licensed Products in whole or in part to any of its Affiliates or to any Third

Parties, subject to prior written notification to Recepta. Mersana shall not be relieved of its obligations under this Agreement as a result of granting any sublicense or subcontracting any of its activities as permitted under this Section 2.2.1, except to the extent such obligations are satisfactorily performed by such sublicensee or subcontractor, as applicable, in a manner consistent with Mersana's obligations under this Agreement. Recepta, its Affiliates and sublicensees shall not be considered sublicensees of Mersana pursuant to this Section 2.2.1. Mersana shall secure all appropriate covenants, obligations and rights from any such sublicensee or subcontractor, including, but not limited to, licenses, intellectual property rights and confidentiality obligations, to ensure that such sublicensee or subcontractor is subject to, and Mersana can comply with, all of Mersana's covenants and obligations to Recepta under this Agreement. With respect to any exclusive sublicenses granted by Mersana to any Third Party for the purpose of collaborating with such Third Party on the Development and/or Commercialization of any Licensed Product pursuant to this Agreement, Mersana will provide Recepta a copy of the applicable sublicense agreement with such Third Party promptly after the parties' execution of the same. Any such agreement shall be considered the Confidential Information of Mersana and may be redacted by Mersana prior to delivery to Recepta to exclude confidential information of Mersana and/or the relevant sublicensee, provided that the redacted copy permits Recepta to determine that the sublicense agreement complies with requirements of this Section 2.2.1. Mersana's rights to sublicense or subcontract are limited as expressly set forth in this Section 2.2.1. Mersana shall use Diligent Efforts to enforce any such sublicense or subcontract and shall be responsible and liable for any failure of its sublicensees and subcontractors to comply with this Agreement, as though the acts and omissions of such sublicensee or subcontractor were the acts or omissions of Mersana itself. Without limiting the foregoing, Mersana shall ensure that any such sublicensee or subcontractor affords Mersana rights in any Know-How Controlled by such sublicensee or subcontractor that is necessary for the Development of the Licensed Products in the Recepta Territory, and any Patents Controlled by such sublicensee or subcontractor that would be infringed by the Commercialization by Recepta of the Licensed Products in the Recepta Territory, that are sufficient for such Know-How or Patents to be Controlled by Mersana within the meaning hereof, and thus licensable by Mersana to Recepta pursuant to Section 2.1.2.

2.2.2 Recepta's Right to Sublicense and Subcontract. Recepta may sublicense or subcontract its rights and obligations under this Agreement in respect of the Licensed Products to any of its Affiliates or to any Third Parties, subject to prior written notification to Mersana; *provided*, *however*, that if Recepta desires to sublicense or subcontract such rights to any Third Parties, it will discuss the proposed arrangement with Mersana so that the Parties may determine whether they are interested in entering into an agreement whereby Mersana would carry out the proposed arrangement in lieu of any Third Party. Recepta shall not be relieved of its obligations under this Agreement as a result of granting any sublicense or subcontracting any of its activities as permitted under this Section 2.2.2, except to the extent such obligations are satisfactorily performed by such sublicensee or subcontractor, as applicable, in a manner consistent with Recepta's obligations under this Agreement. Mersana, its Affiliates and sublicensees shall not be considered sublicensees of Recepta pursuant to this Section 2.2.2. Recepta shall secure all appropriate covenants, obligations and rights from any such subcontractor or sublicensee, including, but not limited to, licenses, intellectual property rights and confidentiality obligations, to ensure that such sublicensee or subcontractor is subject to, and Recepta can comply with, all of Recepta's applicable covenants and obligations to Mersana under this Agreement. With respect to any exclusive sublicenses granted by Recepta to any Third Party for the purpose of collaborating with such Third Party on the Development and/or Commercialization of any Licensed Product pursuant to this Agreement, Recepta will provide Mersana a copy of the applicable sublicense agreement with such Third Party promptly after the parties' execution of the same. Any such agreement shall be considered the Confidential Information of Recepta and may be redacted by Recepta prior to delivery to Mersana to exclude confidential information of Recepta and/or the relevant sublicensee, provided that the redacted

copy permits Mersana to determine that the sublicense agreement complies with requirements of this Section 2.2.2. Recepta's rights to sublicense and subcontract are limited as expressly set forth in this Section 2.2.2. Recepta shall use Diligent Efforts to enforce any such sublicense or subcontract and shall be responsible and liable for any failure of its sublicensees or subcontractors to comply with this Agreement, as though the acts and omissions of such sublicensee or subcontractor were the acts or omissions of Recepta itself.

#### 2.3 Promotional Materials; Trademarks.

2.3.1 <u>Promotional Materials</u>. Except as set forth below in this Section 2.3.1, Licensed Products shall be Commercialized solely in connection with packaging, inserts, digital content and similar information and materials (collectively, "Promotional Materials") selected by Mersana or its sublicensees responsible for Commercializing Licensed Products ("Mersana Promotional Materials"). Recepta may Commercialize Licensed Products in the Recepta Territory using such Promotional Materials used in connection with the relevant Licensed Products in the Major Markets (the "ROW Promotional Materials"), including translations thereof into Portuguese, or other Promotional Materials developed by it or on its behalf (such other Promotional Materials, "Recepta Promotional Materials"), but only if those Recepta Promotional Materials are consistent with the ROW Promotional Materials except for differences (including any additional Promotional Materials) between the Recepta Promotional Materials and the ROW Promotional Materials that are, in Recepta's reasonable determination, either required by Applicable Law or otherwise reasonably necessary to Commercialize the Licensed Products in the Recepta Territory. Any Recepta Promotional Materials that Recepta desires to utilize in the Recepta Territory must be approved in writing in advance by Mersana or its sublicensee responsible for Commercializing Licensed Products in the United States, such approval not to be unreasonably withheld, conditioned or delayed.

2.3.2 Trademarks. Except as set forth below in this Section 2.3.2, Licensed Products shall be Commercialized solely under trademarks and trade dress selected by Mersana or its sublicensees responsible for selling Licensed Products or, with respect to Commercialization in the Recepta Territory and subject to the following sentence, trademarks developed by Recepta. Recepta may utilize trademarks in connection with the Licensed Products in the Recepta Territory that are different from those utilized by Mersana and its sublicensees elsewhere in the Territory (the "ROW Trademarks") only if and to the extent that, after consultation with Mersana and considering in good faith Mersana's comments, Recepta reasonably determines that (i) use of any of such ROW Trademarks in connection with the Licensed Products in the Recepta Territory would infringe, dilute or otherwise violate any Third Party trademark or other proprietary rights in the Recepta Territory, is not permissible under Applicable Law in the Recepta Territory, or would be immoral or scandalous or (ii) use of the ROW Trademarks would adversely affect the Commercialization of the Licensed Products in the Recepta Territory. In the event that Recepta proposes to use any alternative trademark in the Recepta Territory in accordance with the foregoing, it shall so notify Mersana and the Parties shall discuss in good faith what alternative trademarks would be suitable. In any event, Recepta's use of any trademarks other than the ROW Trademarks in connection with the Commercialization of Licensed Products in the Recepta Territory (any such trademarks, "Recepta Trademarks") shall be subject to Mersana's prior written approval, such approval not to be unreasonably withheld, conditioned or delayed.

2.3.3 License to Mersana Promotional Materials and ROW Trademarks. Subject to the terms and conditions of this Agreement, Mersana hereby grants Recepta a non-exclusive, royalty-free, sublicensable, non-transferable (except as expressly set forth in Section 11.10), license to (i) use, reproduce, and display the ROW Trademarks and (ii) use, reproduce, publish, display, distribute, modify, create derivative works and/or translations of the Mersana Promotional Materials, in each case solely in connection with its authorized Commercialization

of Licensed Products in the Recepta Territory pursuant to this Agreement. Recepta may not materially alter its use of the ROW Trademarks without Mersana's express prior written approval. Recepta shall use all ROW Trademarks in a manner that is consistent with Mersana's quality standards and that complies with Mersana's trademark instructions and guidelines, which will be provided by Mersana in writing prior to First Commercial Sale of any Licensed Products in the Recepta Territory and prior to the effectiveness of any material changes thereto. Recepta shall not remove, alter, or obscure in any way any proprietary rights notices (including copyright and trademark notices) appearing in the Promotional Materials unless otherwise expressly authorized by Mersana in writing. Recepta shall do nothing inconsistent with Mersana's sole and exclusive ownership of the Mersana Promotional Materials and ROW Trademarks and all copyright, trademark and/or trade dress registrations thereof or to detract from Mersana's goodwill in the Mersana Promotional Materials and/or ROW Trademarks, including seeking any registration or contesting Mersana's title to or the validity of any such registrations. All use of the Mersana Promotional Materials and ROW Trademarks by Recepta shall inure to the benefit of and be on behalf of Mersana, and Recepta shall not acquire any rights therein or in any other related Promotional Materials or trademarks, other than the Recepta Promotional Materials and the Recepta Trademarks. Nothing in this Agreement shall give Recepta any right, title, or interest in the Mersana Promotional Materials or ROW Trademarks other than the license to use them in accordance with this Agreement. Mersana shall have the sole right and authority, in its discretion, to institute and prosecute lawsuits against Third Parties for infringement of any of the rights licensed under this Section 2.3.3. Recepta agrees to provide all reasonably requested assistance to Mersana in connection with the enforcement of its rights to the Mersana Promotional Materials and ROW Trademarks in the Recepta Territory and shall provide any evidence, documents, and testimony concerning the use by Recepta thereof, which Mersana may request for use in obtaining, defending, or enforcing its rights to the Mersana Promotional Materials and ROW Trademarks in the Recepta Territory. Mersana shall reimburse any reasonable and documented out-of-pocket expenses incurred by Recepta in connection with providing such assistance. Recepta shall not institute any suit or take any action on account of any infringements of the Promotional Materials or ROW Trademarks in the Recepta Territory without first obtaining the written consent of Mersana to do so. Recepta agrees that it is not entitled to share in any proceeds received by Mersana (by settlement or otherwise) in connection with any formal or informal action brought by Mersana with respect to the Mersana Promotional Materials or ROW Trademarks anywhere in the Territory.

2.3.4 Ownership of Promotional Materials and Trademarks. As between the Parties, Mersana shall exclusively own all Mersana Promotional Materials, including all derivative works and translations thereof (whether developed by Mersana, Recepta or any Third Party), and all ROW Trademarks. Mersana shall be responsible for and shall use Diligent Efforts with respect to the procurement, filing and maintenance of trademark registrations for all ROW Trademarks, including all related costs and expenses. To the extent Recepta develops or has developed any translations of the Promotional Materials, Recepta hereby assigns and agrees to assign all rights, title and interests in and to the foregoing to Mersana. As between the Parties, Recepta shall exclusively own all Recepta Promotional Materials and all Recepta Trademarks. Recepta shall be responsible for the procurement, filing and maintenance of trademark registrations for all such Recepta Trademarks in the Recepta Territory and all related costs and expenses.

#### 2.4 Rights to Improvements.

2.4.1 <u>Ownership of Improvements</u>. Mersana shall promptly disclose to Recepta all Specific Improvements and, to the extent contemplated by Section 3.4.3, General Improvements, that Mersana or any of its Affiliates or sublicensees makes, conceives or reduces to practice in the performance of any of its or their Development and/or Commercialization activities in connection with this Agreement. As between the Parties, subject to the licenses

granted in Sections 2.1.2, 2.2.2 and 2.4.2 below, Mersana retains all rights, title and interests, including all intellectual property rights embodied therein, in and to any General Improvements. If Mersana or any of its Affiliates or sublicensees makes, conceives or reduces to practice any Specific Improvements in the performance of any of its or their Development and/or Commercialization activities in connection with this Agreement, Mersana shall assign, and hereby does assign, all rights, title and interests in and to such Specific Improvements to Recepta. Mersana shall assist Recepta, at Recepta's request and expense, to further evidence, confirm, record and perfect such assignment, and to obtain, maintain, and perfect any rights assigned. In addition, Mersana shall secure all appropriate covenants, assignments and transfers of rights from any such Affiliate or sublicensee in and to any and all Specific Improvements necessary for Mersana to fully effect the foregoing assignment of Specific Improvements to Recepta.

2.4.2 License to General Improvements. Subject to the terms and conditions of this Agreement, Mersana hereby grants Recepta a non-exclusive, fully paid up, royalty-free, sublicensable (through multiple tiers), transferable, perpetual license, under all Patents and Know-How owned by Mersana or any of its Affiliates or sublicensees which Cover such General Improvements, to use and practice the General Improvements solely in connection with Recepta's use and exploitation of the Antibody; *provided, however*, that the foregoing license shall not become effective until such time as, and to the extent that, a General Improvement ceases to be included within the scope of the license granted pursuant to Section 2.1.2 hereof. Mersana shall secure all appropriate rights and licenses in and to any and all such General Improvements from its applicable Affiliates and sublicensees involved in the invention thereof as is necessary for Mersana to fully effect the foregoing license to Recepta. The foregoing non-exclusive license shall survive any termination or expiration of this Agreement. Anything to the contrary notwithstanding, except as contemplated by Section 3.4.3, Mersana shall be under no obligation to disclose or transfer to Recepta any Know-How relating to any General Improvement.

2.5 No Implied Rights. Nothing contained in this Agreement confers or will be construed to confer any rights or licenses by implication, estoppel or otherwise, in, to or under any intellectual property rights, other than the rights and licenses expressly granted in this Agreement. All rights not expressly granted by a Party under this Agreement are reserved to such Party. Without limitation, as between the Parties, Recepta retains sole and exclusive ownership of all rights, title and interests in and to the Recepta Technology and Mersana retains sole and exclusive ownership of all rights, title and interests in and to Fleximer® and the Mersana Technology. For the avoidance of doubt, and notwithstanding anything in this Agreement to the contrary, Recepta is not being granted and shall not have any right or license under Section 2.1.2 or otherwise to manufacture any Licensed Products on its own or, except in the circumstances contemplated by Section 3.3.2 or Section 10.3.4, any right or license to have any Licensed Product made for it by any third party; *provided, however*, that the foregoing shall in no way restrict Recepta from manufacturing the Antibody following any termination of this Agreement.

2.6 <u>Third Party Agreements</u>. The Parties acknowledge that (i) certain of the rights granted to Mersana by Recepta pursuant to Section 2.1.1 are sublicenses of rights to Third Party intellectual property which are Controlled by Recepta under the terms of the Third Party Licenses, (ii) any such sublicenses granted to Mersana under Section 2.1.1 are subject to the applicable terms and conditions of such Third Party Licenses, including the research licenses retained by the licensors thereunder and (iii) each of them, together with LICR, is a party to the Three-Party Agreement which provides certain rights and assurances to Mersana concerning the rights licensed by LICR to Recepta pursuant to the LICR License. Mersana acknowledges having received copies, and/or written notice of the applicable terms and conditions, of the Third Party Licenses and that it has reviewed and understands the terms and conditions of such Third Party Licenses.

## **3. DEVELOPMENT AND COMMERCIALIZATION.**

#### 3.1 Development Activities.

3.1.1 By Mersana. Mersana shall use Diligent Efforts to Develop and Commercialize Licensed Products in the Major Markets, including, without limitation, by using Diligent Efforts to conduct such Clinical Trials and carry out such other activities as are necessary to obtain Regulatory Approval for the Licensed Product in the Major Markets and to cause the Development milestones listed in Section 5.2 to be achieved. Mersana shall use Diligent Efforts to include at least [\*\*] in the Recepta Territory in a Phase III Clinical Trial. Mersana shall use Diligent Efforts to carry out such Development in accordance with a written Development plan outlining the significant Development activities it expects to undertake in furtherance of its Development obligations hereunder, which Mersana shall prepare as soon as reasonably practicable after the Effective Date, and shall amend such Development plan from time to time as its Development activities in respect of the Licensed Products progress. Mersana shall furnish Recepta with a copy of such Development plan once the same has been prepared and shall furnish Recepta with copies of each amended Development plan when available. Such Development plan and any amended Development plans are for Recepta's information only and shall be deemed to be the Confidential Information of Mersana. Without limiting Mersana's obligations to use Diligent Efforts to Develop Licensed Products as provided in the first sentence of this Section 3.1.1, any failure by Mersana to undertake or successfully achieve any of the activities set forth in, or to otherwise strictly adhere to, any such Development plan or amended Development plan for any reason shall not, by itself, be deemed a breach of this Agreement.

3.1.2 By Recepta. Promptly after Mersana or any of its sublicensees obtains Regulatory Approval for any Licensed Product in the Territory, Recepta shall use Diligent Efforts to obtain and maintain Regulatory Approval for such Licensed Product in the Recepta Territory. For the avoidance of doubt, it is not anticipated that Recepta will be required to conduct any Clinical Trials in connection with any Licensed Product. If, however, after receipt of Regulatory Approval in the United States, ANVISA or any other applicable Governmental Authority requires Recepta to conduct any Clinical Trials or to undertake any Development activities or any such Clinical Trial or other Development activities are required by Applicable Law or otherwise in order to obtain Regulatory Approval for such Licensed Product in the Recepta Territory (such required activities, collectively, "Additional Development Activities"), and reference to the Clinical Trials and other Development activities undertaken by Mersana in connection with the receipt of Regulatory Approval for such Licensed Product in the United States cannot be used to satisfy such requirement, Recepta shall have the right to undertake such Additional Development Activities subject to the following: (i) prior to commencing such Additional Development Activities, Recepta shall notify Mersana in writing of the need for such Additional Development Activities and the Parties shall discuss in good faith the conduct thereof and any considerations in relation thereto that may be relevant to the Development or Commercialization of the Licensed Products outside the Recepta Territory and (ii) Mersana shall have the option to conduct (or have conducted) some or all of such Additional Development Activities, in lieu of Recepta, on a timeframe to be reasonably determined by Mersana, but in any case designed to not materially delay the receipt of Regulatory Approval in the Recepta Territory. Mersana shall notify Recepta in writing within [\*\*] Business Days after Mersana's receipt of written notification from Recepta of the need for such Additional Development Activities if Mersana intends to conduct (or have conducted) some or all of such Additional Development Activities; otherwise, Recepta shall have the right to conduct such Additional Development Activities at its sole cost and expense in a manner consistent with any requirements agreed-upon by the Parties in order to minimize the risk of any possible adverse impact the same may have on the Development or Commercialization of the Licensed Products outside the Recepta Territory. With respect to any Additional Development Activities to be conducted by or on behalf of Mersana: (1) prior to commencing any such Additional Development Activities, the

Parties shall discuss in good faith and reasonably agree upon a budget and a development plan for such activities; (2) Mersana shall conduct (or have conducted) all such Additional Development Activities in accordance with such development plan (as modified from time to time with the mutual written agreement of the Parties), Applicable Law and the requirements of ANVISA or any other applicable Governmental Authority in relation thereto; (3) Mersana shall keep Recepta informed of all material developments in respect of such activities and shall notify Recepta promptly of any expenses that are expected to exceed such budget or any potential need to deviate from any element of such development plan whereupon the Parties shall promptly meet (by teleconference or otherwise) to discuss the same and endeavor in good faith to agree upon any appropriate adjustments to the development plan and/or; (4) in the event that such activities are expected to exceed such budget, to the extent practicable and permissible pursuant to Applicable Law, Mersana will suspend or modify such Additional Development Activities if and as requested by Recepta; and (5) Recepta shall reimburse Mersana for any reasonable and documented out-of-pocket costs and expenses incurred by Mersana in connection with its conduct of (or having conducted) such Additional Development Activities in accordance with the foregoing, and, at Mersana's request, shall pay all regulatory filing fees, institutional review board fees, investigator stipends and any other Third Party costs and expenses associated with the conduct of such Additional Development Activities directly to the applicable Third Party(ies). With respect to any Additional Development Activities to be conducted by or on behalf of Recepta, (x) prior to commencing any such Additional Development Activities, Recepta shall prepare and provide to Mersana a written development plan in respect thereof, which development plan will be consistent with any such requirements that the Parties may agree upon, as contemplated above in this Section 3.1.2, in order to minimize the risk of any possible adverse impact the same may have on the Development or Commercialization of the Licensed Products outside the Recepta Territory. (v) Recepta shall conduct (or have conducted) all such Additional Development Activities in accordance with such development plan (as modified from time to time in a manner consistent with clause (x) and with notice to Mersana in the case of any material amendment), Applicable Law and the requirements of ANVISA or any other applicable Governmental Authority in relation thereto, and (z) Recepta shall keep Mersana informed of all material developments in respect of such activities.

#### 3.2 Commercialization.

3.2.1 <u>By Mersana</u>. As between the Parties, Mersana shall have the sole right and responsibility for Commercialization of Licensed Products for distribution and sale outside the Recepta Territory and shall use Diligent Efforts to Commercialize Licensed Products in the Major Markets. Mersana shall bear all costs and expenses associated with its Commercialization of Licensed Products outside of the Recepta Territory.

3.2.2 <u>By Recepta</u>. Following receipt of Regulatory Approval for any Licensed Product in the Recepta Territory, Recepta shall use Diligent Efforts to Commercialize such Licensed Product in the Recepta Territory. Recepta shall bear all costs and expenses associated with its Commercialization of Licensed Products in the Recepta Territory.

#### 3.3 Manufacturing.

3.3.1 <u>General</u>. Mersana shall use Diligent Efforts to manufacture or otherwise obtain supply of the requirements of formulated, packaged and labeled Licensed Products in connection with its Development and Commercialization obligations hereunder, in accordance with all Applicable Laws, GMP (as applicable) and this Agreement.

3.3.2 <u>Recepta Territory</u>. With respect to each Licensed Product that receives Regulatory Approval in the Territory, Mersana will, or will cause one or more of its sublicensees to, enter into a supply agreement under which Mersana or the applicable

sublicensee(s) will supply Recepta or Recepta's sublicensee(s) with the Licensed Product for sale to end user customers in the Recepta Territory (the "Supply Agreement"). The Supply Agreement will contain such mutually agreeable and commercially reasonable pricing (not to exceed [\*\*]), lead time, and other supply terms as the parties may mutually agree. Mersana will, or will cause one or more of its sublicensees to, negotiate such Supply Agreement in good faith and use Diligent Efforts to execute such Supply Agreement within [\*\*] Business Days before the date the first Licensed Product receives Regulatory Approval in the Recepta Territory. For the avoidance of doubt, no royalties shall be payable to Recepta on account of sales of Licensed Products to Recepta or its distributors for sale to end user customers in the Recepta Territory and such sales shall not be factored into the calculation of Mersana Annual Net Sales for purposes of determining the royalty rate applicable to Net Sales of Licensed Products by Mersana or its sublicensees.

#### 3.4 Assistance.

3.4.1 Upon Mersana's written request at any time, Recepta shall provide supply samples of the Antibody from Recepta's existing supply thereof, not to exceed [\*\*] grams in the aggregate, to be used solely for comparison and testing by Mersana and/or its sublicensees or subcontractors in connection with Mersana's Development activities. Such supply will be at no charge to Mersana, other than freight charges actually incurred by Recepta, for which Mersana will be responsible and for which Mersana will reimburse Recepta promptly following receipt of written documentation thereof.

3.4.2 In connection with Mersana's Development and Commercialization activities under this Agreement, Recepta shall disclose to Mersana, at no charge, all material information comprising the Recepta Know-How that is owned or Controlled by Recepta as Mersana may reasonably request in order to Develop and Commercialize the Licensed Products. Without limiting the generality of the foregoing, Recepta shall (i) disclose to Mersana all technology, data, information and materials comprising the Recepta Know-How, including information related to the Recepta Patents, (ii) provide, upon request, reasonable personnel and technical assistance, expertise and cooperation as necessary for Mersana's understanding of such disclosed Recepta Know-How, and (iii) provide, to the extent necessary or useful for Mersana, or its sublicensees to Develop and/or Commercialize Licensed Products, and if requested by Mersana, a right of reference and access to any Recepta regulatory filings or documents contained therein. Mersana will be responsible for any pre-approved travel expenses, and other reasonable and documented out-of-pocket expenses, incurred by Recepta at Mersana's request in connection with Recepta fulfilling its obligations under this Section 3.4.2.

3.4.3 If and to the extent necessary in connection with Recepta's permitted Development activities, and its Commercialization activities, under this Agreement, Mersana shall disclose to Recepta, at no charge, all material information comprising the Mersana Know-How that is owned or Controlled by Mersana as Recepta may reasonably request in order to carry out such Development and Commercialization activities in respect of the Licensed Products. Without limiting the generality of the foregoing, and to the extent reasonably necessary in connection with such Development and Commercialization activities, Mersana shall (i) disclose to Recepta all technology, data, information and materials comprising the Mersana Know-How, including information related to the Mersana Patents and (ii) provide, upon request, reasonable personnel and technical assistance, expertise and cooperation as necessary for Recepta's understanding of such disclosed Mersana Know-How. Recepta will be responsible for any pre-approved travel expenses, and other reasonable and documented costs and expenses, incurred by Mersana at Recepta's request in connection with Mersana fulfilling its obligations under this Section 3.4.3.

### 3.5 Reporting.

3.5.1 Within [\*\*] Business Days after the end of each calendar year during the period from the Effective Date until the end of the Royalty Term, Mersana will provide a reasonably detailed written report of its manufacturing, Development and Commercialization activities in respect of the Licensed Products and the results thereof. In addition, to the extent requested by Recepta, Mersana will meet with Recepta (via teleconference or video conference) periodically to discuss Mersana's progress, plans, and performance (including data generated in connection with Clinical Trials) in respect of the Development of the Licensed Products. For the avoidance of doubt, no such meetings will be required with respect to any Licensed Product after the First Commercial Sale of such Licensed Product. Prior to the initiation of the first Clinical Trial in respect of the Licensed Products, such meetings will not be required to occur more often than [\*\*].

3.5.2 Within [\*\*] Business Days after the end of each calendar year during the period from the Effective Date until the end of the Royalty Term, Recepta will provide reasonably detailed annual written reports of its Commercialization efforts in respect of the Licensed Products in the Recepta Territory.

#### 4. REGULATORY MATTERS.

#### 4.1 Major Markets.

4.1.1 Mersana shall be solely responsible for, and shall use Diligent Efforts in connection with, the submission of information to, communicating with, and seeking Regulatory Approval for Licensed Products in the Major Markets and will keep Recepta informed of all significant issues arising therefrom and material developments with respect thereto. Mersana will take into account Recepta's reasonable suggestions and comments with respect to the materials and information which Mersana decides to submit to the Regulatory Authorities outside the Recepta Territory in respect of the Licensed Products.

4.1.2 Mersana hereby grants Recepta a right of reference to all data and information contained or referenced in those sections of regulatory filings for Licensed Products in the Territory that are held by Mersana, its Affiliates or any of its sublicensees, that would be reasonably necessary or useful for Recepta's obtaining Regulatory Approval for such Licensed Products in the Recepta Territory. Mersana shall provide the applicable Regulatory Authority a letter confirming this right of reference at any time within [\*\*] Business Days after Recepta's request and shall take such other actions and execute such other documents as Recepta may reasonably request to further confirm and give effect to this right of reference.

#### 4.2 Recepta Territory.

4.2.1 Subject to Section 3.1.2, Recepta shall be solely responsible for, and shall use Diligent Efforts in connection with, the submission of information to, communicating with, and seeking Regulatory Approvals for Licensed Products in the Recepta Territory and will keep Mersana informed of all significant issues arising therefrom and material developments with respect thereto. Recepta will take into account Mersana's reasonable suggestions and comments with respect to the materials and information which Recepta decides to submit to ANVISA in respect of the Licensed Products in the Recepta Territory. If and to the extent access to information, data (including Clinical Trial results), or materials (including samples of the relevant Licensed Product to the extent required in connection with Recepta's application for Regulatory Approval) to which Recepta is not otherwise afforded access hereunder is necessary for Recepta to obtain and/or maintain Regulatory Approval in the Recepta Territory, Recepta shall notify Mersana in writing and Mersana shall make such information, data and/or materials

available to Recepta as soon as practicable, it being understood that Recepta's receipt, use and disclosure of such information, data and/or materials shall be subject to the terms, conditions and limitations of this Agreement.

4.2.2 As between the Parties, Recepta shall own all Regulatory Approvals for the Recepta Territory. Recepta shall provide Mersana with reasonable advance notice of any meetings and other communications with ANVISA, and shall also provide Mersana with copies of any filings with ANVISA related thereto prior to submission to ANVISA for Mersana's review and approval (such approval not to be unreasonably withheld, conditioned or delayed). Recepta hereby grants to Mersana (or its designated sublicensee), a right of reference to all such filings for all uses in connection with the obtaining or maintaining any Regulatory Approvals for Licensed Products outside the Recepta Territory. For so long as the license granted to Mersana under Section 2.1.1 remains in effect, Recepta shall not assign or transfer any Regulatory Approvals for the Recepta Territory to any Affiliate or Third Party without the prior written consent of Mersana, except in connection with a permitted assignment of the entire Agreement pursuant to Section 11.10. In such case, any Regulatory Approvals in the Recepta Territory must also be contemporaneously assigned and transferred to the applicable assignee unless the Parties agree otherwise in writing.

4.3 <u>Cooperation; Costs and Expenses</u>. Each Party shall provide all reasonably requested assistance to the other Party as may be required by such requesting Party where liaison between the Parties is, or may be, necessary to enable such Party to fulfill its responsibilities hereunder. Each Party shall be fully responsible for bearing all costs and expenses associated with its own submissions of information to, communications with, and seeking of Regulatory Approval for which and for so long as they have the responsibility pursuant to this Article 4, including, but not limited to, the costs of preparing and prosecuting applications for such Regulatory Approvals and fees payable to Regulatory Authorities in obtaining same.

4.4 <u>Drug Safety Information</u>. Both Parties shall comply fully with all applicable adverse event reporting recommendations and requirements in all countries where the Parties intend to market the Licensed Products and agree to exchange such information as may be necessary to achieve that end and to ensure that both Parties are completely informed regarding adverse events with respect to Licensed Products. This includes single case reports, together with an appropriate medical evaluation, as well as aggregate data, such as PSURs required by authorities. Both Parties will execute and implement a detailed pharmacovigilance agreement pertaining to Licensed Products in the Recepta Territory no later than [\*\*] months before the earlier of the following events: (i) Recepta or Mersana is physically and/or legally able to distribute Licensed Products in the market, in a clinical trial or for whatever purpose, or (ii) Recepta or Mersana has a Regulatory Approval, a clinical trial authorization, or has regulatory reporting obligations for any other reason.

4.5 <u>Recalls or Corrective Action</u>. Mersana shall have sole responsibility for and shall make all decisions with respect to any recall, market withdrawal or other corrective action related to the Licensed Products in the Territory, *provided*, *however*, that Mersana shall notify Recepta as soon as reasonably practicable of any anticipated recall, market withdrawal or other corrective action related to any Licensed Products in the Territory and shall consult Recepta prior to making any such decision with respect to Licensed Products sold in the Recepta Territory and take into account Recepta's views and interests in making its decision with respect thereto, provided such consultation does not delay or endanger the recall process. Mersana shall be solely responsible for all costs and expenses associated with such recall, market withdrawal or corrective action, including, but not limited to, all fines, fees and refunds to distributors and other customers and Mersana shall reimburse Recepta for any such amounts incurred by Recepta at Mersana's request in connection therewith, unless the recall was caused by any act, omission or breach of this Agreement by Recepta, in which case Recepta shall bear all such costs and

expenses. Without limiting the foregoing, in the event that Recepta or any of its sublicensees is required by Applicable Law to undertake any recall, market withdrawal or other corrective action in respect of any Licensed Product in the Recepta Territory, Recepta shall promptly notify Mersana in writing. If, after receipt of such written notice, Mersana fails to commence such recall, market withdrawal or other corrective action in the Recepta Territory within the time period mandated by Applicable Law or, in the absence of any legally mandated time period, within [\*\*] Business Days after its receipt of Recepta's written notice, then Recepta or its sublicensee shall have the right to undertake the same on its own behalf, in accordance with Applicable Law and all of Mersana's reasonable instructions with respect thereto until such time as Mersana notifies Recepta in writing that it will assume control over such recall, market withdrawal or corrective action. Mersana shall reimburse Recepta for its costs and expenses with respect thereto unless the recall was caused by an act, omission or breach of this Agreement by Recepta, in which case Mersana shall not be obligated to reimburse Recepta for its costs and expenses.

4.6 <u>Events Affecting Integrity or Reputation</u>. During the Term, the Parties shall notify each other promptly of any circumstances of which they are aware and which could reasonably be expected to impair the integrity and reputation of Licensed Products or if a Party is threatened by or becomes aware of unlawful activity in relation to Licensed Products, including, but not limited to, deliberate tampering with or contamination of Licensed Products.

**5. FINANCIAL PROVISIONS**. In consideration of the rights granted by the Parties to one another hereunder, particularly the licenses set forth in Article 2 above, the Parties agree to make the following payments:

5.1 <u>Execution Payment</u>. Within [\*\*] Business Days after the Effective Date, Mersana shall pay to Recepta a non-creditable, non-refundable license fee of one million dollars (US\$1,000,000).

5.2 Development Milestone Payments. In the event Mersana or its Affiliate or sublicensee achieves a Development milestone specified below, Mersana shall promptly, but in no event more than [\*\*] Business Days after the achievement of each such milestone, notify Recepta in writing of the achievement of such milestone. Mersana shall pay to Recepta the corresponding non-refundable, non-creditable milestone payments as specified below within [\*\*] after achievement of the particular milestone. If requested by Mersana, Recepta shall provide a written invoice for any such Development milestone payment promptly following Mersana's notice to Recepta of the achievement thereof, *provided, however*, that the provision of such invoice shall not be a precondition of Mersana's obligation to make such payment. The full milestone payments shall be payable [\*\*] for each of the first Licensed Product to achieve such milestones, regardless of the total number of Licensed Products to achieve the applicable milestone or the number of times each such milestone is achieved for a given Licensed Product. No milestone payments will be due in respect of subsequent achievement of the same Licensed Product. All

milestone payments will apply whether Licensed Products are Developed and Commercialized as single or Combination Products.

<b>Development Milestones</b>	First Product	Second Product	
	Milesto	Milestone Payment	
[**]	[**]	[**]	
[**]	[**]	[**]	
[**]	[**]	[**]	
[**]	[**]	[**]	
[**]	[**]	[**]	
[**]	[**]	[**]	
[**]	[**]	[**]	
[**]	[**]	[**]	

5.3 <u>Commercialization Milestone Payments</u>. In the event that Mersana Annual Net Sales reach one or more of the amounts set forth below, Mersana will make the corresponding milestone payment(s) specified below to Recepta no later than [\*\*] calendar days following the end of the calendar year in which such Mersana Annual Net Sales milestone(s) was achieved. Each such milestone payment shall be non-refundable and non-creditable and shall be payable one time only. In the event that more than one of the Mersana Annual Net Sales milestones is first achieved in the same calendar year, then each corresponding milestone payment shall be payable following the end of such calendar year in accordance with the foregoing.

Mersana Annual Net Sales Milestone	Milestone Payment
[**]	[**]
[**]	[**]
[**]	[**]

5.4 Royalties on Mersana Annual Net Sales.

5.4.1 Mersana will make royalty payments based on Mersana Annual Net Sales from the date of the First Commercial Sale of the [\*\*] Licensed Product outside the Recepta Territory until the expiration of the Royalty Term. Upon expiration of the Royalty Term for a particular Licensed Product in a particular country, no Net Sales of such Licensed Product in such country following the last day of such Royalty Term shall be included in Mersana's Annual Net Sales for purposes hereof. Such royalty payments shall be calculated based on year-to-date Mersana Annual Net Sales, applying the tiered royalty rates shown below:

Mersana Annual Net Sales	Royalty Rate
[**]	[**]
[**]	[**]
[**]	[**]

For avoidance of doubt, the following example shall illustrate the royalty payment calculation: Royalties on aggregate Net Sales outside the Recepta Territory in a calendar year shall be paid at the rate applicable to the portion of Net Sales within each of the Net Sales levels during such calendar year. For example, if, during a calendar year, aggregate Net Sales outside the Recepta Territory were equal to [\*\*], then the royalties payable would be calculated by adding (i) the royalties with respect to the first [\*\*] at the first-level percentage of [\*\*]; and (ii) the royalties with respect to the next [\*\*] at the second-level percentage of [\*\*], for a total royalty of [\*\*].

5.4.2 Mersana shall be solely responsible for all royalties, milestone payments, fees or other amounts due to any Third Parties to obtain any rights to any intellectual property that Mersana reasonably determines, based on the advice of outside legal counsel, is necessary to exercise the rights granted to Mersana under this Agreement or to enable Mersana to grant Recepta the licenses set forth in Sections 2.1.2 and 2.2.2 hereof ("Third Party IP"). Mersana shall be entitled to deduct from royalties owed to Recepta pursuant to this Section 5.4.2 [\*\*] of all payments made by Mersana to any Third Party that are owed pursuant to any license agreement, settlement or award or judgment (including but not limited to damages) with or to a Third Party for Third Party IP (each, a "Third Party Payment"). Notwithstanding the foregoing, in no event shall Mersana be entitled to reduce the amount of any individual royalty payment owed to Recepta by more than [\*\*] pursuant to this Section 5.4.2.

5.5 <u>Royalties on Recepta Annual Net Sales</u>. Recepta will make royalty payments based on Recepta Annual Net Sales from the date of the First Commercial Sale of the [\*\*] Licensed Product in the Recepta Territory until the expiration of the Royalty Term in the Recepta Territory. Such royalty payments shall be calculated based on year-to-date Recepta Annual Net Sales in the Recepta Territory, applying the tiered royalty rates shown below:

Recepta Annual Net Sales	Royalty Rate
[**]	[**]
[**]	[**]

For avoidance of doubt, the following example shall illustrate the royalty payment calculation: Royalties on aggregate Net Sales in the Recepta Territory in a calendar year shall be paid at the rate applicable to the portion of Net Sales within each of the Net Sales levels during such calendar year. For example, if, during a calendar year, aggregate Net Sales in the Recepta Territory were equal to [\*\*], then the royalties payable would be calculated by adding (i) the royalties with respect to the first [\*\*] at the firstlevel percentage of [\*\*]; and (ii) the royalties with respect to the next [\*\*] at the second-level percentage of [\*\*], for a total royalty of [\*\*]. 5.6 <u>Combination Products</u>. If a Licensed Product under this Agreement is sold in form of a Combination Product, then Net Sales for such Combination Product shall be determined on a [\*\*] as follows:

5.6.1 If the Licensed Product and the Other Product are sold separately, the royalty payments due on the Net Sales of the Combination Product shall be equal to the applicable percentage (royalty rate) multiplied by the Net Sales of the Combination Product multiplied by the fraction, A/(A+B) where "A" is the mean gross selling price of the Licensed Product and "B" is the mean gross selling price of the Other Product.

5.6.2 If the Licensed Product and the Other Product are sold separately, but the mean gross selling price of the Other Product cannot be determined, the royalty payments due on the Net Sales of the Combination Product shall be equal to the applicable percentage (royalty rate) multiplied by the Net Sales of the Combination Product multiplied by the fraction A/C wherein "A" is the mean gross selling price of the Licensed Product and "C" is the mean gross selling price of the Combination Product.

5.6.3 If the Licensed Product and the Other Product are sold separately, but the mean gross selling price of the Licensed Product cannot be determined, the royalty payments due on the Net Sales of the Combination Product shall be equal to the applicable percentage (royalty rate) multiplied by the Net Sales of the Combination Product multiplied by the following formula: one (1) minus B/C wherein "B" is the mean gross selling price of the Other Product and "C" is the mean gross selling price of the Combination Product.

5.6.4 If the Licensed Product and the Other Product are sold separately, but the mean gross selling price of neither the Licensed Product nor the Other Product can be determined, Net Sales of the Licensed Product shall be equal to Net Sales of the Combination Product multiplied by a percentage agreed to by the Parties, acting in good faith. If the Parties are unable to agree upon such a percentage, the dispute shall be resolved by arbitration pursuant to Section 11.7.

5.7 <u>Bundling</u>. In the event a Licensed Product is "bundled" for sale together with one or more other products in a country (a "Product Bundle"), then Net Sales for such Licensed Product may be discounted by no more than the [\*\*] of all products in a particular Product Bundle sold in such country calculated as [\*\*].

#### 5.8 Loss of Patent Coverage.

5.8.1 With respect to any country outside the Recepta Territory, if the manufacture, use, importation, offering for sale or sale of any Licensed Products in such country is Covered as of the date of the First Commercial Sale in such country, or becomes Covered thereafter, by a Valid Claim of at least one Recepta Patent and the manufacture, use, importation, offering for sale or sale of such Licensed Product in such country subsequently ceases to be Covered by a Valid Claim of at least one Recepta Patent, then, for the remaining period of the Royalty Term applicable to such Licensed Product in such country, the Net Sales of such Licensed Product in such country to be included in the Mersana Annual Net Sales for the purpose of the calculation of the royalties due under Section 5.4.1 shall be reduced by [\*\*]. With respect to any country is not Covered by a Valid Claim of at least one Recepta Product in such country to be included in the First Commercial Sale in such country is not Covered by a Valid Claim of at least one Recepta Patent as of the date of the First Commercial Sale in such country, the Net Sales of such Licensed Product in such country to be included in the Mersana Annual Net Sales for the purpose of such Licensed by a Valid Claim of at least one Recepta Patent as of the date of the First Commercial Sale in such country, the Net Sales of such Licensed Product in such country to be included in the Mersana Annual Net Sales for the purpose of the calculation of the royalties due under Section 5.4.1 shall be reduced by [\*\*]; *provided, however*, that such reduction shall not apply to any Net Sales in such country that are received by Mersana after such time, if any, during the Royalty Term applicable

to such Licensed Product, as such Licensed Product becomes Covered by a Valid Claim of at least one Recepta Patent in such country, and continues to be Covered by at least one such Valid Claim. The Parties hereby acknowledge and agree that royalties that are payable by Mersana for a Licensed Product for which no Patents exist shall be in consideration of (i) Recepta's expertise and know-how concerning its Development of the Recepta Know-How and (ii) the licenses granted to Mersana hereunder with respect to Recepta Know-How that are not within the claims of any Recepta Patents.

5.8.2 With respect to the Recepta Territory, if the manufacture, use, importation, offering for sale or sale of any Licensed Products in such territory is Covered as of the date of the First Commercial Sale in such territory, or becomes Covered thereafter, by a Valid Claim of at least one Mersana Patent and the manufacture, use importation, offering for sale or sale of such Licensed Product in such territory subsequently ceases to be Covered by a Valid Claim of at least one Mersana Patent, then for the remaining period of the Royalty Term applicable to such Licensed Product in such territory, the Net Sales of such Licensed Product in such territory to be included in the Recepta Annual Net Sales for the purpose of calculation of the royalties due under Section 5.5 shall be reduced by [\*\*]. With respect to the Recepta Territory, if the manufacture, use, importation, offering for sale or sale of any Licensed Products in such territory, the Net Sales of such Licensed Product in such territory to be included in the Recepta Territory, if the manufacture, use, importation, offering for sale or sale of any Licensed Products in such country is not Covered by a Valid Claim of at least one Mersana Patent as of the date of the First Commercial Sale in such territory, the Net Sales of such Licensed Product in such territory to be included in the Recepta Annual Net Sales for the purpose of the calculation of the royalties due under Section 5.5 shall be reduced by [\*\*]; *provided, however*, that such reduction shall not apply to any Net Sales in such territory that are received by Recepta after such time, if any, during the Royalty Term applicable to such Licensed Product, as such Licensed Product becomes Covered by a Valid Claim of at least one Mersana Patent in such territory, and continues to be Covered by at least one such Valid Claim. The Parties hereby acknowledge and agree that royalties that are payable by Recepta for a Licensed Product for which no Patents exist shall be in consideration of (i) Mersana's expertise an

5.9 Payment Terms. Each Party shall make all royalty payments owed under this Agreement within [\*\*] Business Days following the end of each calendar quarter for Net Sales from the previous calendar quarter, and together with such payment, shall submit to the other Party a written report setting forth (i) a reasonably detailed calculation of the Net Sales for such calendar quarter in each country in its respective territory upon which such royalty payments are based including all deductions from gross sales made in arriving at the same, (ii) year-to-date, total royalty payments due to the other Party in respect of Licensed Products and Combination Products, and (iii) any other information needed to support the calculation of such Net Sales and royalty payments. All sums due under this Agreement shall be payable in United States dollars by bank wire transfer in immediately available funds to such bank account(s) as the applicable payee shall designate.

5.10 <u>Currency</u>. When Licensed Products are sold for monies other than United States dollars, the Net Sales of such Licensed Products will first be determined in the foreign currency of the country in which such Licensed Products were sold and then converted into equivalent United States funds. The exchange rate will be the applicable rate published by the *Wall Street Journal* on the last Business Day of the calendar quarter in which such royalties accrued.

#### 5.11 Tax Withholding, Financial Records and Audits.

5.11.1 <u>Tax Withholding</u>. If Applicable Law requires either Party to withhold any taxes from payments made to the other Party under this Agreement, then such taxes

shall be deducted by the withholding Party as required by and shall be paid by the withholding Party to the proper tax authorities. Official receipts of payment of any withholding tax shall be secured and sent to Party whose payments were subject to withholding as evidence of such payment. The Parties shall exercise their best efforts to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of any relevant tax treaty. The Parties agree that Recepta is transferring substantially all of its rights in the Recepta Technology for the Field and, as such, agree to treat such transfer as a sale (versus a license) for U.S. Federal tax purposes. Accordingly, Mersana agrees that no U.S. withholding shall be made with respect to the upfront payment to be paid by Mersana pursuant to Section 5.1 or any of the milestone payments to be paid by Mersana pursuant to Sections 5.2 or 5.3. However, if any relevant Governmental Authority or any change in Applicable Law requires Mersana to make such withholdings or to remit any amounts which were required to have been withheld in respect of any previous payments to Recepta hereunder, Mersana shall notify Recepta promptly in writing and Mersana may make such withholdings and may remit such amounts. Recepta shall indemnify Mersana for any withholding amounts it is required to remit to the applicable Governmental Authority in respect of such previous payments to Recepta, together with any fines or penalties incurred solely as a result of Mersana's failure to make such withholding.

5.11.2 Financial Records and Audits. Each Party shall keep accurate and complete records of all financial information needed to calculate Net Sales and/or any payments due to such Party under this Agreement. Each Party shall retain all records relating to Net Sales and/or any payments made to such Party during the [\*\*] preceding calendar years. During the Royalty Term applicable to a Party and for [\*\*] thereafter, at the other Party's written request, such records shall be made available for inspection, review and audit, during normal business hours and with reasonable advance notice to the audited Party, by an independent certified public accountant appointed by the auditing Party and reasonably acceptable to the audited Party for the purpose of verifying the accuracy of the audited Party's reports and payments related to or based on Net Sales pursuant to this Agreement and reporting to the auditing Party the findings (but not the underlying data) of said examination of records as are necessary to evidence whether or not the audited Party has complied with its payment and other financial obligations related to or based on Net Sales under this Article 5 and the extent of any inaccuracy bearing on a Party's payment obligations related to of copy of any report provided to the auditing Party by the accountant shall be given concurrently to the audited Party. The auditing Party may perform such an audit no more than [\*\*]. The auditing Party shall be responsible for all costs and expenses incurred in performing any such audit unless the audit discloses at least a [\*\*] shortfall, in which case the audited Party shall bear the full cost of the audit. If any such examination reveals an underpayment of royalties or that any Commercialization milestone payment contemplated in Section 5.3 was achieved by the corresponding milestone payment was not paid, then the audited Party shall promptly, and in any event within [\*\*] Business Days following delivery of such audit report, pay the amount of the underpayment or the unpaid milestone payment to the other Party, together with interest on the amount owing calculated at a rate of [\*\*] per annum form the date on which the amount owing was to be paid until the date of payment in full. If said examination of records reveals any overpayment of royalties, then the auditing Party shall credit the amount overpaid against the audited Party's future royalty payment(s). Notwithstanding the foregoing, if the audited Party disputes the findings of such examination in good faith, the audited Party may notify the auditing Party in writing and the matter shall be resolved in accordance with the dispute resolution procedure set forth in Section 11.7. The time for making any relevant payments due under this Section 5.11.2 shall be tolled during the pendency of any such dispute resolution, *provided*, that interest on any amount determined to be owing shall in any event accrue from the date on which such amount was to be paid.

### 6. CONFIDENTIAL INFORMATION AND PROPRIETARY RIGHTS.

6.1 Definition. "Confidential Information" means confidential or proprietary information, data or know-how, whether provided in written, oral, visual or other form, provided by one Party (the "Disclosing Party") to the other Party (the "Receiving Party") in connection with this Agreement, including, but not limited to, the terms of this Agreement and information relating to the Disclosing Party's existing or proposed research, development efforts, patent applications, business or products. Confidential Information shall not include any such information that: (i) is already known to the Receiving Party or its Affiliates (other than under an obligation of confidentiality) at the time of disclosure (as evidenced by written records of the Receiving Party); (ii) is or becomes generally available to the public other than through any act or omission of the Receiving Party or its Affiliates; (iii) is disclosed to the Receiving Party or its Affiliates by a Third Party who, to the Receiving Party's knowledge, had no separate nondisclosure obligation in respect of such information; or (iv) is independently discovered or developed by or on behalf of the Receiving Party or its Affiliates without the use of the Confidential Information of the Disclosing Party (as evidenced by written records of the Receiving Party). The terms of this Agreement shall be deemed Confidential Information of each Party.

6.2 Confidentiality. The Receiving Party shall keep in confidence all Confidential Information of the Disclosing Party with the same degree of care it employs to maintain the confidentiality of its own Confidential Information, but no less than a reasonable degree of care. The Receiving Party shall not use such Confidential Information for any purpose other than in performance of this Agreement or the exercise of its rights hereunder, or disclose the same to any other Person other than to such of its own and its Affiliates' employees, agents, sublicensees and subcontractors who have a need to know such Confidential Information in connection with such permitted use. A Receiving Party shall advise any employee, agent, sublicensee or subcontractor who receives Confidential Information of such obligations, and the Receiving Party shall ensure (through enforcement of written agreements or otherwise) that all such employees, agents, sublicensees and subcontractors comply with such obligations as if they had been a Party hereto. The Receiving Party will be liable for breach of this Article 6 by any of its employees, agents, sublicensees and subcontractors.

6.3 <u>Permitted Disclosure and Use</u>. The Receiving Party shall have the right to disclose Confidential Information if, (i) in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is required by any Applicable Laws (including the rules of any stock exchange), provided that, to the extent permitted pursuant to Applicable Law, the Receiving Party gives adequate prior notice of such disclosure to the Disclosing Party and the Receiving Party seeks confidential treatment of such Confidential Information to the maximum extent permitted by the relevant Governmental Authority; or (ii) a court, tribunal, administrative agency or other Governmental Authority orders such disclosure, provided that, to the extent permitted pursuant to Applicable Law, the Receiving Party gives adequate prior notice of such disclosure to the Disclosing Party to permit the Disclosing Party to intervene and to request protective orders or other confidential treatment. The Receiving Party will cooperate reasonably with any such efforts by the Disclosing Party. Furthermore, notwithstanding any other provision of this Agreement, either Party may disclose Confidential Information as necessary in connection with any actual or proposed financing, acquisition, merger, collaboration, licensing transaction or similar transaction, subject to confidentiality, or as necessary to obtain legal or financial advice from its attorneys, accountants and legal or financial advisors, provided, however, that the applicable Party shall limit such disclosure to the extent possible including the provision of redacted documents and provided further that the Person to whom such disclosure is made is subject to obligations of confidentiality to the Party making such disclosure that are no less stringent than those contained in this Article 6. The Receiving Party making any disclosure pursuant to the immediately preceding sentence will be responsible for the compliance by such

Persons with the requirements of this Article 6 as though such Persons were the Receiving Party hereunder and shall be liable for any breach by such Persons of this Article 6. The Parties shall also be permitted to make disclosures consistent with, and pursuant to, Sections 11.1 and 11.2.

6.4 <u>Return</u>. Upon termination of this Agreement, the Receiving Party shall return or destroy all documents or other media containing Confidential Information of the Disclosing Party with the exception of one (1) copy for the sole purpose of monitoring and documenting the confidentiality obligations hereunder.

6.5 <u>Remedies</u>. Money damages will not be an adequate remedy if this Article 6 is breached and, therefore, either Party may, in addition to any other legal or equitable remedies, seek an injunction or other equitable relief against such breach or threatened breach without the necessity of posting any bond or surety.

6.6 <u>Survival</u>. This Article 6 shall survive the expiration or termination of this Agreement for a period of [\*\*] years.

# 7. REPRESENTATIONS AND WARRANTIES.

7.1 <u>Mutual Representations and Warranties</u>. Mersana and Recepta each represents and warrants to the other as of the Effective Date, that:

7.1.1 Such Party (i) is duly organized, validly existing and in good standing under the Applicable Laws of the jurisdiction of its organization; (ii) has the requisite corporate power and authority and the legal right to conduct its business as now conducted and hereafter contemplated to be conducted; and (iii) has or will obtain all necessary licenses, permits, consents, or approvals from or by, and has made or will make all necessary notices to, all Governmental Authorities having jurisdiction over such Party, required for performance of this Agreement;

7.1.2 The execution, delivery and performance of this Agreement by such Party (i) are within the corporate power of such Party; (ii) have been duly authorized by all necessary or proper corporate action on the part of such Party; (iii) do not conflict with any provision of the organizational documents of such Party; (iv) does not, as of the Effective Date, violate any Applicable Laws or any order or decree of any court or Governmental Authority; and (v) will not violate or conflict with any terms of any indenture, mortgage, deed of trust, lease, agreement or other instrument to which such Party is a party, or by which such Party is bound or becomes bound during the Term;

7.1.3 This Agreement has been duly executed and delivered by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms; and

7.1.4 No governmental authorization, consent, approval except Regulatory Approvals, license, registration, filing or exemption therefrom with any court or other Governmental Authority is or will be necessary for, or in connection with, the transaction contemplated by this Agreement or any other agreement or instrument executed in connection therewith.

7.2 Recepta Representations and Warranties. Recepta represents, warrants and covenants to Mersana that:

7.2.1 as of the Effective Date, (i) Recepta has not previously assigned, transferred, licensed, conveyed or otherwise encumbered its right, title and interest in the

Recepta Patents or any component of the Recepta Know-How in a manner that precludes or is inconsistent with the license rights granted to Mersana pursuant to this Agreement, (ii) there are no Patents owned or Controlled by Recepta, other than the Recepta Patents, that would prevent Mersana or its sublicensees from Developing, manufacturing and/or Commercializing Licensed Products as set forth herein, and from exploiting the rights granted under Section 2.1.1, (iii) there are no pending claims, judgments or settlements affecting any of the Recepta Technology owned by Recepta and Recepta has received no written notice thereof, (iv) to Recepta's knowledge, there are no pending claims, judgments or settlements affecting any of the Recepta Technology otherwise Controlled by Recepta and Recepta has received no written notice thereof, and (v) to Recepta's knowledge, none of the foregoing contemplated by clauses (iii) or (iv) above is threatened;

7.2.2 with respect to any agreements or other instruments pursuant to which Recepta acquires its rights to the Recepta Patents and Recepta Know-How, Recepta will not knowingly commit any act or omission that would reasonably be expected to give rise to any Third Party right to terminate such agreements or other instruments and, with respect to the LICR License, shall exercise its rights and perform its obligations thereunder to the extent necessary to maintain such rights under the LICR Agreement in a manner consistent with the license rights granted to Mersana pursuant to this Agreement; *provided*, *however*, that in no event shall Recepta be in breach of this Section 7.2.2 by virtue of any breach under the LICR License or any other Third Party agreement to the extent such breach is directly attributable to any act or omission of Mersana or its Affiliate, sublicensee or subcontractor in respect of any Licensed Product; and

7.2.3 Recepta shall not exercise any right it may have to terminate the LICR License or otherwise amend the LICR License in a way that adversely affects Mersana's rights hereunder with respect to the Recepta Technology without the prior written consent of an officer of Mersana.

### 7.3 Mersana Representations and Warranties. Mersana represents and warrants to Recepta that:

7.3.1 as of the Effective Date, (i) Mersana has not previously assigned, transferred, exclusively licensed, conveyed or otherwise encumbered its right, title and interest in the Mersana Technology in a manner inconsistent with the licenses granted to Recepta under Sections 2.1.2 and 2.2.2, (ii) there are no pending claims, judgments or settlements affecting any of the Mersana Technology owned by Mersana and Mersana has received no written notice thereof, (iii) to Mersana's knowledge, there are no pending claims, judgments or settlements affecting any of the Mersana Technology otherwise Controlled by Mersana and Mersana has received no written notice thereof, (iii) to formation of the foregoing contemplated by clauses (ii) or (iii) above is threatened;

7.3.2 with respect to any agreements or other instruments pursuant to which Mersana acquires its rights to the Mersana Technology, Mersana will not knowingly commit any act or omission that would reasonably be expected to give rise to any Third Party right to terminate such agreements or other instruments and shall maintain such rights in a manner consistent with the license rights granted to Recepta pursuant to this Agreement. There are no Patents owned or Controlled by Mersana, other than the Mersana Patents, that would prevent Recepta or its sublicensees from exploiting the rights granted under Section 2.1.2 or 2.2.2; and

7.3.3 Mersana has utilized its own scientific, marketing and distribution expertise and experience to analyze and evaluate both the scientific and commercial value of the

rights granted under this Agreement, and Mersana has entered into this Agreement based on its own independent assessment and evaluation.

7.4 Disclaimer of Warranty. Except for the express warranties set forth in this Article 7, nothing in this Agreement shall be construed as a representation or warranty by either Party (i) that any Licensed Product made, used, sold or otherwise disposed of under this Agreement is or will be free from infringement of patents, copyrights, trademarks or other intellectual property rights of any Third Party; (ii) regarding the effectiveness, value, safety, or non-toxicity of any technology; or (iii) that any Licensed Product will obtain Regulatory Approval or that any specific level of Net Sales will be achieved. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES AND EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, RELEASES AND RENOUNCES ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A

PARTICULAR PURPOSE, AND ALL WARRANTIES ARISING FROM ANY COURSE OF DEALING OR PERFORMANCE OR USAGE OF TRADE.

### **8. INDEMNIFICATION.**

8.1 Indemnification by Mersana. Subject to Section 8.3, Mersana shall indemnify, defend and hold harmless Recepta and its Affiliates and each of their officers, directors, shareholders, employees, successors and permitted assigns from and against all Third Party Claims, and pay all associated Losses, arising out of (i) Mersana's or its Affiliate's or its or their sublicensee's, distributor's, subcontractor's or its or their respective director's, officer's, employee's or agent's gross negligence or willful misconduct in performing any of its obligations under this Agreement, or otherwise in relation to its or their Development or Commercialization of the Licensed Products, (ii) any violation of Applicable Law in connection with the Development, Commercialization, manufacture, use, handling, storage, marketing, sale, distribution or other disposition of Licensed Products by Mersana, its agents, subcontractors or sublicensees (iii) any breach by Mersana of any of its representations, warranties or covenants under this Agreement, or (iv) any personal injury, death or property damage resulting from the Development, Commercialization, manufacture, use, handling, storage, marketing, sale, distribution or other disposition of Licensed Products by Mersana, its Affiliates, its agents, subcontractors or sublicensees. Notwithstanding the preceding sentence, Mersana shall have no obligation with respect to Third Party Claims or associated Losses to the extent they are subject to Recepta's indemnification obligations pursuant to Section 8.2 or to the extent otherwise attributable to any of the circumstances set forth in clauses (i) through (iv) thereof.

8.2 Indemnification by Recepta. Subject to Section 8.3, Recepta shall indemnify, defend and hold harmless Mersana and its Affiliates and each of their officers, directors, shareholders, employee's, successors and permitted assigns from and against all Third Party Claims, and pay all associated Losses, to the extent arising out of (i) Recepta's or its Affiliate's or its or their sublicensee's, distributor's, subcontractor's or its or their respective director's, officer's, employee's or agent's gross negligence or willful misconduct in performing any of its obligations under this Agreement, or otherwise in relation to its or their Development or Commercialization of the Licensed Products, (ii) any violation of Applicable Law in relation to the Development, Commercialization, use, handling, storage, marketing, sale, distribution or other disposition of Licensed Products by Recepta, its agents, subcontractors or sublicensees, (iii) any breach by Recepta of any of its representations, warranties or covenants under this Agreement, or (iv) any personal injury, death or property damage resulting from the Development, Commercialization, manufacture, use, handling, storage, marketing, sale, distribution or other disposition of Licensed Products by Recepta, its Affiliates, its agents, subcontractors or sublicensees. Notwithstanding the preceding sentence, Recepta shall have no obligation with respect to Third Party Claims or associated Losses to the extent they are subject to Mersana's indemnification obligations pursuant to Section 8.1 or to the extent otherwise attributable to any of the circumstances set forth in clauses (i) through (iv) thereof.

### 8.3 Procedure for Indemnification.

8.3.1 <u>Notice</u>. Each Party ("Indemnified Party") will notify promptly the other Party ("Indemnifying Party") in writing if it becomes aware of a Claim (actual or potential) by any Third Party or any proceeding commenced by a Third Party (including any investigation by a Governmental Authority) (any of the foregoing, a "Third Party Claim") for which indemnification may be sought and will give such related information as the Indemnifying Party shall reasonably request; *provided, however*, that no failure or delay in giving such notice shall limit the Indemnified Party's right to indemnification hereunder except to the extent that the Indemnifying Party is prejudiced thereby.

8.3.2 Defense of Claim. The Indemnifying Party shall defend or control the defense of Third Party Claims. The Indemnifying Party shall be responsible for satisfying and discharging any award made to or settlement reached with the Third Party pursuant to the terms of this Agreement. The Indemnifying Party shall retain counsel reasonably acceptable to the Indemnified Party (such acceptance not to be unreasonably withheld, refused, conditioned or delayed) to represent the Indemnified Party and shall pay the fees and expenses of such counsel related to such proceeding. In any such proceeding, the Indemnified Party shall have the right to participate in, but not control, the defense of such proceeding at its own cost and expense, and shall have the right to retain its own counsel, at its own cost and expense. Neither Party shall settle any Third Party Claim without the prior written consent of the other Party, which consent shall not be unreasonably withheld, refused, conditioned or delayed. The Indemnified Party shall cooperate in all reasonable respects in the defense of such Third Party Claim, as requested by the Indemnifying Party. The Indemnifying Party shall not, without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld, refused, conditioned or delayed), effect any settlement of any such Third Party Claim, unless such settlement includes an unconditional release of the Indemnified Party from all liability on such Claims. Notwithstanding the foregoing, if the Indemnifying Party notifies the Indemnified Party in writing that it does not intend to assume the defense of any Third Party Claim subject to indemnification hereunder in accordance with the foregoing or fails to assume the defense of any Third Party Claim at least [\*\*] Business Days before any deadline the passing of which could adversely affect the outcome without responsive action by or on behalf of the Indemnified Party (or, if the Indemnifying Party receives less than [\*\*] Business Days' notice of such deadline, if it fails to assume such defense as soon as practicable following receipt of notice), the Indemnified Party shall have the right to assume and control such defense and shall have the right to settle or compromise the same without the Indemnifying Party's consent, and the fees and expenses incurred by the Indemnified Party in connection therewith, including its reasonable legal fees and expenses, will be included in the indemnifiable Losses in connection with such Third Party Claim.

8.4 <u>Insurance</u>. During the Term of this Agreement, the Parties shall obtain and maintain at their sole cost and expense, an adequate liability insurance or self-insurance program (including product liability insurance) to protect against potential liabilities and risk arising out of the Development, manufacture and Commercialization of any Licensed Product and upon such terms (including coverages, deductible limits and self-insured retentions) as are customary in the biopharmaceutical industry in such Party's territory. The Party maintaining any such Third Party insurance coverage shall ensure that the other Party is named as an additional insured thereunder and shall provide a certificate evidencing such coverage to the other Party upon request.

### 9. PATENTS.

9.1 Prosecution and Maintenance.

9.1.1 <u>Recepta Patents</u>. For so long as the license grants to Mersana set forth in Section 2.1.1 remain in effect, Recepta shall use reasonable efforts to, or, to the extent LICR has the right to conduct the following activities pursuant to the LICR License, shall use reasonable efforts to cause LICR to file, prosecute and maintain the Recepta Patents in such jurisdictions within the Territory as Mersana may specify in writing. Recepta shall keep, or, as applicable, shall cause LICR to keep, Mersana reasonably informed of the progress with regard thereto, and shall promptly provide, or, as applicable, shall cause LICR to provide, Mersana with all material correspondence, filings, notifications and other communications, relating to the preparation, filing, prosecution and maintenance of such Recepta Patents in the Territory and Recepta, as applicable, shall provide Mersana's comments to LICR; *provided, however*, that LICR or Recepta, as applicable, shall make the final determination with respect thereto after considering any such comments in good faith. Mersana will reimburse Recepta's out-of-pocket costs and expenses incurred after the Effective Date in connection with any of Recepta's contractual obligations to LICR relating to the LICR's prosecution and maintenance of the Recepta Patents in the Territory or, if mutually agreed in writing by the Parties and LICR, directly pay the relevant costs and expenses to LICR.

9.1.2 Mersana Patents. As between the Parties, Mersana is solely responsible for the filing, prosecution and maintenance of the Mersana Patents. For so long as the license grants to Recepta set forth in Section 2.1.2 remain in effect, Mersana shall use reasonable efforts to file, prosecute and maintain the Mersana Patents in the Recepta Territory. Recepta shall provide Mersana, at Mersana's sole cost and expense, all reasonably requested assistance in connection therewith. Mersana shall keep Recepta informed of all material issues and developments relating to the preparation, filing, prosecution and maintenance of such Mersana Patents in the Recepta Territory. Without limiting the foregoing, Mersana will provide Recepta with copies of all material correspondence, filings, notifications and other correspondence with the Brazilian National Institute of Industrial Property relating to the preparation, filing and maintenance of the Mersana Product Patents in the Recepta Territory and shall consider in good faith any comments that Recepta may have in relation thereto. In the event that (i) Mersana intends not to prosecute or maintain any Mersana Product Patent in the Recepta Territory or (ii) Mersana intends to abandon or otherwise cause or allow any Mersana Product Patent to be forfeited, and, in either case, one or more Valid Claims of such Patent Cover a Licensed Product in the Recepta Territory, then Mersana shall provide timely written notice to Recepta of such intention.

9.2 Notice of Patent Challenge. Each Party shall promptly, but in any event no later than [\*\*] Business Days after receipt of notice of such action, notify the other Party in writing upon becoming aware of any re-examination, interference, opposition, nullity or similar actions, or challenges to the validity or enforceability of, or any alleged or threatened infringement by any Third Party of, either (i) the Recepta Patents in the Territory or (ii) the Mersana Patents in the Recepta Territory, in each case, with respect to the Field, or if such Party or any of their respective Affiliates or sublicensees shall be individually named as a defendant in

a legal proceeding in the Territory by a Third Party alleging infringement or violation of such Third Party's Patents (any of the foregoing occurrences, a "Patent Challenge").

9.3 <u>Patent Challenge Regarding Mersana Patents</u>. As between the Parties, to the extent a Patent Challenge directly concerns any Mersana Patents in the Recepta Territory, Mersana shall have the first right, but not the obligation, to respond to, defend or prosecute any

such Patent Challenge, including defending against any counter-claims of invalidity and unenforceability with respect to such Patents. If Mersana elects to pursue any such Patent Challenge, Mersana will be solely responsible for, and will have the full control of, the proceedings. In making its determination whether to take any action to prosecute any Patent Challenge involving any alleged or threatened infringement of the Mersana Patents in the Recepta Territory, Mersana may take into account the potential effect such action could have on the entirety of Mersana's patent portfolio and not solely the Mersana Patents in the Recepta Territory. If a Patent Challenge involves a Third Party claim of infringement against Recepta or its Affiliates or sublicensees involving the use, marketing or sale of the Licensed Products in the Recepta Territory and Mersana elects not to exercise its right to defend them against such an allegation, then Recepta may defend such Third Party Claim at its own expense and Mersana shall cooperate with Recepta at Recepta's request and expense and shall have the right to be represented by counsel selected by Mersana. In connection with any Patent Challenge relating to the Mersana Patents in the Recepta Territory: (i) the Party not responsible for the Patent Challenge will cooperate with the other Party ("Responsible Party") and its legal counsel, join in such suits as may be brought by the Responsible Party, and be available at the Responsible Party's reasonable request to be an expert witness or otherwise to assist in such proceedings at the Responsible Party's expense; (ii) the Responsible Party will keep the other Party and its counsel reasonably informed at all times as to the status of the Responsible Party's response or defense; (iii) legal fees and other costs and expenses of the Responsible Party associated with such response or defense shall be paid by the Responsible Party; (iv) legal fees and other costs and expenses associated with such response or defense incurred by the other Party at the Responsible Party's request shall be paid by the Responsible Party; and (v) any amounts recovered from Third Parties in connection with any such Patent Challenge shall be applied [\*\*] to Recepta and [\*\*] to Mersana, subject first to reimbursement of expenses of the Responsible Party.

### 9.4 Patent Challenge Regarding Recepta Patents.

9.4.1 As between the Parties, to the extent a Patent Challenge directly concerns the Recepta Patents in the Territory, Mersana shall have the first right, but not the obligation, to respond to, defend or prosecute any such Patent Challenge, including defending against any counterclaims of invalidity and unenforceability with respect to such Patents. In the event Mersana elects to do so, it will be solely responsible for and have the full control of the proceedings. In connection therewith: (i) Recepta will cooperate with Mersana and its legal counsel, join in such suits as may be brought by Mersana, and be available at Mersana's reasonable request to be an expert witness or otherwise to assist in such proceedings at Mersana's response or defense and Recepta shall have the right to participate in, but not control, any such proceeding with its own counsel at Recepta's sole cost and expense (except as provided in clause (iv) below); (iii) legal fees and other costs and expenses of Mersana, associated with such response or defense shall be paid by Mersana; (iv) legal fees and other costs and expenses associated with such response or defense shall be paid by Mersana; and (v) any amounts recovered from Third Parties in connection with such response or defense shall be applied [\*\*] to Recepta and [\*\*] to Mersana, subject first to reimbursement of expenses of Mersana.

9.4.2 In the event that Mersana elects not to respond to, defend or prosecute any Patent Challenge that directly concerns the Recepta Patents in the Recepta Territory, or Mersana elects to abandon any such action, Mersana shall promptly notify Recepta of such election in writing. In such event, Recepta shall have the option to respond, defend or prosecute such Patent Challenge at Recepta's sole cost and expense, *provided* that Mersana shall cooperate with and provide assistance to Recepta at Recepta's expense, including by allowing Recepta to initiate or continue any such action in Mersana's name. Recepta shall keep Mersana

informed of the status of such Patent Challenge and notify it promptly in writing of any judgment, settlement or other disposition thereof. If any amounts are recovered from any Third Party in connection with any such Patent Challenge which Recepta responds to, defends or prosecutes pursuant to this Section 9.4.2, Recepta shall first deduct its expenses from the amount of such recovery and then promptly pay Mersana an amount equal to the [\*\*] of the remaining recovery amount.

9.5 Defense of Infringement Claims. The Party responsible for managing the defense against any Third Party claim of Patent infringement pursuant to Sections 9.3 or 9.4, as applicable, shall have the right to settle such claim on terms deemed appropriate by such Party, *provided*, *however*, that any such settlement must include a full and unconditional release from all liability of the other Party and may not adversely affect the rights of the other Party without such other Party's prior written consent (such consent not to be unreasonably withheld or delayed).

9.6 <u>Biosimilars</u>. Each Party shall promptly, but in any event no later than [\*\*] Business Days after receipt of notice of such application, notify the other Party if it becomes aware of any application for regulatory approval of a biosimilar anywhere in the Territory where any Licensed Product is a reference product under such application. Mersana shall take the lead and be responsible for preparing and filing any responses with any Regulatory Authority and negotiating any patent resolution in connection with any such application as set forth in paragraphs 2 through 6 of Section 351(l) of the United States Public Health Service Act (42 U.S.C. § 262(l)(2)-(6)), or any foreign equivalent thereof and shall use Diligent Efforts in relation thereto. Recepta shall cooperate with Mersana's reasonable requests for assistance in connection therewith.

# **10. TERM AND TERMINATION.**

10.1 Term. This Agreement shall come into effect on the Effective Date and continue until it is terminated in its entirety by either Party pursuant to Section 10.2 (such period, the "Term"). Effective upon the expiration of the Royalty Term for a Licensed Product with respect to any country outside the Recepta Territory, the license granted to Mersana pursuant to Section 2.1.1 with respect to such Licensed Product in such country shall automatically become fully paid-up and royalty-free. Effective upon the expiration of the Royalty Term in the Recepta Territory for a Licensed Product, the license granted to Recepta pursuant to Section 2.1.2 with respect to such Licensed Product shall automatically become fully paid-up and royalty-free.

### 10.2 Termination.

10.2.1 <u>Convenience</u>. Mersana may terminate this Agreement, in its entirety or a country-by-country, Licensed Product-by-Licensed Product basis with or without cause at any time by giving Recepta at least one hundred eighty (180) calendar days' prior written notice (if terminating this Agreement in its entirety) or forty-five (45) calendar days' prior written notice (if terminating this Agreement with respect to one or more countries); *provided*, *however*, that Mersana may not terminate this Agreement for convenience with respect to the Recepta Territory unless such termination is in connection with a termination of this Agreement in its entirety.

# 10.2.2 Material Breach.

(a) In the event of a material breach of this Agreement, the non-breaching Party may deliver notice of such breach to the breaching Party, such notice containing the material details of said breach to the extent known to the non-breaching Party. The breaching Party shall have, subject to Section 10.2.2(b), [\*\*] Business Days to cure such breach [\*\*]

Business Days in the case of a Party's breach of its payment obligations). Subject to Section 10.2.2(b), if the Party receiving notice of breach fails to cure such breach within the [\*\*] Business Day period or [\*\*] Business Day period (as applicable), the Party originally delivering the notice may terminate this Agreement upon written notice to the other Party, *provided*, that if the breach applies only to a given country, the non-breaching Party may only terminate this Agreement with respect to such country and thereafter, in the case of a breach by Mersana, the Territory shall no longer include the country in which such termination has occurred.

(b) If a Party gives notice of breach under Section 10.2.2(a) and the other Party, acting in good faith, disputes in writing prior to the end of the applicable cure period whether such notice was proper, then the issue of whether a material breach has occurred shall be resolved in accordance with Section 11.7. If as a result of such dispute resolution process it is determined that the notice of breach was proper, then such notice shall be deemed to have been effective if the breaching Party fails thereafter to cure such breach in accordance with the determination made in the resolution process within the applicable cure period following such determination. If as a result of such dispute resolution process it is determined that the notice of breach was improper, then no such notice shall be deemed to have been effective and this Agreement shall remained in effect. All of the terms and conditions of this Agreement shall remain in full force and effect during the pendency of such dispute resolution process.

10.2.3 <u>Bankruptcy</u>. Either Party may terminate this Agreement in its entirety immediately upon written notice, if the other Party makes an assignment for the benefit of creditors, or a receiver, trustee in bankruptcy or similar officer is appointed to take charge of any or all of the other Party's property, or the other Party seeks protection under any bankruptcy, receivership, trust deed, creditors arrangement, composition or comparable proceeding or such a proceeding is instituted against the other Party and is not dismissed within [\*\*] Business Days, or the other Party becomes insolvent or, without a successor, dissolves or liquidates.

# 10.2.4 Patent Challenge.

(a) Recepta may terminate this Agreement, with respect to any Licensed Product in a given country, immediately upon the issuance of written notice to Mersana, if Mersana or any of its Affiliates performing [\*\*].

(b) Mersana may terminate this Agreement with respect to any Licensed Product in the Recepta Territory immediately upon the issuance of written notice to Recepta if Recepta or any of its Affiliates performing [\*\*].

### 10.3 Effects of Termination.

10.3.1 <u>Termination by Recepta or by Mersana for Convenience</u>. In the event that this Agreement is terminated by Recepta pursuant to the terms of this Agreement or by Mersana pursuant to Section 10.2.1, (i) all rights and licenses on a [\*\*] basis granted to Mersana, as well as all sublicenses granted under this Agreement by Mersana and/or any of its sublicensees, shall immediately terminate; however, Mersana and its sublicensees shall be entitled to sell, for a period of [\*\*] months after the effective date of termination, any inventories of Licensed Products in the Field in the Territory that are on-hand as of the effective date of termination, subject to Mersana's payment of royalties to Recepta in respect of such sales, in accordance with Article 5 hereof and (ii) except as otherwise contemplated in Section 10.3.2(a), all of the rights and licenses granted to Recepta under Sections 2.1.2, 2.2.2, 2.3.3 and 2.4.2, including any sublicenses already granted by Recepta pursuant to Section 2.2.2, shall remain in effect, subject to Recepta's ongoing obligations to make royalty payments in accordance with Sections 5.5 through 5.7 and subject to Section 5.8.2 which, for clarity, shall also remain in effect. In addition, Recepta may, at its option, offset any amounts due and payable to Mersana in

respect of the aforementioned royalties by the amount of any damages awarded to Recepta by the arbitrator pursuant to Section 11.7.

### 10.3.2 Termination by Mersana.

(a) In the event that this Agreement is terminated by Mersana either (i) in respect to the Recepta Territory pursuant to Sections 10.2.2, 10.2.3 or 10.2.4(b) or (ii) in its entirety pursuant to Section 10.2.1 and following such termination no sales of any Licensed Product by or for Recepta or Mersana or any of their respective Affiliates or sublicensees have been made for [\*\*] month period (the last day of such period, the "Cessation Date"), then (1) all rights and licenses granted to Recepta in respect of the Mersana Technology, Promotional Materials and ROW Trademarks, as well as all sublicenses granted under this Agreement by Recepta and/or any of its sublicensees in respect of the foregoing, shall immediately terminate in respect of all Licensed Products as of the effective date of termination (in the case of a termination contemplated by the foregoing clause (i)) or as of the Cessation Date (in the case of a termination contemplated by the foregoing clause (ii)), (2) following the effective date of termination (in the case of a termination contemplated by the foregoing clause (i)) or following the Cessation Date (in the case of a termination contemplated by the foregoing clause (ii)), if requested by Mersana, at its option, Recepta will either (x) in the case of a termination contemplated by the foregoing clause (i), promptly assign or transfer, or cause to be assigned and transferred to Mersana (or if not so assignable, Recepta shall use reasonable efforts to make available to Mersana the benefits of), all Regulatory Approvals specifically relating to all Licensed Products in the Recepta Territory, together with all related filings with any Regulatory Authority and any other supporting documentation and dossier submissions in respect of such Licensed Products or (y) in the case of a termination contemplated by the foregoing clause (ii), promptly withdraw or otherwise terminate the effectiveness of all Regulatory Approvals specifically relating to all Licensed Products in the Recepta Territory and transfer to Mersana all related filings with any Regulatory Authority and any other supporting documentation and dossier submissions in respect of such Licensed Products, and (3) following the effective date of termination (in the case of a termination contemplated by the foregoing clause (i)) or following the Cessation Date (in the case of a termination contemplated by the foregoing clause (ii)), if requested by Mersana, Recepta shall promptly cause all of Recepta's rights, title and interest in and to the Recepta Trademarks (other than any corporate names or logos) and Promotional Materials (including all translations thereof) specifically relating to the Licensed Products in the Recepta Territory to be transferred and assigned solely and exclusively to Mersana or Mersana's designee and use reasonable efforts to take such further action as Mersana determines is reasonably necessary for ownership and Control thereof to vest solely and exclusively in Mersana or Mersana's designee(s). In the case of a termination by Mersana pursuant to Section 10.2.2 or 10.2.4(b), such transfers and other actions contemplated by the immediately preceding sentence shall be at Recepta's sole cost. Otherwise, Mersana shall promptly reimburse Recepta for all of the direct, out-of-pocket costs and expenses incurred by Recepta (x) in connection with obtaining any Regulatory Approvals which Mersana requests to have withdrawn or terminated pursuant to the foregoing clause (2), including all fees paid by Recepta to any Regulatory Authority in connection with any application for Regulatory Approval with respect to any Licensed Product in the Recepta Territory and (y) in connection with obtaining or maintaining any Recepta Trademarks or Promotional Materials which Mersana requests to have assigned or transferred to it pursuant to the foregoing clause (3). For clarity, Mersana shall not be obligated to reimburse Recepta pursuant to this Section 10.3.2(a) for (A) any other costs or expenses of Recepta incurred in connection with any Development activities undertaken by Recepta, or undertaken by Mersana and reimbursed by Recepta, in relation thereto, (B) any fees associated with actually effecting any such transfers of filings, approvals, trademarks or rights, or (C) any associated legal fees or expenses. Notwithstanding the foregoing, Recepta and its existing sublicensees shall be entitled [\*\*] by Mersana pursuant to any of the Sections referenced in clause (ii) above, any inventories of Licensed Products in the Field

in the Recepta Territory that are on-hand with Recepta or its sublicensees as of the effective date of termination, as well as any quantities of Licensed Product supplied pursuant to Section 10.3.4, subject to Recepta's payment of royalties to Mersana in respect of such sales, in accordance with Sections 5.5 through 5.7 and subject to Section 5.8.2 which, for clarity, shall also remain in effect.

(b) In the event of any termination of this Agreement by Mersana pursuant to Sections 10.2.2, 10.2.3, or 10.2.4(b), all of the rights and licenses granted to Mersana under Sections 2.1.1 and 2.2.1, including any sublicenses already granted by Mersana pursuant to Section 2.2.1, shall remain in effect, subject to Mersana's ongoing obligations to make the milestone and royalty payments in accordance with Sections 5.2, 5.3, 5.4, 5.6 and 5.7 and subject to Section 5.8.1, all of which, for clarity, shall also remain in effect; *provided*, *however*, that to the extent Mersana is obligated to pay any such milestone and/or royalty payments directly to LICR pursuant to the terms of the Three-Party Agreement, Mersana shall make such payments directly to LICR in accordance with such terms and Mersana shall not have any further obligation hereunder or otherwise to make such payments to Recepta. In addition, Mersana may, at its option, offset any amounts due and payable to Recepta in respect of the aforementioned milestones and royalties by the amount of any damages awarded to Mersana by the arbitrator pursuant to Section 11.7.

10.3.3 <u>Partial Termination</u>. For the avoidance of doubt, if Recepta exercises its right to terminate this Agreement pursuant to Section 10.2.2 or Section 10.2.4(a) due to Mersana's breach of this Agreement or challenge to Recepta's Patents, or Mersana terminates this Agreement pursuant to Section 10.2.1, in respect of one or more (but not all) countries in the Territory, this Agreement shall terminate only with respect to those specific country(ies) such that, thereafter, the Territory shall no longer include the country in which such termination has occurred.

## 10.3.4 Continued Supply Rights.

(a) If this Agreement terminates in its entirety or in respect of any Licensed Product(s) in respect of which Regulatory Approval has been received in the Recepta Territory, other than pursuant to a termination by Mersana pursuant to Sections 10.2.2, 10.2.3, or 10.2.4(b), and one or more of the Licensed Product(s) affected by such termination will not be manufactured by or for Mersana or its Affiliates or sublicensees for Commercialization anywhere outside the Recepta Territory following such termination, then (i) Mersana shall discuss in good faith with Recepta the terms under which it might continue to supply Recepta or its designated sublicensee with such Licensed Product(s) for sale to end user customers in the Recepta Territory, on terms as close as reasonably possible to those contemplated by Section 3.3.2, it being understood that (a) Mersana may not Control all of the intellectual property rights necessary to manufacture the Licensed Products and shall have no obligation to develop or acquire any intellectual property rights in order to arrange for such manufacture and (b) in no event shall Mersana be required, as a condition of such supply arrangement, to transfer or otherwise disclose (or to authorize the transfer or disclosure of) any Mersana Technology to a Third Party not already in possession of such Mersana Technology. Such discussions shall begin on the date Mersana or Recepta, as applicable, gives effective notice of termination and, unless the Parties agree otherwise or a supply arrangement is sooner agreed to in writing, shall end on the effective date of termination if Mersana is the terminating Party or [\*\*] calendar days after the effective date of termination if Recepta or its designated sublicensee, for a purchase price equal to Mersana's cost, a quantity of Licensed Product equal to Recepta or its designated sublicensee's) forecasted requirements for the [\*\*] period following the effective date of such termination.

(b) If this Agreement terminates in its entirety or in respect of any Licensed Product(s) in respect of which Regulatory Approval has been received in the Recepta Territory, other than pursuant to a termination by Mersana pursuant to Sections 10.2.2, 10.2.3, or 10.2.4(b), and one or more of the Licensed Product(s) affected by such termination will continue to be manufactured by or for Mersana or its Affiliates or sublicensees for Commercialization anywhere outside the Recepta Territory following such termination, then Recepta shall be entitled to continue to receive supply of such Licensed Product(s) pursuant to and in accordance with any Supply Agreement then in effect or, if no such Supply Agreement is then in effect, then Section 3.3.2 hereof shall remain in effect in relation to such Licensed Product(s) following such termination and Recepta shall be entitled to obtain supply of such Licensed Product(s) under any Supply Agreement entered into pursuant thereto after termination.

(c) During the Royalty Term for the Recepta Territory, Recepta's Net Sales received pursuant to sales or transfers of Licensed Products by Recepta following termination will be subject to royalty payments as set forth in Sections 5.5 through Section 5.7 and subject to Section 5.8.2 all of which, for clarity, shall remain in effect. Thereafter, Recepta's license under the Mersana Technology pursuant to Section 2.1.2 shall automatically become royalty-free and fully-paid upon the expiration of the Royalty Term in the Recepta Territory.

10.4 <u>Availability of Cell Lines</u>. In the event of any termination of this Agreement in its entirety by Mersana pursuant to Section 10.2.1 or by Recepta pursuant to Sections 10.2.2, 10.2.3 or 10.2.4(a), within [\*\*] Business Days after Recepta's written request, Mersana will make available to Recepta and extend to Recepta all necessary rights to use, without charge, any new cell lines owned or Controlled by Mersana as of the effective date of termination which are necessary or useful for the development and/or manufacture of the Antibody, subject to any restrictions or limitations set forth in any Third Party agreements governing the transfer or use or such cell lines. Such assistance may include, but will not be limited to, executing such agreements as may be necessary to release Mersana's rights to such cell lines under Mersana's agreements with its Third Party manufacturers. For the avoidance of doubt, Recepta shall be responsible for any reasonable and documented costs incurred by Mersana in connection with the storage and/or maintenance of the cell line(s) until such time as Recepta assumes responsibility for such storage and/or maintenance.

10.5 Accrued Rights; Surviving Obligations. Except as provided elsewhere, termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration. Such termination or expiration shall not relieve any Party from obligations which are expressly or by implication intended to survive termination or expiration of this Agreement, including, but not limited to, Articles 1 and 6 (but only for the [\*\*] specified in Section 6.6), and Sections 2.4, 2.5, 4.4, 4.5, 5.9, 5.10, 5.11, 7.4, 8.1-8.3, 9.3, 9.4 (but only for so long as the license granted to Mersana under Section 2.1.1 remains in effect), 9.5, 10.3, 10.4, 11.1, 11.2, 11.4, 11.5, 11.7-11.19 and this Section 10.5. Termination or expiration of this Agreement shall not affect or prejudice any right of either Party to receive payments due hereunder or for which the event giving rise to such payment obligation has occurred prior the effectiveness of such termination or expiration (which, in the case of the payment contemplated by Section 5.1 is the execution and delivery of this Agreement by both Parties) and shall not preclude or hinder the terminating Party from also bringing, amending or pursuing an action against the other Party for damages and all other available legal and equitable remedies, subject to Section 11.7. In addition, Mersana's obligations pursuant to Sections 5.2, 5.3, 5.4, 5.6 and 5.7 shall, subject to Section 5.8.1, survive and continue in accordance with their terms following any termination or expiration of this Agreement in respect of Mersana's or any of its Affiliates' or licensees' continued Development or Commercialization of any Licensed Product, the Development, manufacture, use or Commercialization of which by Mersana or any of its Affiliates or sublicensees prior to the effective time of termination or expiration of this Agreement utilized any Recepta Know-How.

### **11. MISCELLANEOUS.**

11.1 Publications. As between the Parties, and except for any required filings with any Regulatory Authority pursuant to a Party's obligations hereunder to obtain Regulatory Approval in any jurisdiction, Mersana shall have the sole and exclusive right, but not the obligation, to make any publication in respect of the results arising out of Development of Licensed Products and Recepta shall make no such publication without the prior written consent of Mersana. Without limiting the preceding sentence, if Recepta wishes to make such a publication, then it will submit the proposed publication to Mersana at least [\*\*] calendar days prior to the intended date of publication so that Mersana may, within [\*\*] calendar days after its receipt of such proposed publication, identify to Recepta any of Mersana's Confidential Information contained in the proposed publication. Recepta shall withhold publication of any of information timely identified to Recepta as Mersana's Confidential Information for a period of up to [\*\*] calendar days to allow for the filing of patent applications or the taking of such measures as may be appropriate to preserve proprietary rights in and the confidentiality of the information in the material being submitted for publication or presentation (including withholding such publication). By agreement of the Parties, this period may be further extended. The Parties will each comply with standard academic practice regarding authorship of scientific publications and recognition of other parties in any such publications or presentations.

11.2 <u>Public Announcements</u>. Except as may be expressly permitted under this Section 11.2 or mandated by Applicable Laws or the rules of any stock exchange, neither Party will make any public announcement of any information regarding this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. Once any statement is approved for disclosure by the Parties, either Party may make a subsequent public disclosure containing the same information disclosed in such prior public announcement without further approval of the other Party. Notwithstanding the above, the Parties shall issue the joint press release attached hereto as Exhibit 2 on the Effective Date.

11.3 <u>No Debarred Personnel</u>. Each Party agrees that it and its sublicensees shall not use, during the Term of this Agreement, the services of any employee, consultant, contractor or clinical investigator that has been debarred by the FDA or any other Governmental Authority or that is the subject of debarment proceedings by the FDA or any other Governmental Authority. If a Party becomes aware that it or its sublicensees has breached the foregoing obligation, it will immediately notify the other Party in writing and provide full details of the circumstances and extent of such breach.

11.4 <u>Relationship of the Parties</u>. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other except as expressly provided in this Agreement. Neither Party shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee benefits of such employee. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, the Parties' legal relationship under this Agreement to each other shall be that of independent contractor. This Agreement is not a partnership agreement and nothing in this Agreement shall be construed to establish a relationship of partners or joint venturers between the Parties.

11.5 <u>Registration of this Agreement</u>. To the extent, if any, that either Party concludes in good faith that it or the other Party is required to file or register this Agreement or a notification thereof with any Governmental Authority, such Party shall inform the other Party thereof. If both Parties jointly agree that either Party is required to submit or obtain any such

filing, registration or notification, they shall cooperate (Mersana's cost and expense) in such filing, registration or notification and shall execute all documents reasonably required in connection therewith. In such filing, registration or notification, the Parties shall request confidential treatment of sensitive provisions of this Agreement, to the extent permitted by Applicable Law. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall reasonably cooperate to respond to any request for further information therefrom on a timely basis. Mersana shall be responsible for all costs and expenses associated with any such filings or requirements.

11.6 Force Majeure. The occurrence of an event which materially interferes with the ability of a Party to perform its obligations or duties hereunder which is not within the reasonable control of the Party affected or any of its sublicensees, and which could not with the exercise of Diligent Efforts have been avoided ("Force Majeure Event"), including, but not limited to, war, rebellion, earthquake, fire, accident, strike, riot, civil commotion, act of God, inability to obtain raw materials, delay or errors by shipping companies or change in Applicable Law, shall not excuse such Party from the performance of its obligations or duties under this Agreement, but shall merely suspend such performance during the Force Majeure Event. The Party subject to a Force Majeure Event shall promptly notify the other Party of the occurrence and particulars of such Force Majeure Event and shall provide the other Party, from time to time, with its best estimate of the duration of such Force Majeure Event and with notice of the termination thereof. The Party so affected shall use Diligent Efforts to avoid or remove such causes of non-performance as soon as is reasonably practicable. Upon termination of the Force Majeure Event, the performance of any suspended obligation or duty shall without delay recommence. The Party subject to the Force Majeure Event shall not be liable to the other Party for any damages arising out of or relating to the suspension or termination of any of its obligations or duties under this Agreement by reason of the occurrence of a Force Majeure Event, *provided* such Party complies in all material respects with its obligations under this Section 11.6.

11.7 Dispute Resolution. In the event of any dispute, controversy or claim hereunder arising out of or relating to this Agreement, either Party may, on [\*\*] Business Days written notice to the other Party, initiate binding arbitration in accordance with the then-current rules of the ICC governing the arbitration of commercial disputes. The Parties shall select a mutually acceptable arbitrator within [\*\*] Business Days after the request of the Party invoking this dispute resolution procedure. If the Parties are unable to agree upon an arbitrator, the ICC shall select a qualified, independent arbitrator. Such arbitration will be held in New York, New York. The decision of the arbitrator will be final and binding on the Parties. The prevailing Party may enforce any arbitration decision or award exclusively in the federal and state courts in the State of New York, New York, USA. Notwithstanding the foregoing, either Party may seek injunctive, equitable or similar relief (without the requirement of arbitration) exclusively in any federal and state courts in the State of New York, USA.

11.8 <u>Governing Law</u>. This Agreement shall be construed, and the respective rights of the Parties determined, according to the substantive law of New York without regard to the provisions governing conflict of laws, except matters of intellectual property law, which shall be determined in accordance with the intellectual property laws relevant to the intellectual property in question. The United Nations Convention on the International Sale of Goods shall not apply to this Agreement.

11.9 <u>Attorneys' Fees and Related Costs</u>. In the event that any legal proceeding is brought to enforce or interpret any of the provisions of this Agreement, the prevailing Party shall be entitled to recover its reasonable attorneys' fees, court costs and expenses of litigation whether or not the action or proceeding results in a final judgment.

11.10 <u>Assignment</u>. This Agreement may not be assigned or transferred by either Party, in whole or in part, whether voluntarily or by operation of law, without the prior written consent of the other Party; *provided* that either Party may assign this Agreement, in whole or in part, to any of its Affiliates if such Party guarantees the performance of this Agreement by such Affiliate; and *provided further* that either Party may assign this Agreement to a successor to all or substantially all of the business or assets of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or other similar transaction. Any assignment in violation of this provision is void and without effect. This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns. In the event that Recepta assigns or transfers any of the Recepta Technology to a Third Party, Recepta shall impose on such assignee or transferee such obligations as are necessary so that Mersana retains and obtains all of the rights to which it is entitled with respect to such Recepta Technology under this Agreement.

11.11 <u>Notices</u>. All demands, notices, consents, approvals, reports, requests and other communications hereunder must be in writing, in English, and will be deemed to have been duly given only if delivered personally, by mail (first class, postage prepaid), or by overnight delivery using a globally-recognized carrier, to the Parties at the following addresses:

Mersana:	Recepta:
Mersana Therapeutics, Inc.	Recepta Biopharma, S.A.
840 Memorial Drive	Rua Tabapuã, 1123 conj 36
Cambridge, MA 02139	Itaim Bibi - São Paulo, SP
USA	CEP 04533 - 014
Attn: Chief Business Officer	Brazil
	Attn: CEO

with a copy to:	with a copy to:
Gunderson Dettmer Stough Villeneuve	Mayer Brown LLP
Franklin and Hachigian, LLP	
One Marina Park Drive, Suite 900	1221 Avenue of the Americas
Boston, MA 02210	New York, NY 10020
USA	USA
Attn: Timothy H. Ehrlich, Esq.	Attn: Reb D. Wheeler

or to such other address as the addressee shall have last furnished in writing in accord with this provision. All notices shall be deemed effective upon receipt by the addressee.

11.12 <u>Severability</u>. If any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect, that provision shall be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect and enforceable.

11.13 <u>Headings</u>. The headings used in this Agreement have been inserted for convenience of reference only and do not define or limit the provisions hereof.

11.14 <u>Waiver</u>. No waiver of any term or condition of this Agreement shall be effective unless set forth in a written instrument duly executed by or on behalf of the waiving Party. No waiver by any Party of any term or condition of this Agreement, in any one or more instances, shall be deemed to be or construed as a waiver of the same or any other term or condition of this Agreement on any prior, concurrent or future occasion. Except as expressly set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by Applicable Law or otherwise, will be cumulative and not in the alternative to any other rights or remedies that may be available to such Party.

11.15 Entire Agreement. This Agreement (including any exhibits or schedules hereto), together with the Three-Party Agreement, constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof and supersedes all previous agreements and understandings between the Parties, whether written or oral, including, but not limited, to all proposals, negotiations, conversations, letters of intent, memoranda of understanding or discussions, between the Parties relating to the subject matter of this Agreement and all past dealing or industry custom.

11.16 <u>Modification</u>. This Agreement may be altered, amended or changed only by a writing making specific reference to this Agreement and the clause to be modified, which amendment is signed by duly authorized representatives of Mersana and Recepta.

11.17 <u>No Third Party Beneficiaries</u>. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including, but not limited to, any creditor of either Party hereto.

11.18 <u>Ambiguities</u>. This Agreement shall be deemed to have been drafted jointly by both Parties; and ambiguities, if any, shall not be construed against either Party, irrespective of which Party may have actually drafted the ambiguous provision.

11.19 <u>Counterparts</u>. This Agreement may be executed in counterparts, each of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document.

[Remainder of Page Intentionally Left Blank]

**IN WITNESS WHEREOF**, Mersana and Recepta, by their duly authorized officers, have executed this Agreement as of the Effective Date.

# MERSANA THERAPEUTICS, INC.

# **RECEPTA BIOPHARMA S.A.**

By:	/s/ Eva M. Jack	By:	/s/ José Fernando Perez
Name:	Eva M. Jack	Name:	José Fernando Perez
Title:	Chief Business Officer	Title:	President

# EXHIBIT 1 <u>RECEPTA PATENTS</u>

No.	Country Code	Filing Type	Application Number	Filing Date	Patent/publication Number	Issue Date	Status	Title	Inventors
1.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
2.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
3.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
4.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
5.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
6.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
7.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
8.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	

EXHIBIT 1 TO LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

No.	Country Code	Filing Type	Application Number	Filing Date	Patent/publication Number	Issue Date	Status	Title	Inventors
9.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
10.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
11.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
12.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
13.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
14.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
15.	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	

EXHIBIT 1 TO LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

# EXHIBIT 2 JOINT PRESS RELEASE

[Please see attached]

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

#### **EXECUTION VERSION**

### AGREEMENT REGARDING LICR TECHNOLOGY

This Agreement Regarding LICR Technology ("Agreement"), effective as of July 9, 2015, is by and between Ludwig Institute for Cancer Research, a Swiss not-for-profit entity with a principal office at Stadelhoferstrasse 22, 8001 Zurich, Switzerland ("LICR"), Recepta Biopharma S.A., a Brazilian corporation with a principal office at Rua Tabapuã, 1123 conj 36, Itaim Bibi, São Paulo, SP, CEP 04533 - 014, Brazil ("Recepta") and Mersana Therapeutics, Inc., a Delaware corporation with a principal office at 840 Memorial Drive, Cambridge, MA 02139 ("Mersana"). LICR, Recepta and Mersana are collectively referred to herein as the "Parties" and each individually as a "Party".

WHEREAS LICR and Recepta entered into that certain Research, Development and License Agreement dated as of October 10, 2006 and amended on February 14, 2012 and April 10, 2012 (as amended, the "LICR Agreement"), providing for the license of certain LICR Technology (as defined in the LICR Agreement) by LICR to Recepta as set forth therein;

WHEREAS, certain of the LICR Technology that relates to the humanized antibody NaPi2b is referred to in the LICR Agreement as "[\*\*]" (such LICR Technology, the "[\*\*] Technology");

WHEREAS, Recepta is planning to license certain rights to Mersana, including, without limitation, a sublicense of the [\*\*] Technology licensed by LICR to Recepta under the LICR Agreement, pursuant to the License, Development and Commercialization Agreement in the form attached hereto as <u>Exhibit A</u> (the "Sublicense Agreement");

WHEREAS, the Parties recognize that the Sublicense Agreement will be beneficial to the Parties, and that the Parties desire that Recepta and Mersana execute the Sublicense Agreement; and

WHEREAS, the Parties desire to enter into this Agreement to, among other things, provide for certain rights and assurances to Recepta and Mersana that Recepta and Mersana will receive and continue to enjoy all the rights and licenses granted to them, respectively, under the LICR Agreement and the Sublicense Agreement in relation to the [\*\*] Technology.

#### NOW THEREFORE, the Parties hereby agree as follows:

1. <u>Preservation of License Rights</u>. In the event that (i) the LICR Agreement is terminated for any reason and (ii) Recepta thereupon ceases to possess a license to, and does not otherwise control, the [\*\*] Technology or any portion thereof, such that Mersana's sublicense of the [\*\*] Technology (or such portion thereof) under the Sublicense Agreement is no longer valid, then, in each such case, notwithstanding anything to the contrary contained in the LICR Agreement, the Parties agree that, at the option of Mersana, on written notice to LICR and Recepta (and provided that Mersana is not in breach of any of its obligations under the Sublicense Agreement): (a) subject to the foregoing and to the remaining provisions of this Agreement, including clause 1(c), below, LICR shall, and hereby does, grant a direct right and license to Mersana with respect to the [\*\*] Technology (or such portion thereof), on the terms of the LICR Agreement relevant to the [\*\*] Technology, which license shall be reflected in a written agreement reflecting such terms that LICR and Mersana agree to promptly prepare and execute following such election on the part of Mersana; (b) without prejudicing any rights or remedies Mersana may have as a result of such termination of the LICR Agreement, Mersana shall have no further obligations to Recepta under Article 9 of the Sublicense Agreement with respect to the [\*\*] Technology; (c) if such termination of the LICR Agreement to the contrary, Mersana shall pay all amounts owing to Recepta in respect of milestones and royalties accruing under the Sublicense Agreement after the effective date of such termination to LICR directly and Mersana shall have no obligation under the Sublicense Agreement after the effective date of such termination to LICR directly and Mersana shall have no obligation under the Sublicense Agreement to the contrary, Mersana shall pay all amounts owing to Recepta in respect of milestones and royalties accruing under the Sublicense Agreement or otherwise to pay such amounts to Re

this Agreement, including without limitation the preservation of rights and licenses granted to Mersana under the Sublicense Agreement. For clarity, LICR shall look only to Recepta with respect to the events giving rise to any termination of the LICR Agreement and Mersana shall have no liability to LICR in connection therewith.

#### 2. Patent Prosecution and Infringement Claims.

a. LICR agrees that it will prepare, file, prosecute and maintain LICR Patents (as defined in the LICR Agreement) comprising the [\*\*] Technology in all jurisdictions as Mersana or Recepta may specify in writing, at Mersana's expense, subject to Section 4.3(b) of the LICR Agreement. The parties agree that Mersana may elect to reimburse LICR for such expenses directly, in which case Mersana shall not be obligated to reimburse Recepta pursuant to Section 9.1.1 of the Sublicense Agreement for any costs or expenses in relation to LICR's conduct of such activities that are reimbursed directly by Mersana, but Mersana shall notify Recepta in writing of all such expenses and reimbursements thereof that it makes to LICR.

b. As used in this Agreement, "Infringement Claims" means any nullity actions or declaratory judgment actions involving, or any alleged or threatened infringement of, any patent rights comprising the [\*\*] Technology licensed to Recepta under the LICR Agreement or misappropriation of intellectual property comprising such patent rights, or any action in which any Party or any of such Party's respective affiliates shall be individually named as a defendant in a legal proceeding by a third party alleging infringement of any such patent rights or misappropriation of any such intellectual property, in each case that are brought anywhere in the world with respect to the Field (as defined in the Sublicense Agreement) while the Sublicense Agreement is in effect.

c. Notwithstanding anything in the LICR Agreement to the contrary, in the event of any Infringement Claims, LICR shall not exercise its rights under Sections 4.5(b)(ii) or 4.5(b)(iii) of the LICR Agreement to take appropriate action against any person directly or contributorily infringing the relevant patent rights unless neither Mersana nor Recepta responds to, defends or prosecutes such Infringement Claim as provided in Section 9.4 of the Sublicense Agreement.

d. Notwithstanding anything in the LICR Agreement to the contrary, in the event Mersana responds to, defends or prosecutes such Infringement Claim as provided in Section 9.4 of the Sublicense Agreement: (i) LICR will cooperate with Mersana and its legal counsel, join in such suits as may be brought by Mersana, and be available at Mersana's reasonable request to be an expert witness or otherwise to assist in such proceedings at Mersana's expense; (ii) legal fees and other costs and expenses of Mersana associated with such response or defense shall be paid by Mersana; (iv) legal fees and other costs and expenses associated with such response or defense incurred by LICR at Mersana's request shall be paid by Mersana; and (v) any amounts recovered from Third Parties in connection with such response or defense shall be applied as set forth in the Sublicense Agreement. Mersana shall pay, or, if applicable, reimburse Recepta or LICR for, any amounts that may be owing to [\*\*] (as defined below) or [\*\*] (as defined below) by virtue of their participation or cooperation in relation to any Infringement Claim as requested by Mersana.

### 3. Status of LICR Agreement; Relationship to Sublicense Agreement.

a. LICR and Recepta each hereby represent and warrant that, as of the Effective Date, (i) the LICR Agreement is in full force and effect, (ii) except as set forth in the Section 3(b) below, LICR and Recepta are in full compliance with all of the terms and conditions of the LICR Agreement and (iii) the execution, delivery and performance of this Agreement and the Sublicense Agreement by Recepta, shall not constitute a breach of the LICR Agreement.

b. The Parties acknowledge and agree that as of the Effective Date, one or more of the Project Development Milestones (as defined in the LICR Agreement) listed in Section 2.4 of the LICR Agreement have not been achieved as contemplated in the LICR Agreement. Any failure to achieve the Project Development Milestones for any reason is not now and will not in the future be deemed a breach

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of the LICR Agreement and LICR hereby waives any and all claims for damages or any other remedies it may have against Recepta and/or Mersana, whether or not now existing, arising out of any such failure. LICR agrees that (i) Mersana's performance of the Sublicense Agreement shall be deemed to satisfy Recepta's diligence obligations in respect of the [\*\*] Antibody under Section 2.4 of the LICR Agreement and otherwise and (ii) Recepta's delivery to LICR of such development plans as Mersana provides to Recepta from time to time under the Sublicense Agreement shall satisfy Recepta's obligations under section 2.6 of the LICR Agreement.

4. <u>Enforcement of Side Letters</u>. While the Sublicense Agreement is in effect, LICR shall maintain in full force and effect, and, upon the request of Mersana, take all appropriate steps to enforce the terms of that certain side letter between LICR and [\*\*], and that certain side letter between LICR and [\*\*] (collectively, the "Side Letters"), to the extent that the terms of the Side Letters apply to Mersana or the [\*\*] Technology. Without limiting the foregoing, LICR shall not amend, replace or assign any of its rights under either of the Side Letters or its other agreements with [\*\*] referenced in the Side Letters in any manner that affects the [\*\*] Technology, without Mersana's prior written approval.

#### 5. Miscellaneous.

a. The Parties hereby acknowledge and agree that references to a party to a given agreement shall include any successor to such party to such agreement, including, without limitation, by operation of this Agreement. The Parties further agree and acknowledge that the rights and obligations of a Party under this Agreement shall be binding on, and inure to the benefit of, its successors and assigns, including, without limitation, a successor or assign with respect to the LICR Agreement or the Sublicense Agreement, as applicable.

b. This Agreement may be executed by the Parties hereto in multiple counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile signatures (including scanned .PDF versions) shall be deemed to be originals.

c. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, without regard to its conflicts of laws rules.

d. The Parties intend for this Agreement to be an amendment of the LICR Agreement as and to the extent set forth herein.

e. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized representative of each Party.

#### [NO FURTHER TEXT ON THIS PAGE]

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**IN WITNESS WHEREOF,** the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

# RECEPTA BIOPHARMA, S.A.

By:	/s/ José Fernando Perez
Name:	José Fernando Perez
Title:	President

# LUDWIG INSTITUTE FOR CANCER RESEARCH

By:	/s/ Edward A. McDermott, Jr.
Name:	Edward A. McDermott, Jr.
Title:	President

# MERSANA THERAPEUTICS, INC.

By:	/s/ Eva M. Jack
Name:	Eva M. Jack
Title:	Chief Business Officer

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# <u>Exhibit A</u>

# **Sublicense Agreement**

[See attached]

### Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002

I, Anna Protopapas, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Mersana Therapeutics, 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(s) 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(s) 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

Mersana Therapeutics, Inc.

Dated: May 9, 2023

By:

/s/ Anna Protopapas

Anna Protopapas President and Chief Executive Officer (Principal Executive Officer)

# Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002

I, Brian DeSchuytner, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Mersana Therapeutics, 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(s) 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(s) 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.

Mersana Therapeutics, Inc.

Dated: May 9, 2023

By:

/s/ Brian DeSchuytner Brian DeSchuytner Chief Financial Officer (Principal Financial Officer)

#### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Mersana Therapeutics, 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 of the company, hereby certifies, pursuant to Section 1350 of Chapter 63 of Title 18, United States Code, that to the best of her or his 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 9, 2023

/s/ Anna Protopapas

Anna Protopapas President and Chief Executive Officer (Principal Executive Officer)

Dated: May 9, 2023

/s/ Brian DeSchuytner

Brian DeSchuytner Chief Financial Officer (Principal Financial Officer)