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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022.

OR

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

For the transition period from to

Commission file number 001-38129

Mersana Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**04-3562403**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
840 Memorial Drive Cambridge, MA	**02139**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code **(617) 498-0020**

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

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

NONE

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

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

As of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates was $403,311,770, based on the last reported sale price of such stock on the Nasdaq Global Select Market as of such date.

As of February 24, 2023, the registrant had 108,026,074 shares of common stock outstanding at a par value $0.0001 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement that will be filed for the 2023 Annual Meeting of Stockholders within 120 days of the end of the registrant's fiscal year ended December 31, 2022 are incorporated by reference in Part III of this Annual Report on Form 10-K to the extent stated herein.

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REFERENCES TO MERSANA

Throughout this Annual Report on Form 10-K, 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.

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K 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, XMT-2056 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 Annual Report on Form 10-K, 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K.

RISK FACTOR 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 I, Item 1A, *Risk Factors* of this Annual Report on Form 10-K.

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.

INDUSTRY DATA

This Annual Report on Form 10-K 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.

NOTE REGARDING TRADEMARKS

We own various trademark registrations and applications, and unregistered trademarks, including our name and our corporate logo. All other trade names, trademarks and service marks of other companies appearing in this report are the property of their respective holders. Solely for convenience, the trademarks and trade names in this report may be referred to without the ®,™ or © symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PART I

ITEM 1. BUSINESS

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 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 good manufacturing practices supply chain established for our Dolaflexin, Dolasynthen and Immunosynthen platforms, 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.

We have assembled a management team with extensive and relevant experience, including specific ADC experience, from prior work at leading pharmaceutical companies such as Bayer AG; Bristol Myers Squibb, or BMS; Centocor Inc.; Constellation Pharmaceuticals, Inc.; Cubist Pharmaceuticals, Inc.; GlaxoSmithKline plc; Millennium Pharmaceuticals, Inc.; Momenta Pharmaceuticals, Inc.; Sanofi S.A.; Sunovion Pharmaceuticals Inc.; Takeda Pharmaceuticals, Inc., or Takeda; Tesaro, Inc. and Vertex Pharmaceuticals Inc. We are supported by our board of directors and scientific advisory board, who offer complementary experience in drug discovery, development and commercialization, business development and public company management. We believe that our highly differentiated platforms, together with the team we have assembled, position us well to discover and develop life-changing ADCs for patients fighting cancer.

Strategy

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 benefit to patients. We believe that executing against the following strategic objectives will help us achieve our goal:

- **Build UpRi (upifitamab rilsodotin) into a Foundational Medicine in Ovarian Cancer.** 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 patients with 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 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, we believe that 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-treated to those in earlier lines of treatment for the disease. The European Commission granted orphan medicinal product designation to UpRi for the treatment of ovarian cancer in December 2022.

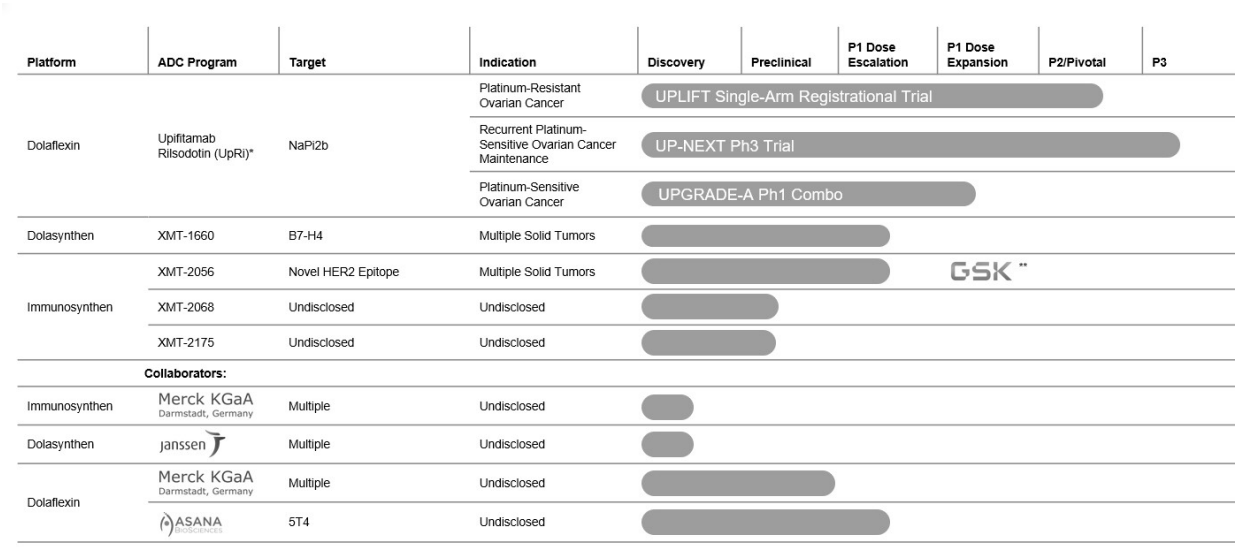
- **Build Out Our Pipeline of Highly Impactful Cancer Medicines.** We are investigating two additional ADC product candidates, XMT-1660 and XMT-2056, in Phase 1 clinical trials. XMT-1660 is a B7-H4-directed Dolasynthen ADC designed with a precise, target-optimized drug-to-antibody ratio, or DAR, of 6 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, and began dosing patients in August 2022. We expect to complete the dose escalation portion of this 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. The FDA granted orphan drug designation to XMT-2056 for the treatment of gastric cancer in May 2022.

- **Build Innovation and Scientific Leadership in ADCs.** We believe we are establishing a leading position in the field of ADCs by leveraging our existing platforms, Dolaflexin, Dolasynthen and Immunosynthen, and continuing to advance new innovations. Additionally, we are discovering new product candidates for ourselves and for collaborators that we believe hold the potential to be first- and best-in-class medicines for patients with cancer in areas of high unmet medical need. XMT-2068 and XMT-2175 are among our preclinical candidates that leverage our Immunosynthen platform.

- **Build Relationships with Strategic Collaborators.** We aim to leverage our technical expertise and experience with respect to our innovative and diversified platforms, to attract and cultivate strategic collaborations that facilitate our ability to bring differentiated product candidates to patients. We have established strategic research and development collaborations with Janssen Biotech, Inc., or Janssen, and Merck KGaA, Darmstadt, Germany, or Merck KGaA, and its affiliate Ares Trading S.A., or MRKDG, for the development and commercialization of additional ADC product candidates leveraging our proprietary Dolasynthen, Dolaflexin and Immunosynthen platform technologies against a limited number of targets selected by our collaborators. We have also granted GlaxoSmithKline Intellectual Property (No. 4) Limited, or GSK, an exclusive option for an exclusive global license to co-develop and commercialize XMT-2056. We believe the potential of our ADC technologies, 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.

- **Build Mersana with Top Talent.** We aim to attract and retain talented team members with deep experience in drug discovery, development, manufacturing, and commercialization as well as in general business and administration. Our team is driven by a shared passion to advance therapies that can make a significant difference in the lives of cancer patients. We will continue to cultivate the collaborative and passionate workplace culture and diverse workforce that has allowed us to advance this mission.

Our current pipeline is summarized in the chart below:



*NaPi2b antibody used in UpRi (formerly XMT-1536) is in-licensed from Recepta Biopharma. Recepta has rights to commercialize UpRi in Brazil.
**XMT-2056 is wholly owned by Mersana, with GSK having an exclusive global license option to co-develop and commercialize the candidate.

ADC Background

ADCs are a validated therapeutic modality in oncology with 11 products currently approved for use by the FDA, and over 100 being tested in clinical trials. We believe that the field has not yet realized its full potential due to the limitations of first-generation ADCs and a scarcity of clinically meaningful platform innovation.

First-generation ADCs were developed to deliver cytotoxic therapy specifically to neoplastic cells while sparing normal tissue. A cytotoxic ADC consists of three components: the antibody, the cytotoxic payload, and a linker to join the two. The antibody portion of the ADC achieves specific targeting by binding to an antigen that ideally has high expression on the surface of the tumor cells and low expression in healthy tissues. Once the antibody binds to the target, the ADC enters the cell, and the payload is typically released, killing the cell.

The payload, the DAR, the linker, and conjugation site of the linker with the antibody all can influence the overall efficacy and tolerability of ADCs. There has been limited innovation in these ADC components since the development of first-generation ADC platforms. We believe optimizing an ADC requires developing payload(s) with optimal properties, varying DAR for a specific target, and optimizing the conjugation site, all of which can contribute to the overall drug-like properties. We believe that our proprietary platforms improve upon first-generation ADC approaches in these aspects and have the potential to advance the field and improve patient outcomes.

Our Technologies and Platforms

We believe the development of ADCs is not a one-size-fits-all approach. In fact, a number of diverse factors impact the properties of an ADC, including payload, DAR, site of conjugation and homogeneity. For each target antigen, there may be an optimal combination of these factors. Our novel and highly differentiated platforms are designed to allow us to optimize these properties for a given target and develop ADCs that are designed to best address patient needs.

DolaLock Payload

We refer to the cytotoxic payload we use with our Dolaflexin and Dolasynthen platforms as our DolaLock payload. Our DolaLock payload is a highly potent, proprietary auristatin anti-tubulin agent selectively toxic to rapidly dividing cells. The DolaLock payload has been shown in *in vitro* and *in vivo* preclinical studies to control the bystander effect by locking the cytotoxic drug inside cells after allowing a short period of antigen-independent diffusion throughout the tumor. As the drug diffuses through neighboring cells, the DolaLock payload is metabolized to a form that is still highly potent but is designed to no longer be able to cross the cell membrane. We believe this "controlled bystander effect" may allow for enhanced safety and efficacy.

A common mechanism of resistance in cancer is the up-regulation of multi-drug resistance, or MDR, pumps, such as P-glycoproteins, or PgPs, which can actively pump drugs out of cancer cells to help them survive. Once metabolized, our DolaLock payload is not a substrate for PgPs, thereby avoiding this resistance mechanism. Our DolaLock payload, with its controlled bystander effect, is designed to enable the creation of ADCs that have the potential of being highly potent, well-tolerated and specifically targeted cancer therapies.

In addition, our proprietary auristatin payload has also been shown in preclinical studies to cause immunogenic cell death and to stimulate the immune system through dendritic cell activation. Because of this, we have observed synergy with immuno-oncology agents such as PD-1 inhibitors in preclinical models.

Dolaflexin Platform

The Dolaflexin platform was designed to increase the efficacy, safety and tolerability of ADCs. Dolaflexin utilizes our proprietary Fleximer polymer, a biodegradable, highly biocompatible, water-soluble polymer that is able to carry multiple payloads. Instead of direct conjugation to an antibody, payloads are attached through an optimized, cleavable linker to the Fleximer scaffold, which is then conjugated to the antibody through a non-cleavable linker. Our Fleximer polymer allows for an increased number of payloads carried by each ADC as compared to other ADC therapies and has demonstrated dramatically improved drug solubility and pharmacokinetics with higher DAR.

As a result, we believe Dolaflexin has the potential to offer the following benefits relative to first-generation ADCs:

- **Proprietary DolaLock Payload:** Dolaflexin is loaded with our proprietary auristatin cytotoxic drug, which is a highly potent anti-tubulin agent that is selectively toxic to rapidly dividing cells and has a controlled bystander effect.

- **Higher Drug-to-Antibody Ratio:** Historically, ADCs typically have been limited to a DAR of 3-4. The Dolaflexin platform can deliver ADCs with DAR of approximately 10, which has enabled ADCs created using this platform to demonstrate greater preclinical efficacy while also maintaining pharmacokinetics and drug-like properties.

- **Expanded Range of Addressable Tumor Targets:** The higher DAR enabled by Dolaflexin results in a higher amount of cytotoxic drug released into the tumor cell for every ADC that is internalized. As a result, we believe that Dolaflexin ADCs may demonstrate efficacy against tumor targets with lower levels of antigen expression that traditional ADCs have been unable to address.

We believe Dolaflexin's advantageous characteristics provide a substantial opportunity to address a broader range of cancers than first generation ADC-based approaches. Our lead clinical candidate, UpRi, is a Dolaflexin ADC that targets NaPi2b. We are currently evaluating UpRi in the UPLIFT, UP-NEXT and UPGRADE-A clinical trials.

Dolasynthen Platform

The Dolasynthen platform enables an iterative approach to designing customized ADCs for a given target while retaining the use of our proprietary DolaLock payload for a controlled bystander effect. Dolasynthen ADCs consist of a proprietary synthetic scaffold carrying an exact number of DolaLock payloads for precise control of DAR. The Dolasynthen scaffold is then

bioconjugated to the antibody in a site-specific manner. The Dolasynthen scaffold has been precisely designed to provide optimal water solubility, charge balance, linker stability and DAR, which together offer an opportunity for our ADCs to have superior physicochemical and pharmacokinetic properties relative to other ADC therapies.

We believe Dolasynthen ADCs have broad therapeutic potential as cancer therapies, and our preclinical data demonstrate the ability of the Dolasynthen platform to generate and identify the optimal ADC for a given target and antibody.

We believe that Dolasynthen offers the benefits of Dolaflexin, including the proprietary DolaLock payload, while also providing the following potential additional benefits relative to traditional ADC platforms:

- **Precise Control of DAR:** The optimal DAR may vary between different targets and antibodies. Dolasynthen uses a proprietary scaffold that allows for precise DARs between two and 24, enabling optimization of the DAR for specific antigens and antibodies.

- **Site-Specific Bioconjugation:** The site of scaffold bioconjugation to an antibody impacts the overall properties of that ADC. Dolasynthen enables site-specific bioconjugation, allowing further ADC optimization.

- **Homogenous ADC Development:** The DAR and antibody bioconjugation is consistent for each ADC developed with the Dolasynthen platform, allowing for consistent and precise drug delivery to targeted cancer cells. We believe this homogeneity may allow for enhanced safety, tolerability and efficacy.

- **Increased Hydrophilicity:** The precise optimization of the hydrophilic moiety on Dolasynthen ADCs allows for increased aqueous solubility and enhanced pharmacokinetic properties.

We are currently conducting a Phase 1 clinical trial of XMT-1660, our B7-H4-targeted Dolasynthen ADC.

ImmunoLock Payload

We refer to the STING agonist that is used as the payload with our Immunosynthen platform as our ImmunoLock Payload. It was designed to have very low cell permeability in order to control delivery and localization of its innate immune-activating effect. STING is a well-studied innate immune pathway capable of inducing anti-tumor immune activity. Our preclinical data show that the anti-tumor activity of Immunosynthen ADCs carrying the ImmunoLock payload is driven by the targeted activation of the STING pathway in tumor-resident immune cells and in tumor cells, in a target-dependent manner. STING pathway activation in both cell types within the tumor provides the potential for enhanced anti-tumor activity with a STING-agonist ADC compared to other innate immune approaches, such as toll-like receptor, or TLR, agonists, that activate only the immune cells and are not capable of activating the tumor cells.

Immunosynthen Platform

Immunosynthen is our novel immunostimulatory ADC platform designed to take ADCs beyond the delivery of traditional cytotoxic payloads by enabling the targeted stimulation of the innate immune system. Through the tumor-targeted delivery of a novel STING agonist, ADCs created with our Immunosynthen platform have the potential to address the challenges of efficacy, delivery and tolerability posed by intratumoral or intravenous injection of free (unconjugated) STING agonists. We have generated preclinical data across multiple, diverse targets by creating Immunosynthen ADCs based on a variety of antibodies directed to those targets and evaluating them in a range of tumor models. In each case, we have demonstrated significant anti-tumor activity *in vivo* (including complete tumor regressions) after a single low, well-tolerated dose. Additional characterization has demonstrated increased cytokine expression and immune cell infiltration in the tumor microenvironment, as well as the induction of immunological memory. We have demonstrated tolerability and characterized the favorable pharmacokinetic profile of Immunosynthen ADCs in non-human primates after multiple intravenous doses and at exposures significantly higher than those required for robust efficacy in mice.

Immunosynthen ADCs have been designed to overcome the limitations of free STING agonists and to offer a highly differentiated approach from other innate immune activators due to the following:

- **Non-Cell Permeable STING Agonist ImmunoLock Payload:** Our novel and proprietary payload has very low cell permeability, remaining in the cell to which it is delivered by the antibody, where it can exert its effect.

- **Enhanced Pharmacokinetic Properties:** The prolonged pharmacokinetics of ADCs and active transport into tumor cells and tumor-resident immune cells can overcome pharmacokinetic and permeability issues of the free agonists, resulting in more robust and sustained activation of the innate immune response in the tumor.

- **Targeted Activation in Two Cell Types:** Because STING, unlike other innate immune pathways, can be activated in tumor cells and tumor-resident immune cells, target-dependent delivery can result in innate immune activation of both cell types, providing potent and robust anti-tumor responses and the induction of immunological memory.

Together these features have the potential to improve the applicable therapeutic index by selectively activating the innate immune system in the tumor environment and minimizing activation in other tissues. We are building a pipeline of Immunosynthen ADC candidates applicable to a broad range of clinical indications. In January 2023, we initiated a Phase 1 clinical trial of our first Immunosynthen ADC product candidate, XMT-2056, which targets a novel epitope of HER2.

Our product candidates

We are leveraging our platforms to develop a robust pipeline of product candidates that have the potential to become clinically meaningful cancer therapies. Our pipeline strategy focuses on targets that have been biologically validated (either through ADCs or other modalities), where the advantages of our platforms may lead to clinically superior therapeutic benefits and where we have the potential to achieve first-in-class status by pursuing fast-to-market development strategies. Our lead product candidate, UpRi, is currently being evaluated in three clinical trials: UPLIFT, UP-NEXT and UPGRADE-A. We are also advancing XMT-1660, a B7-H4-targeted Dolasynthen ADC, and XMT-2056, our first Immunosynthen ADC targeting a novel epitope of HER2, both of which are currently in Phase 1 clinical trials. In addition, our collaborators have multiple ADC product candidates in various stages of development. In May 2022, we decided to discontinue development of XMT-1592, a Dolasynthen ADC targeting NaPi2b that had been in a Phase 1 dose exploration trial in patients with ovarian cancer and non-small cell lung cancer, or NSCLC, and we closed this company-sponsored trial in September 2022.

UpRi: our NaPi2b-targeted Dolaflexin ADC

UpRi, a first-in-class ADC targeting the sodium-dependent phosphate transport protein NaPi2b, utilizes the Dolaflexin platform to deliver about 10 DolaLock payload molecules per antibody. We believe the NaPi2b antigen is broadly expressed in ovarian cancer and other cancers with limited expression in normal tissue. NaPi2b is a member of the SLC34 family of sodium-dependent transporters and plays an important role in maintaining phosphate homeostasis. We initiated a Phase 1/2 clinical trial of UpRi in December 2017 with the primary objectives of determining the recommended Phase 2 dose and characterizing UpRi's efficacy, safety and tolerability. Our secondary objective was to assess the potential correlation of NaPi2b biomarker expression and efficacy. The dose escalation portion of the trial established a dose of 43 mg/m^2, up to a maximum of approximately 80 mg, as the maximum tolerated dose. The expansion portion of the trial evaluated two dose levels, 36 mg/m^2 and 43 mg/m^2, up to a maximum of approximately 80 mg.

There are currently no tests approved by the FDA to measure NaPi2b expression on tumor cells. While our initial clinical trials have not prospectively identified patients with NaPi2b-expressing tumors, our development plan for UpRi includes the development of a proprietary immunohistochemistry assay to measure NaPi2b expression in tumors. Based on our retrospective evaluation of tumors collected in the dose escalation and expansion portions of our initial UpRi Phase 1 trial, our evaluation of patient tissue bank materials and other published data we believe that high NaPi2b expression is present in at least a majority of ovarian cancer patients. We intend to continue developing our assay in order to confirm our estimates of the prevalence of NaPi2b expression in our target patient populations while evaluating the correlation of those expression levels with the efficacy observed in such patients. We are currently collaborating with a third party to create and obtain regulatory approval for our assay as a commercial companion or complementary diagnostic, and we expect that the third party would seek such approval simultaneously with our submission of a BLA, if any, for UpRi around the end of 2023. We are using and expect to continue to use the assay to evaluate Tumor Proportion Score of greater than or equal to 75%, TPS75, to identify patients with tumors that have high NaPi2b tumor expression and to help us enrich our data analyses based on biomarker expression. We refer to patients with cancers with TPS75 as "NaPi2b positive."

Over the course of 2020, we presented early Phase 1 UpRi clinical data, including presentations at the American Society of Clinical Oncology and the European Society for Medical Oncology and in company presentations to investors. These data were from the dose escalation and expansion portions of our UpRi Phase 1 trial, and they demonstrated encouraging clinical activity in heavily pretreated patients with a safety profile differentiated from those of first-generation ADCs. In August 2020, the FDA 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. In January 2021, September 2021 and March 2022, we provided interim clinical data updates from our expansion cohort. The interim data presented in September 2021 and March 2022 was based on approximately 100

ovarian cancer patients. All of the data from these patients were from our ongoing Phase 1/2 clinical trial. These data supported UpRi's clinically meaningful activity in heavily pretreated ovarian cancer patients with an ORR of approximately 34%, including complete responses, in evaluable patients with NaPi2b positive tumors. The data also showed that UpRi was generally well tolerated without the severe toxicities commonly seen with other ADCs such as neutropenia, ocular toxicities, or peripheral neuropathy. The most common grade 3 or higher adverse events reported in this heavily pretreated trial population included fatigue and transiently increased aspartate aminotransferase. Other adverse events of clinical interest included infrequent, generally low-grade pneumonitis that generally resolves with dose reduction, delay, discontinuation and treatment with steroids. Based on these safety and efficacy data and our population pharmacokinetics analyses of the overall group of approximately 200 patients administered UpRi as of the data cut off, we determined that the Phase 2 recommended dose of UpRi is 36 mg/m^2, up to a total dose of approximately 80 mg. This is the dose that we are currently evaluating in UPLIFT.

In April 2021, we initiated UPLIFT to enroll patients with platinum-resistant ovarian cancer who had been treated with one to four prior lines of therapy, without regard to NaPi2b expression. In this trial, we are seeking to confirm the potentially predictive role of the Napi2b biomarker retrospectively using our novel diagnostic assay to identify NaPi2b positive patients. Patients who had been treated with three to four prior lines of therapy were able to enroll without prior bevacizumab treatment, accommodating differences in bevacizumab use in early disease. Additionally, patients who had experienced grade 1 or grade 2 neuropathy on previous treatments were eligible to enroll in UPLIFT. The primary endpoint is ORR in the NaPi2b positive patient population, and the secondary endpoints are ORR in the overall population, duration of response and safety. In October 2022, we completed the enrollment of approximately 270 patients in UPLIFT at sites in the United States, Europe and Australia. We expect to announce top-line data from UPLIFT in mid-2023 following the major oncology conferences scheduled for June. If we achieve positive results from UPLIFT, we believe that the trial may enable us to submit a BLA for UpRi for the treatment of patients with platinum-resistant ovarian cancer with one to four prior lines of therapy under the FDA's accelerated approval pathway around the end of 2023.

In July 2021, we initiated UPGRADE-A, a Phase I open-label clinical trial in which we are evaluating the combination of UpRi and carboplatin, a standard platinum chemotherapy used to treat patients with platinum-sensitive ovarian cancer, in patients with platinum-sensitive high-grade serous ovarian cancer following one to three prior lines of treatment. Patients in the trial receive combination treatment every four weeks for six cycles followed by UpRi as a single-agent maintenance therapy. While patients in the trial are not preselected for NaPi2b-positive status, we are conducting a retrospective assessment of expression. We have completed the dose escalation portion of the trial, which investigated carboplatin combined with UpRi doses up to 36 mg/m2. There were no dose-limiting toxicities at any dose level. In January 2023, we initiated the dose expansion portion of UPGRADE-A, in which we are investigating a 30mg/m^2 dose, up to a maximum of 66 mg, of UpRi. We expect to report interim data from UPGRADE-A in the second half of 2023. We believe data from UPGRADE-A will inform further development of UpRi both in combination with carboplatin and in combination with other therapies used in patients with platinum-sensitive ovarian cancer, which we may explore in a series of UPGRADE trials.

We continue to enroll patients in our UP-NEXT clinical trial, for which we initiated patient dosing in late 2022. The design of UP-NEXT was informed by discussions with the FDA and the Committee for Medicinal Products for Human Use, or CHMP. UP-NEXT is enrolling recurrent platinum-sensitive ovarian cancer patients who have achieved an objective response or stable disease after platinum therapy. Eligible patients with BRCA mutation must have received prior treatment with poly-adenosine diphosphate ribose polymerase, or PARP, inhibitor therapy. Additionally, eligible patients must have NaPi2b positive tumor expression. Due to the lack of a standard of care for patients in the recurrent ovarian cancer maintenance setting, the trial is randomized against placebo and is investigating a 30 mg/m^2 dose, up to a maximum of 66 mg, of UpRi. We believe that if the data from the trial is positive, UP-NEXT could serve as a post-approval confirmatory trial in the United States, support potential approvals outside of the United States and support the expansion of UpRi into earlier lines of therapy.

XMT-1660: our B7-H4-targeted Dolasynthen ADC candidate

XMT-1660 is our B7-H4-targeted ADC created with our Dolasynthen platform and equipped with our DolaLock payload designed for differentiated tolerability without severe neutropenia, peripheral neuropathy or ocular toxicities associated with other anti-tubulin payloads. We believe the expression profile of B7-H4, is well suited for our unique DolaLock payload. B7-H4 can be expressed on tumor cells and on immunosuppressive tumor associated macrophages, or TAMs, which may lead to additional processing of the ADC and more payload in the tumor environment. We believe DolaLock's direct cytotoxic effect, as well as its immunostimulatory effect through immunogenic cell death and dendritic cell activation, are well suited to the biology of the B7-H4 target. We have generated favorable preclinical efficacy data and non-human primate tolerability data with Dolasynthen ADCs targeting B7-H4 with precise DARs of 2 and 6. We selected the DAR6 variant based on these preclinical data, as well as a comparison to preclinical data generated with a B7-H4 Dolaflexin ADC with a DAR of approximately 12. We believe that targeting B7-H4 with XMT-1660 provides significant opportunities for development in areas of high unmet need. We are currently investigating XMT-1660 in a multicenter Phase 1 clinical trial in patients with breast, endometrial and ovarian cancers.

XMT-2056: our First Immunosynthen ADC candidate

XMT-2056 is our first Immunosynthen STING-agonist ADC. As described above, the therapeutic rationale of an Immunosynthen ADC is to selectively deliver the STING agonist to tumor cells and tumor-resident immune cells in a target-dependent manner while avoiding delivery to healthy tissues. XMT-2056 is designed to offer a differentiated and complementary therapeutic approach to the treatment of HER2-expressing tumors. XMT-2056 targets a novel HER2 epitope that is distinct from the epitopes targeted by trastuzumab or pertuzumab, providing an opportunity for development as a monotherapy as well as in combination with well-established or investigational anti-HER2 agents. In preclinical studies, XMT-2056 was generally well-tolerated in non-human primate studies with no adverse findings in clinical pathology or histopathology after repeat doses as high as 36 mg/kg. In January 2023, we initiated a multicenter Phase 1 open-label clinical trial of XMT-2056 in patients with advanced/recurrent solid tumors expressing HER2, including breast, gastric, colorectal and NSCLC.

Ovarian cancer unmet need and epidemiology

According to the World Cancer Research Fund International, in 2020, the incidence of ovarian cancer worldwide was approximately 314,000, with the disease causing an estimated 207,000 deaths. With a U.S. incidence of approximately 20,000 and mortality of 13,000 in 2022 according to the National Cancer Institute Surveillance, Epidemiology and End Results Program, ovarian cancer was the second most common gynecologic malignancy and the most common cause of gynecologic cancer death in the United States. Diagnosis is made histologically, and evaluation is commonly performed following surgical removal of an ovary or fallopian tube or biopsies of the peritoneum. The ovarian cancer standard of care is characterized by initial surgery followed by platinum-containing chemotherapy followed by either observation or maintenance treatment. Approximately 80% of ovarian cancer patients typically relapse following initial treatment. Subsequent treatment depends on the duration of response to initial platinum treatment. Ovarian cancer patients who progress within six months of completion of platinum-based therapy are considered to have platinum-resistant disease. Unmet medical need is significant for patients with platinum-resistant ovarian cancer as treatment options are mainly limited to single-agent chemotherapies such as pegylated liposomal doxorubicin, topotecan or paclitaxel. Multiple Phase 3 trials of single agent chemotherapies in patients with platinum-resistant disease and one to three prior therapies have exhibited an overall response rate of 4-12% and median progression-free survival of 3-4 months. In 2022, mirvetuximab soravtansine was approved under an accelerated approval pathway in the United States for patients with FRα positive, platinum-resistant ovarian cancer who have received one to three prior systemic treatment regimens. Only a minority of ovarian cancer patients are FRα positive, and the unmet need remains high for the majority of platinum-resistant ovarian cancer patients. In addition, mirvetuximab soravtansine is associated with significant toxicities, including a boxed warning for ocular toxicity.

With targeted agents approved in platinum-resistant disease increasingly being prescribed in earlier lines of therapy, the unmet need in later lines is expected to remain severe. Bevacizumab in combination with chemotherapy is indicated in the United States to treat a subset of platinum-resistant ovarian cancer patients with no more than two prior therapies, but it is not always well-tolerated and has not shown an overall survival benefit. Use of bevacizumab in combination with platinum-containing chemotherapy in the frontline and platinum-sensitive recurrent settings means an increasing number of platinum-resistant patients are pre-treated with bevacizumab. Previously, PARP inhibitors had been approved for heavily pretreated ovarian cancer including platinum-resistant disease. Recently, the indications for PARP inhibitors in the United States were changed so that they are no longer approved for use in platinum-resistant ovarian cancer. They are currently approved only for use as maintenance treatment in the frontline or platinum-sensitive ovarian cancer setting, in patients who are responding to platinum-based chemotherapy. In addition, they are increasingly restricted to use in a subset of patients with cancers harboring BRCA1 and BRCA2 mutations in the recurrent setting.

Breast cancer unmet need and epidemiology

Worldwide, breast cancer was the most common cancer, with an incidence of approximately 2.3 million and estimated 685,000 deaths in 2020. The U.S. incidence was approximately 288,000 new cases with approximately 43,250 deaths in 2022. While patients with localized disease typically have a relatively good prognosis, the five-year survival of patients with distant metastasis is only 29%. There are four main female breast cancer subtypes, which are, in order of prevalence: Hormone Receptor, or HR, positive (HR+)/HER2 negative (HER2-), which is referred to as Luminal A; HR negative (HR-)/HER2-, which is referred to as Triple Negative; HR+/HER2 positive (HER+), which is referred to as Luminal B; and HR-/HER2+, which is referred to as HER2-enriched. This categorization of patients is being revisited given the approval of trastuzumab deruxtecan for the treatment of HER2-low metastatic breast cancer in 2022. Treatment choice is driven by both subtype and stage of disease. Surgical resection offers the best opportunity for long-term survival and cure in patients with resectable early-stage disease. Some patients receive radiation therapy and/or systemic therapy post-surgery, with treatment choice driven by cancer subtype.

Systemic therapy is the mainstay of treatment for metastatic breast cancer. Once again, the treatment choice is determined by cancer subtype and by what treatments patients have received previously. The primary treatment option for patients who are HR+ is endocrine therapy, including aromatase inhibitors. Patients who are HER2+ are usually treated with HER2-targeting agents such as trastuzumab and pertuzumab, among others. In 2022, the HER2 targeting therapy trastuzumab deruxtecan was approved for the treatment of patients with HER2-low metastatic breast cancer. Other targeted agents that are used in metastatic breast cancer include CDK4/6 inhibitors, mTOR inhibitors, PARP inhibitors, phosphoinositide 3-kinase, or PI3K, inhibitors, immunotherapy and ADCs. Patients can also receive chemotherapies, alone or in combination with other agents. In addition, a number of new therapeutic options are under clinical investigation. Despite the availability of these treatment options, outcomes in metastatic breast cancer continue to be poor, and new treatments that improve survival and quality of life are urgently needed.

Strategic Collaborations

We view business development as a core pillar of our overall corporate strategy, and our platforms and product candidates allow us to consider multiple potential types of strategic collaborations. We believe that our ADC platforms have broad applicability across a number of targets, allowing us to consider collaborations in which a partner provides proprietary antibodies for a select number of targets and we utilize our platforms to discover novel ADC product candidates. Under these collaboration agreements, we own the rights to any improvements to our ADC platform(s). For instance, we have entered into two discovery collaborations with Merck KGaA and a separate discovery collaboration with Janssen. We believe platform-based collaborations allow us to leverage the potential of our platforms, provide near-term capital and help us potentially bring important new therapeutic options to patients.

We also have internally developed ADC product candidates that allow us to consider arrangements in which a collaborator may assume certain preclinical, clinical and/or commercial responsibilities. For instance, we have granted GSK an exclusive option for an exclusive global license to co-develop and commercialize XMT-2056. We believe product-focused collaborations could provide near-term funding, allow us to advance and broaden preclinical, clinical or commercial development efforts beyond those we could independently, and potentially bring new therapeutic options to patients.

2022 Merck KGaA Collaboration

In December 2022, we entered into a collaboration and commercial license agreement with Ares Trading S.A., or MRKDG, a wholly owned subsidiary of Merck KGaA, or the 2022 Merck KGaA Agreement. Pursuant to the 2022 Merck KGaA Agreement, we will grant MRKDG an exclusive license to use our proprietary technology to develop, manufacture and commercialize Immunosynthen ADCs directed to up to two specific target antigens, or the Designated Targets, selected by MRKDG within a certain period following the effectiveness of the 2022 Merck KGaA Agreement. MRKDG has already selected the first Designated Target under the 2022 Merck KGaA Agreement.

Under the terms of the 2022 Merck KGaA Agreement, the parties will conduct up to two research programs. Each research program will involve activities related to Immunosynthen ADCs for a selected Target (with each such ADC developed under the 2022 Merck KGaA Agreement being a Licensed ADC) until the submission of an investigational new drug application, or IND, (or foreign equivalents) for a Licensed ADC directed at such Designated Target, or each an MRKDG Licensed Product, or until the earlier expiration of the defined research period. Each research program will follow a research plan agreed between the parties. For each Designated Target, MRKDG is responsible for providing up to a specified number of antibodies against such Designated Target, and we are responsible for conjugating such antibodies using our Immunosynthen platform to create Licensed ADCs. Each party will be responsible for their own costs under the research programs. In addition, we will be responsible for certain chemistry, manufacturing and controls development and certain manufacturing activities for the Licensed ADCs, up to and including manufacturing of drug substance for Licensed ADCs to be used in certain preclinical studies and clinical trials, in each case at MRKDG's expense, some of which will be prepaid by MRKDG. Except as provided above, MRKDG is solely responsible for in vitro and in vivo characterization of any Licensed ADCs, other preclinical work, and all clinical development and potential commercialization activities relating to any resulting MRKDG Licensed Products.

Under the terms of the 2022 Merck KGaA Agreement, we received an upfront payment of $30.0 million in February 2023. Certain development and regulatory milestones will be payable by MRKDG to us for the research programs, including upon certain discovery milestones, initiation of certain clinical trials, and regulatory approval of MRKDG Licensed Products in certain geographies, with an aggregate total of up to $200 million in the event MRKDG advances MRKDG Licensed Products directed to both Designated Targets to regulatory approval.

In the event the commercialization of the MRKDG Licensed Product results in commercial sales, commercial milestones will be payable by MRKDG to us for each program upon the achievement of specified aggregate sales thresholds for an MRKDG Licensed Product for the applicable Designated Target, with an aggregate total of up to $600 million in the event MRKDG Licensed Products directed to both Designated Targets are commercialized by MRKDG. In addition, we are eligible to receive

tiered royalties at percentages ranging from the single digits to the low double digits on future net sales of MRKDG Licensed Products.

MRKDG's royalty obligations continue with respect to each country and each MRKDG Licensed Product until the latest of (i) the date on which such MRKDG Licensed Product is no longer covered by certain intellectual property rights in such country, (ii) the 10th anniversary of the first commercial sale of such MRKDG Licensed Product in such country and (iii) the expiration of marketing or data exclusivity for such MRKDG Licensed Product in such country.

Under the terms of the 2022 Merck KGaA Agreement, subject to certain exceptions and for an agreed period of time, we will not, either ourselves or through third parties, research, develop, manufacture or commercialize other ADCs utilizing our Immunosynthen platform that are directed to the Designated Targets. We and MRKDG will form a joint research committee, joint manufacturing committee, and joint intellectual property committee responsible for coordinating activities pursuant to the 2022 Merck KGaA Agreement.

Each party has the right to sublicense its rights under the 2022 Merck KGaA Agreement subject to certain conditions. The 2022 Merck KGaA Agreement will continue, unless earlier terminated, until the expiration of the last-to-expire royalty term for the last MRKDG Licensed Product or, if MRKDG does not advance any MRKDG Licensed Products, upon the expiration of the last-to-expire research program. MRKDG may, at its convenience, terminate the 2022 Merck KGaA Agreement in its entirety or on a Designated Target-by-Designated Target basis upon certain notice to us. Either we or MRKDG may terminate the 2022 Merck KGaA Agreement for the other party's insolvency or certain uncured breaches. In lieu of terminating the 2022 Merck KGaA Agreement, in the event MRKDG is entitled to terminate the 2022 Merck KGaA Agreement due to our uncured material breach, MRKDG may make an election, as its sole and exclusive remedy with respect to our applicable material breach of the 2022 Merck KGaA Agreement, to invoke a specified financial penalty impacting one or more future payments that may become payable to us following such uncured material breach. We may terminate the 2022 Merck KGaA Agreement with respect to a Designated Target in the event of certain failures by MRKDG to progress the corresponding research program. Additionally, we may terminate the 2022 Merck KGaA Agreement if MRKDG or any of its sublicensees or affiliates challenge, subject to certain exceptions, the validity, enforceability, of patentability of certain of our patents.

GSK Collaboration

In August 2022, we entered into a collaboration, option and license agreement with GSK, or the GSK Agreement, to provide GSK with an exclusive option to obtain an exclusive global license to co-develop and to commercialize products containing XMT-2056, or Licensed Products, exercisable within a specified time period, or the Option Period, after we deliver to GSK a data package, or the Option Data Package, 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, or HSR Clearance. Upon GSK's exercise of the Option following any applicable HSR Clearance, or the GSK Option Exercise, GSK is obligated to pay us an option exercise payment of $90.0 million.

We will lead research and development activities related to our XMT-2056 program prior to the GSK Option Exercise, if any, and we are obligated to use commercially reasonable efforts to generate the Option Data Package by an agreed time. Prior to the GSK Option Exercise, we will be responsible for the costs of manufacturing, research and early clinical development activities related to the XMT-2056 program.

Following the GSK Option Exercise, if any, GSK may elect to manufacture XMT-2056, and we and GSK will co-develop XMT-2056 in accordance with a joint development plan to be established by the parties and aimed at approval of Licensed Products in the United States and the European Union, with GSK being responsible for the majority of the development activities and costs. GSK will be responsible for all of the development costs aimed solely at gaining approval outside the United States and the European Union. Subject to certain exceptions set forth in the GSK Agreement, our aggregate share of U.S.- and E.U.-focused development costs pursuant to this cost-sharing arrangement is capped at a fixed amount, or the Mersana Development Cost Cap. We may also, subject to certain limitations provided in the GSK Agreement, elect to opt out of sharing in development costs for certain later-stage clinical trials of Licensed Products requested by GSK, subject to certain payment obligations in the event that data from any such later-stage clinical trial for which we have opted out of sharing in development costs results in certain marketing approvals for a Licensed Product in the United States or European Union, or a Deemed Buy-In Payment. Any development costs in excess of the Mersana Development Cost Cap, including any amounts arising from any Deemed Buy-In Payments, will be borne by GSK unless and until we exercise our Profit Share Election (as defined below). Development costs in excess of the Mersana Development Cost Cap will accrue interest at a variable rate equal to the prime rate plus a specified margin and will later either be repaid by us or offset against future regulatory and sales milestone or royalty payments that may become due to us. If we exercise our Profit Share Election, the Mersana Development Cost Cap will no longer apply, we must pay any then-outstanding excess plus accrued interest, and we shall continue to share in further U.S.- and E.U.-focused development costs.

Following the GSK Option Exercise, if any, we will have the option, during a specified time period following our receipt of certain later-stage clinical data and other data and information from GSK, to elect to receive (or bear) a specified share of U.S. profits (or losses) for any Licensed Products, or the Profit Share Election. Additionally, if we exercise our Profit Share Election, we may also simultaneously elect to co-promote any Licensed Products in the United States. The co-promotion arrangement may be terminated by either party, notwithstanding the continued effectiveness of the rest of the GSK Agreement, in the event of certain breaches by the other party, or by GSK, in the event of certain specified changes of control of Mersana. In addition, in the event of certain specified changes of control of Mersana, GSK can prohibit us from executing development activities that are initiated under the GSK Agreement following such change of control.

We received an upfront payment of $100 million from GSK for the Option. We are eligible to receive up to $30 million upon satisfaction of early clinical development milestones that may occur prior to the GSK Option Exercise. Subject to the GSK Option Exercise, if we do not exercise our Profit Share Election, we will be eligible to receive additional future clinical development and regulatory milestone payments of up to $592 million, commercial milestone payments of up to $652 million and tiered double-digit royalties up to the mid-twenty percent range on global sales of Licensed Products, if approved, subject to customary reductions. If we exercise our Profit Share Election, we will, in lieu of the foregoing regulatory and commercial milestone amounts, be eligible to receive reduced regulatory and commercial milestone payments and reduced royalty rates on sales outside of the United States. Additionally, whether or not we exercise our Profit Share Election, GSK will be responsible for certain milestone payments or royalties due to specified third parties with which we currently have agreements that relate to the XMT-2056 program.

GSK's royalty obligations continue with respect to each country and each Licensed Product until the latest of (i) the date on which such Licensed Product is no longer covered by certain intellectual property rights in such country, (ii) the 12th anniversary of the first commercial sale of such Licensed Product in such country and (iii) the expiration of regulatory exclusivity for such Licensed Product in such country.

Under the terms of the GSK Agreement, subject to certain exceptions and for an agreed period of time, we and GSK will not, either directly or through third parties, develop or commercialize other products or compounds that (a) comprise or contain an ADC that is conjugated with a STING agonist and (b) are directed to HER2. In addition, we have granted GSK a right of first negotiation for future ADCs that are conjugated to payloads other than STING agonists and directed to HER2. Following the GSK Option Exercise, if any, we and GSK will form a joint steering committee, joint development committee, joint manufacturing committee, joint commercialization committee, and financial working group responsible for coordinating all activities under the GSK Agreement, with GSK having final decision-making authority over most issues, subject to certain enumerated exceptions.

The GSK Agreement will terminate at the end of the Option Period if GSK does not exercise its Option. If GSK exercises its Option but we do not obtain HSR Clearance within specified time periods following the latest date on which the parties have made their respective applicable filings related to such HSR Clearance, each party has a right to terminate the GSK Agreement. In the event of the GSK Option Exercise, the GSK Agreement will continue in effect on a Licensed Product-by-Licensed Product and country-by-country basis until the expiration of the obligation to make payments under the GSK Agreement with respect to such Licensed Product in such country, unless earlier terminated by either party pursuant to the terms of the GSK Agreement. Either we or GSK may terminate the GSK Agreement for the other party's insolvency, and each party may terminate the GSK Agreement for certain uncured breaches by the other party. In lieu of terminating the GSK Agreement, in the event of certain uncured material breaches by us, GSK may make a one-time election, in addition to other contractual remedies available at law or in equity, to invoke a specified financial penalty impacting one or more future payments that may become payable to the Company following such uncured material breach. We may terminate GSK's license to certain of our patents if GSK or any of its sublicensees or affiliates challenge the validity, enforceability, of patentability of such patents. GSK may terminate the GSK Agreement for convenience upon certain notice to us.

Janssen Collaboration

In February 2022, we entered into a research collaboration and license agreement with Janssen, or the Janssen Agreement, pursuant to which we granted Janssen an exclusive license to use our proprietary Dolasynthen platform and other technology to develop, manufacture and commercialize antibody-drug conjugates directed to up to three targets selected by Janssen. Our responsibilities are to perform bioconjugation activities to create ADCs for Janssen based on antibodies provided by Janssen. We will also perform certain chemistry, manufacturing and controls development and early stage manufacturing activities for ADCs that Janssen progresses through development, up to and including the manufacturing of clinical drug substance, at Janssen's cost. Except with respect to this limited manufacturing, Janssen will be responsible for the further development, manufacturing and commercialization of the ADCs developed under the Janssen Agreement, including obtaining any necessary regulatory approvals, at Janssen's cost.

Under the terms of the Janssen Agreement, we received an upfront payment of $40 million. Certain development and regulatory milestones will also be payable by Janssen for the research programs, including upon certain discovery milestones, initiation of certain clinical trials, and regulatory approval of certain licensed products in certain geographies, with an aggregate total of up to $501 million in the event ADCs directed to all three targets are advanced by Janssen. In the event the ADCs developed by Janssen are commercialized, we are eligible to receive certain commercial milestones for each program upon the achievement of specified aggregate sales thresholds based on all ADCs for an applicable target, with an aggregate total of up to approximately $530 million in the event ADCs directed to all three targets are commercialized by Janssen. In addition, we are eligible to receive tiered royalties at percentages ranging from the mid-single digits to the low-double digits on future net sales of ADCs.

The Janssen Agreement will remain in effect, unless earlier terminated, until the expiration of the last-to-expire royalty term for the last ADC. Royalty term means on an ADC-by-ADC and country-by-country basis, the period commencing upon the first commercial sale of an ADC in such country and ending upon the latest to occur of: (a) the date of expiration of the last royalty-bearing patent claim with respect to such ADC in such country; (b) the expiration of regulatory exclusivity for such ADC in such country, if any; and (c) the tenth (10th) anniversary of the first commercial sale of such ADC in such country. Upon the expiration of the royalty term with respect to an ADC in a country, Janssen's license becomes a perpetual, irrevocable, non-exclusive, fully-paid and royalty-free right and license, with the right to grant sublicenses, under the relevant platform technology and our interest in any joint technology to develop, manufacture, commercialize and otherwise exploit such ADC in such country.

2014 Merck KGaA Collaboration

In June 2014, we entered into a collaboration and commercial license agreement with Merck KGaA, or the 2014 Merck KGaA Agreement, under which we formed a strategic relationship with Merck KGaA because of their expertise in oncology drug development. Under the 2014 Merck KGaA Agreement, we are responsible for generating ADC product candidates against Merck KGaA-selected target antigens. Merck KGaA received rights to select up to six target antigens, of which it has selected all six. 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. With respect to each target antigen selected by Merck KGaA, we granted Merck KGaA an exclusive, worldwide license under certain of our Fleximer ADC-related patents and know-how to develop, manufacture and commercialize ADC product candidates directed to such target antigen. Merck KGaA is then responsible for the further development and commercialization of these ADC product candidates. In addition, if Merck KGaA advances candidates, we are responsible for manufacturing these ADC product candidates for good laboratory practices toxicology studies and Phase 1 clinical trials at Merck KGaA's expense and Merck KGaA is responsible for all further manufacture of these ADC product candidates. Merck KGaA is required to pay its own costs in the development, commercialization and manufacture of these ADC product candidates and to reimburse us for our costs incurred in performing our research activities under this agreement.

Through December 31, 2022, we have received an upfront payment of $12 million and milestone payments of $3 million under the 2014 Merck KGaA Agreement. If products are successfully developed and commercialized against all six target antigens, we would be entitled to receive future development, regulatory and commercial milestones of up to $777 million. We are entitled to receive tiered royalties in the low- to mid-single digit percentages on net sales of products targeting Merck KGaA's target antigens during the applicable royalty term if products are successfully developed and commercialized by Merck KGaA under the 2014 Merck KGaA Agreement.

Unless earlier terminated, the 2014 Merck KGaA Agreement will expire upon the expiration of the last royalty term for a product under the agreement in all countries or, if Merck KGaA does not designate any ADC product candidates produced by us under the agreement as preclinical development candidates, upon the expiration of the last-to-expire research program. The royalty term means, on a product-by-product and country-by-country basis, the period commencing upon the first commercial sale of a product and ending upon the later to occur of: (i) the expiration of the last Mersana patent right that covers or claims the exploitation of such product in such country, or (ii) 10 years from the date of first commercial sale of such product in such country. Upon the expiration of each royalty term for each product on a country-by-country basis, Merck KGaA's exclusive license will convert to a perpetual, non-exclusive, royalty-free license with respect to such product in such country. Merck KGaA may terminate the 2014 Merck KGaA Agreement in its entirety or with respect to any target antigen for convenience upon 60 days' prior written notice. Each party may terminate the 2014 Merck KGaA Agreement in its entirety upon an uncured material breach of the agreement by the other party.

Asana Biosciences Collaboration

In March 2012, we entered into a collaboration agreement with Asana Biosciences, or Asana (by assignment from Endo Pharmaceuticals Inc.). Pursuant to the terms of this agreement, we used Asana's novel antibodies to develop novel ADCs using our Fleximer technology. Asana is responsible for product development, manufacturing and commercialization of any ADC products.

Strategic relationships to access antibodies and develop new platforms to progress our proprietary pipeline

Our focus is to progress our proprietary pipeline of ADCs. For this reason, we have collaborated with biotechnology companies that have the capability to generate high quality antibodies or that have existing antibodies that we can license for inclusion in our ADCs. We have also entered into license agreements with biotechnology companies that own certain patent rights and related know-how that enable us to develop new ADC platforms. These strategic relationships have facilitated the advancement of our proprietary pipeline.

Recepta license for the NaPi2b antibody

In July 2015, we entered into a license agreement with Recepta Biopharma S.A., or Recepta, a Brazilian biopharmaceutical company, licensing Recepta's NaPi2b antibody for use in UpRi and our former product candidate XMT-1592 and granting Recepta the exclusive right to commercialize UpRi and XMT-1592 in Brazil, which was amended in September 2021. We refer to this as the Recepta License. Under the Recepta License, Recepta granted us an exclusive license and sub-license with respect to certain patents licensed by Recepta from Ludwig Institute for Cancer Research and technology owned by Recepta to develop and exploit products containing Recepta's NaPi2b antibody, including UpRi and XMT-1592, worldwide for the diagnosis, prophylaxis and treatment of human cancer. We granted Recepta an exclusive license under our rights in such patents and technology and certain of our ADC-related patents and technology to commercialize any such products developed by us, including UpRi and XMT-1592, in Brazil. We are responsible for using commercially reasonable efforts to develop and commercialize products under the Recepta License globally, with at least one trial site in our Phase 3 clinical trials, and at our own expense in certain major markets. Recepta may conduct development activities in Brazil at its own expense after providing us the opportunity to first conduct such activities at Recepta's expense. If a product is successfully developed and commercialized by Recepta in Brazil, we will use diligent efforts to enter into an agreement for the supply of such products to Recepta for sale in Brazil.

Under the Recepta License, we paid Recepta an upfront payment of $1 million during the year ended December 31, 2015 and are obligated to pay Recepta up to $65.5 million in development, regulatory and commercial milestones and tiered royalties in the low-single digit percentages on net sales of products outside of Brazil until the expiration of the royalty term if products are successfully developed and commercialized. We have incurred and paid $4.0 million in development milestones. We are entitled to receive tiered royalties in the low- to mid-single digit percentages on net sales of products in Brazil until the expiration of the royalty term if products are successfully developed and commercialized. The royalty term means, on a product-by-product and country-by-country basis, the period ending upon the later of (i) with respect to products commercialized by Mersana, the expiration of the last-to-expire Recepta patent that covers the product in such country (including the term of any applicable supplementary protection certificate) or with respect to products commercialized by Recepta, the expiration of the last-to-expire Mersana patent that covers the product in Brazil (including the term of any applicable supplementary protection certificate) or (ii) 10 years from the date of first commercial sale of such product in such country. Upon the expiration of each royalty term in each country for each applicable product, the exclusive licenses granted to each party under the agreement will become fully-paid up and royalty-free. The Recepta License will remain in effect until otherwise terminated as set forth below. We may terminate the Recepta License for convenience in its entirety or on a country-by-country basis (except with respect to Brazil) or product-by-product basis upon 180 days' prior written notice for a termination in its entirety or upon 45 days' prior written notice for a termination in part. Each party may terminate the Recepta License in its entirety upon bankruptcy or similar proceedings of the other party, upon a patent challenge by the other party or upon an uncured material breach of the agreement by the other party. However, if such breach only relates to one country, the Recepta License may only be terminated with respect to such country.

Synaffix commercial license agreement

In January 2019, we entered into a commercial license agreement with Synaffix B.V., or Synaffix, which we amended and restated in November 2021 to expand our relationship with Synaffix and amended again in February 2022 in connection with our collaboration with Janssen. We refer to the amended and restated agreement as the Synaffix License. Under the Synaffix License, we have the right to develop, manufacture and commercialize ADCs directed to targets using Synaffix's proprietary site-specific conjugation technology for up to twelve targets. We have licensed five targets in connection with our development programs and collaborations, and we have the right to license up to six additional targets. We have paid $6.8 million related to

the Synaffix License, comprised of $4.0 million in reservation and license fees, $1.8 million in milestone payments and $1.0 million which may be applied to future reservation and license fees, as well as certain portions of potential future development milestones. We will be obligated to pay in the range of $48.0 million to $132.0 million for development, regulatory and commercial milestones.

Upon commencement of commercial sales of any ADC product directed to a licensed target, if any, we are required to pay to Synaffix tiered royalties in the low-single digit percentages on net sales of the respective products. The Synaffix License remains in effect on a country-by-country and licensed product-by-licensed product basis until the expiration of the last-to-expire valid claim in a patent licensed under the Synaffix License covering such product in such country. Upon the expiration of the Synaffix License for each licensed product in each country, the licenses granted to us for such product in such country will become fully paid-up and perpetual. We may terminate the Synaffix License in its entirety or on a licensed product-by-licensed product basis at any time. Either party may terminate the Synaffix License, subject to a specified notice and cure period, for a breach by the other party of a material provision of the agreement or upon an insolvency-related event experienced by the other party.

Manufacturing

We do not own or operate and currently have no plans to establish any current good manufacturing practices, or cGMP, compliant manufacturing facilities. We currently rely, and expect to continue to rely, on external Contract Manufacturing Organizations, or CMOs, for the manufacture of product to support our activities through regulatory approval and commercial manufacturing. We have personnel with pharmaceutical development and manufacturing experience who are responsible for the relationships with our CMOs. In the future, we expect to use these CMOs to manufacture commercial supply of our products, which will require these CMOs to increase scale of production. We do not currently have qualified alternate suppliers in the event the current CMOs that we utilize are unable to scale production for commercial manufacturing. The Dolaflexin, Dolasynthen and Immunosynthen manufacturing processes involve readily available starting materials and use unit operations that are well-precedented in the field of chemical/pharmaceutical production. The current UpRi supply chain utilizes the same vendors that we could use for commercialization. The current supply chains for XMT-1660 and XMT-2056 have several vendors in common, and based on what we know today, we believe we could use these vendors or would be able to identify and contract with other vendors on commercially reasonable terms for commercialization purposes.

Government regulation

The research, development, testing, manufacture, quality control, packaging, labeling, storage, record-keeping, distribution, import, export, promotion, advertising, marketing, sale, pricing and reimbursement of drug and biologic products are extensively regulated by governmental authorities in the United States and other countries. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory requirements, both pre-approval and post-approval, require the expenditure of substantial time and financial resources. The regulatory requirements applicable to biological product development, approval and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by the agencies in ways that may have a significant impact on our business.

U.S. government regulation of biological products

In the United States, the FDA licenses biological products, or biologics, under the Public Health Service Act, or the PHSA, and regulates such products under the Food, Drug and Cosmetic Act, or FDCA. A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products, and for their regulatory approval, is typically referred to as a sponsor. A sponsor seeking approval to market and distribute a new biologic in the United States must satisfactorily complete each of the following steps:

- completion of preclinical laboratory tests, animal studies and formulation studies according to good laboratory practices, or GLP, regulations or other applicable regulations;
- design of a clinical protocol and submission to the FDA of an IND, which must become effective before human clinical trials may begin and must be updated when certain changes are made;
- approval by an independent institutional review board, or IRB, or ethics committee representing each clinical trial site before each clinical trial may be initiated;

- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practices, or GCPs, and other clinical-trial related regulations to evaluate the safety and efficacy of the investigational product for each proposed indication;

- preparation and submission to the FDA of a BLA requesting marketing approval for one or more proposed indications, including payment of application user fees;

- review of the BLA by an FDA advisory committee, where applicable;

- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the biologic is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;

- satisfactory completion of any FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data submitted in support of the BLA; and

- FDA review and approval of the BLA, which may be subject to additional post- approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and any post- approval clinical trials required by the FDA.

Preclinical studies

Before a sponsor begins testing a product candidate with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as other studies to evaluate, among other things, the toxicity of the product candidate. These studies are often referred to as IND-enabling studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including GLP regulations and standards and the United States Department of Agriculture's Animal Welfare Act, if applicable. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

The IND and IRB processes

An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. An IND must be secured prior to interstate shipment and administration of any product candidate that is not the subject of an approved BLA. In support of a request for an IND, sponsors must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial may proceed. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a partial clinical hold might state that a specific protocol or part of a protocol may not proceed, while other parts of a protocol or other protocols may do so. No more than 30 days after the imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following the issuance of a clinical hold or partial clinical hold, a clinical investigation may only resume once the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed or recommence. Occasionally, clinical holds are imposed due to manufacturing issues that may present safety issues for the clinical trial subjects.

A sponsor may choose, but is not required, to conduct a foreign clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all IND requirements must be met unless waived by the FDA. When a foreign clinical trial is not conducted under an IND, the sponsor must ensure that the trial complies with certain regulatory requirements of the FDA in order to use the trial data as support for an IND or application for marketing approval. Specifically, the trials must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee, or IEC, and seeking and receiving informed consent from subjects. GCP requirements encompass both ethical and data integrity standards for clinical trials. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and re-approve the trial at least annually. The IRB, which must operate in compliance with FDA regulations, must review and approve, among other things, the clinical trial protocol and informed consent information to be provided to trial subjects and must monitor the trial until completed. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board, or DSMB. This group provides authorization as to whether or not a trial may move forward at designated checkpoints based on review of available data from the trial, to which only the DSMB maintains access. Suspension or termination of development during any phase of a clinical trial can occur if the DSMB determines that the participants or patients are being exposed to an unacceptable health risk.

Expanded access

Expanded access, sometimes called "compassionate use," is the use of investigational new products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational products for patients who may benefit from investigational therapies. FDA regulations allow access to investigational products under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the investigational product under a treatment protocol or Treatment IND Application.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational product for the requested treatment will not interfere with the initiation, conduct or completion of clinical investigations that could support marketing approval of the product or otherwise compromise the potential development of the product.

There is no obligation for a sponsor to make its investigational products available for expanded access; however, as required by amendments to the FDCA included in the 21st Century Cures Act, or the Cures Act, passed in 2016, if a sponsor has a policy regarding how it responds to expanded access requests with respect to product candidates in development to treat serious diseases or conditions, it must make that policy publicly available. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 trial for a covered investigational product; or 15 days after the investigational product receives designation from the FDA as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

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

Human clinical trials

Clinical trials involve the administration of the investigational product candidate to human subjects under the supervision of a qualified investigator in accordance with GCP requirements which include, among other things, the requirement that all research subjects provide their informed consent in writing before they participate in any clinical trial. Clinical trials are conducted under written clinical trial protocols detailing, among other things, the objectives of the trial, inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol, and any subsequent material amendment to the protocol, must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. The FDA has issued regulations authorizing a sponsor to transfer certain responsibilities for the conduct of a clinical trial to a contract research organization, or CRO.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap or be combined. Additional trials may also be required after approval.

Phase 1 clinical trials are initially conducted in a limited population, which may be healthy volunteers or subjects with the target disease, to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or in patients. During Phase 1 clinical trials, information about the product candidate's pharmacokinetics and pharmacological effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials. Phase 2 clinical trials are typically well-controlled and closely monitored.

Phase 3 clinical trials proceed if the Phase 2 clinical trials demonstrate that a dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken using a larger patient population to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple geographically dispersed clinical trial sites. A well-controlled, statistically robust Phase 3 clinical trial may be designed to deliver the data that regulatory authorities will use to decide whether or not to approve, and, if approved, how to appropriately label a new biologic product. Such Phase 3 clinical trials are referred to as "pivotal" trials.

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the trial will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. Moreover, as noted above, a pivotal trial is a clinical trial that is believed to satisfy FDA requirements for the evaluation of a product candidate's safety and efficacy such that it can be used, alone or with other pivotal or non-pivotal trials, to support regulatory approval. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

In some cases, the FDA may approve a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials, typically referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of a larger number of patients in the intended treatment group. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials, such as to verify clinical benefit in the case of products approved under accelerated approval regulations. Failure to exhibit due diligence with regard to conducting mandatory Phase 4 clinical trials could result in withdrawal of FDA approval for products. In December 2022, with the passage of the Food and Drug Omnibus Reform Act, or 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. Specifically, action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In addition to these requirements, the legislation directs the FDA to issue new guidance on diversity action plans.

In March 2022, the FDA released final guidance entitled "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics," which outlines how developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology biological product development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA.

Expansion cohort trials can potentially bring efficiency to product development and reduce developmental costs and time.Finally, sponsors of clinical trials are required to register and disclose certain clinical trial information on a public registry (clinicaltrials.gov) maintained by the U.S. National Institutes of Health, or NIH. In particular, information related to the product, patient population, phase of investigation, clinical trial sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. The NIH's Final Rule on registration and reporting requirements for clinical trials became effective in 2017. Although the FDA has historically not enforced these reporting requirements due to the long delay of the U.S. Department of Health and Human Services, or HHS, in issuing final implementing regulations, those regulations have now been issued and the FDA has issued several Notices of Noncompliance to manufacturers since April 2021.

Interactions with FDA during the clinical development program

Following the clearance of an IND and the commencement of clinical trials, the sponsor will continue to have interactions with the FDA. Progress reports detailing the results of clinical trials must be submitted annually within 60 days of the anniversary dates that the IND went into effect and more frequently if serious adverse events occur. These reports must include a development safety update report, or DSUR. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other trials or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the occurrence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

In addition, sponsors are given opportunities to meet with the FDA at certain points in the clinical development program. Specifically, sponsors may meet with the FDA prior to the submission of an IND (Pre-IND meeting), at the end of Phase 2 clinical trial (EOP2 meeting) and before a BLA is submitted (Pre-BLA meeting). Meetings at other times may also be requested. There are four types of meetings that occur between sponsors and the FDA. Type A meetings are those that are necessary for an otherwise stalled product development program to proceed or to address an important safety issue. Type B meetings include pre-IND and pre-BLA meetings, as well as end of phase meetings such as EOP2 meetings. A Type C meeting is any meeting other than a Type A or Type B meeting regarding the development and review of a product, including for example meetings to facilitate early consultations on the use of a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use. Finally, a Type D meeting is focused on a narrow set of issues, which should be limited to no more than two focused topics, and should not require input from more than three disciplines or divisions.

Manufacturing and other regulatory requirements

Concurrent with clinical trials, sponsors usually complete additional animal safety studies, develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing commercial quantities of the product candidate in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other criteria, the sponsor must develop methods for testing the identity, strength, quality, and purity of the finished product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Specifically, the FDA's regulations require that pharmaceutical products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. Manufacturers and other entities involved in the manufacture and distribution of approved pharmaceuticals are required to register their establishments with the FDA and some state agencies, and they are subject to periodic unannounced inspections by the FDA for compliance with cGMPs and other requirements. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug or biologic undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States.

Inspections must follow a "risk-based schedule" that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated. Changes to the manufacturing process, specifications or container closure system for an approved product are strictly regulated and often

require prior FDA approval before being implemented. The FDA's regulations also require, among other things, the investigation and correction of any deviations from cGMP and the imposition of reporting and documentation requirements upon the sponsor and any third-party manufacturers involved in producing the approved product.

Pediatric trials

Under the Pediatric Research Equity Act, or PREA, applications and certain types of supplements to applications must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor must submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-phase 2 meeting or as may be agreed between the sponsor and the FDA. Those plans must contain an outline of the proposed pediatric clinical trial or trials that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric trials along with supporting information. The sponsor and the FDA must reach agreement on a final plan. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs.

For investigational products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of a sponsor, meet to discuss preparation of the initial PSP or to discuss deferral or waiver of pediatric assessments. In addition, the FDA will meet early in the development process to discuss pediatric study plans with sponsors, and the FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than ninety days after the FDA's receipt of the PSP.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The law now requires the FDA to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although FDA has recently taken steps to limit what it considers abuse of this statutory exemption in PREA. The FDA also maintains a list of diseases that are exempt from PREA requirements due to low prevalence of disease in the pediatric population.

Expedited review programs

The FDA is authorized to expedite the review of applications in several ways. Under the Fast Track program, the sponsor of a product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND. Candidate products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track application before the application is complete, a process known as rolling review.

Any product candidate submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as breakthrough therapy designation, priority review and accelerated approval.

- *Breakthrough therapy designation.* To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review and rolling review.

- *Priority review.* A product candidate is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention compared

to marketed products. FDA aims to complete its review of priority review applications within six months as opposed to 10 months for standard review.

- *Accelerated approval.* Biologic products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a biologic product candidate receiving accelerated approval perform adequate and well controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials.

  With passage of 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.

- *Regenerative advanced therapy.* With passage of the 21st Century Cures Act, or the Cures Act, in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with the FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

None of these expedited programs changes the standards for approval but each may help expedite the development or approval process governing product candidates.

Submission and filing of BLAs

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, along with information relating to the product's chemistry, manufacturing, controls, safety updates, patent information, abuse information and proposed labeling, are submitted to the FDA as part of an application requesting approval to market the product candidate for one or more indications. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, potency and purity of the biological product to the satisfaction of the FDA. The fee required for the submission and review of an application under the Prescription Drug User Fee Act, or PDUFA, is substantial (for example, for FY2023 this application fee is approximately $3.25 million), and the sponsor of an approved application is also subject to an annual program fee, currently more than $394,000 per eligible prescription product. These fees are typically adjusted annually, and exemptions and waivers may be available under certain circumstances, including where the applicant is a small business submitting its first human therapeutic application for review.

The FDA conducts a preliminary review of all applications within 60 days of receipt and must inform the sponsor at that time or before whether an application is sufficiently complete to permit substantive review. In pertinent part, FDA's regulations state that an application "shall not be considered as filed until all pertinent information and data have been received" by the FDA. In the event that FDA determines that an application does not satisfy this standard, it will issue a Refuse to File, or RTF, determination to the applicant. Typically, an RTF will be based on administrative incompleteness, such as clear omission of information or sections of required information such that substantive and meaningful review is precluded. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

After the submission is accepted for filing, the FDA begins an in-depth substantive review of the application. The FDA reviews the application to determine, among other things, whether the proposed product is safe and effective for its intended use,

whether it has an acceptable purity profile and whether the product is being manufactured in accordance with cGMP. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard application that is a new molecular entity, and six months from the filing date for an application with "priority review." The review process may be extended by the FDA for three additional months to consider new information or in the case of a clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission. Despite these review goals, it is not uncommon for FDA review of an application to extend beyond the PDUFA goal date.

In connection with its review of an application, the FDA will typically submit information requests to the applicant and set deadlines for responses thereto. The FDA will also conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the manufacturing processes and facilities comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications.

The FDA also may inspect the sponsor and one or more clinical trial sites to assure compliance with IND and GCP requirements and the integrity of the clinical data submitted to the FDA. With passage of FDORA, Congress clarified the FDA's authority to conduct inspections by expressly permitting inspections of facilities involved in the preparation, conduct, or analysis of clinical and non-clinical studies submitted to the FDA as well as other persons holding study records or involved in the study process.

Additionally, the FDA may refer an application, including applications for novel product candidates which present difficult questions of safety or efficacy, to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making final decisions on approval.

The FDA also may require submission of a REMS if it determines that a REMS is necessary to ensure that the benefits of the product outweigh its risks and to assure the safe use of the product. The REMS could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS and the FDA will not approve the application without a REMS.

Decisions on BLAs

After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA will issue either a Complete Response Letter, or CRL, or an approval letter. To reach this determination, the FDA must determine that the expected benefits of the proposed product outweigh its potential risks to patients. This assessment is informed by the severity of the underlying condition and how well patients' medical needs are addressed by currently available therapies; uncertainty about how the premarket clinical trial evidence will extrapolate to real-world use of the product in the post-market setting; and whether risk management tools are necessary to manage specific risks.

A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time- consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant will have one year to respond to the deficiencies identified by the FDA, at which time the FDA can deem the application withdrawn or, in its discretion, grant the applicant an additional six month extension to respond. The FDA has committed to reviewing resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter, on the other hand, authorizes commercial marketing of the product with specific prescribing information for specific indications. That is, the approval will be limited to the conditions of use (e.g., patient population, indication) described in the FDA-approved labeling. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to

monitor the product after commercialization or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-approval requirements

Following approval of a new prescription product, the manufacturer, the approved product and the product's manufacturing locations are subject to pervasive and continuing regulation by the FDA, governing, among other things, monitoring and record-keeping activities, reporting of adverse experiences with the product and product problems to the FDA, product sampling and distribution, manufacturing and promotion and advertising. Although physicians may prescribe legally available products for unapproved uses or patient populations (i.e., "off-label uses"), manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. 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 biologic.

It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in non-promotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. Moreover, with passage of the Pre-Approval 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. Previously, such communications were permitted under FDA guidance but the new legislation explicitly provides protection to sponsors who convey certain information about products in development to payors, including unapproved uses of approved products.

If a company is found to have promoted off-label uses, it may become subject to administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes products, as well as adverse public relations and reputational harm. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the sponsor may be required to submit and obtain FDA approval of a new application or supplement, which may require the sponsor to develop additional data or conduct additional preclinical studies and clinical trials. Securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled clinical trials to demonstrate the product's safety and efficacy in the new indication. Even if such trials are conducted, the FDA may not approve any expansion of the labeled indications for use in a timely fashion, or at all. There also are continuing, annual user fee requirements that are now assessed as program fees for certain products.

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

Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about a product;
- mandated modification of promotional materials and labeling and issuance of corrective information;

- fines, warning letters, untitled letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs.

Regulatory exclusivity governing biologics

When a biological product is licensed for marketing by FDA with approval of a BLA, the product may be entitled to certain types of market and data exclusivity barring FDA from approving competing products for certain periods of time. In March 2010, the Patient Protection and Affordable Care Act was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, the FDA has approved a number of biosimilars and the first interchangeable biosimilar product was approved on July 30, 2021 and a second product previously approved as a biosimilar was designated as interchangeable in October 2021.

Under the BPCIA, a manufacturer may submit an application for a product that is "biosimilar to" a previously approved biological product, which the statute refers to as a "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and the proposed biosimilar product in terms of safety, purity and potency. The biosimilar sponsor may demonstrate that its product is biosimilar to the reference product on the basis of data from analytical studies, animal studies and one or more clinical trials to demonstrate safety, purity and potency in one or more appropriate conditions of use for which the reference product is approved.
For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find not only that the product is biosimilar to the reference product but also that it can be expected to produce the same clinical results as the reference product such that the two products may be switched without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. Following approval of the interchangeable biosimilar product, the FDA may not grant interchangeability status for any second biosimilar until one year after the first commercial marketing of the first interchangeable biosimilar product. Congress clarified through FDORA that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the first day on which such a product is approved as interchangeable with the reference product.

A reference biological product is granted 12 years of exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. Even if a product is considered to be a reference product eligible for exclusivity, however, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of their product. There have been recent government proposals to reduce the 12-year reference product exclusivity period, but none has been enacted to date. At the same time, since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products.

Orphan drug designation and exclusivity

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for treatment of rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for tax credits and potentially market exclusivity for seven years following the date of the product's approval if granted by the FDA. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. A product becomes an orphan when it receives

orphan drug designation from the Office of Orphan Products Development at the FDA based on acceptable confidential requests. The product must then go through the review and approval process like any other product.

A sponsor may request orphan drug designation of a previously unapproved product or new orphan indication for an already marketed product. In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first approved product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same product for the same disease or condition for seven years, except in certain limited circumstances. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

The period of market exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the disease or condition for which the product has been designated. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if the company with orphan drug exclusivity is not able to meet market demand or the subsequent product is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care. Under Omnibus legislation signed by President Trump on December 27, 2020, the requirement for a product to show clinical superiority applies to drug products that received orphan drug designation before enactment of amendments to the FDCA in 2017 but have not yet been approved by FDA.

In September 2021, the Court of Appeals for the 11th Circuit held that, for the purpose of determining the scope of market exclusivity, the term "same disease or condition" in the statute means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, 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.

Pediatric exclusivity

Pediatric exclusivity is a type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of exclusivity. For biologic products, the six month period may be attached to any existing regulatory exclusivities but not to any patent terms. The conditions for pediatric exclusivity include the FDA's determination that information relating to the use of a new product in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric clinical trials, and the sponsor agreeing to perform, and reporting on, the requested clinical trials within the statutory timeframe. This six-month exclusivity may be granted if a sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patents that cover the product are extended by six months. Although this is not a patent term extension, it effectively extends the regulatory period during which the FDA cannot approve another application.

Patent term restoration and extension

In the United States, a patent claiming a new product, its method of use or its method of manufacture may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent extension of up to five years for patent term lost during product development and FDA regulatory review. Assuming grant of the patent for which the extension is sought, the restoration period for a patent covering a product is typically one-half the time between the effective date of the IND involving human beings and the submission date of the BLA, plus the time between the submission date of the application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date in the United States. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension in consultation with the FDA.

Companion diagnostics

In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, for novel biologics, a companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product's labeling. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. In July 2016, the FDA issued a draft guidance intended to assist sponsors of the therapeutic product and *in vitro* companion diagnostic device on issues related to co-development of the products.

The 2014 guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a biologic product candidate generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA's Investigational Device Exemption, or IDE, regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a product are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND application alone, or both an IND- and IDE-application.

In April 2020, the FDA issued additional guidance which describes considerations for the development and labeling of companion diagnostic devices to support the indicated uses of multiple biological oncology products, when appropriate. This guidance builds upon existing policy regarding the labeling of companion diagnostics. In its 2014 guidance, the FDA stated that if evidence is sufficient to conclude that the companion diagnostic is appropriate for use with a specific group of therapeutic products, the companion diagnostic's intended use/indications for use should name the specific group of therapeutic products, rather than specific products. The 2020 guidance expands on the policy statement in the 2014 guidance by recommending that companion diagnostic developers consider a number of factors when determining whether their test could be developed, or the labeling for approved companion diagnostics could be revised through a supplement, to support a broader labeling claim such as use with a specific group of oncology therapeutic products (rather than listing an individual therapeutic product(s)).

Under the FDCA, *in vitro* diagnostics, including companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import and post-market surveillance. Unless an exemption applies, diagnostic tests require pre-notification marketing clearance or approval from the FDA prior to commercial distribution.The FDA previously has required *in vitro* companion diagnostics intended to select the patients who will respond to the product candidate to obtain pre-market approval, or PMA, simultaneously with approval of the therapeutic product candidate. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the sponsor must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. PMA applications are subject to an application fee. For federal fiscal year 2023, the standard fee is $441,547 and the small business fee is $110,387.

Healthcare compliance

In the United States, biopharmaceutical manufacturers and their products are subject to extensive regulation at the federal and state level, such as laws intended to prevent fraud and abuse in the healthcare industry. Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Arrangements with providers, consultants, third-party payors, and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to healthcare providers and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, including certain laws and regulations applicable only if we have marketed products, include the following:

- 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;

- federal healthcare program anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving or providing 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 healthcare programs such as Medicare and Medicaid;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- 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;

- federal Open Payments (or federal "sunshine" law), which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with certain healthcare providers to the Center for Medicare & Medicaid Services, or CMS, within the HHS for re-disclosure to the public, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- analogous state laws and regulations, including: state anti-kickback and false claims laws; state laws requiring pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments to health care providers or marketing expenditures; and state laws governing privacy, security and breaches of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- laws and regulations prohibiting bribery and corruption such as the Foreign Corrupt Practices Act, which, among other things, prohibits U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations or foreign government-owned or affiliated entities, candidates for foreign public office, and foreign political parties or officials thereof.

Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, such as Medicare and Medicaid. Ensuring compliance is time consuming and costly. Similar healthcare laws and regulations exist in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information.

Healthcare reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and reimbursement for medical products and other changes to the healthcare system in the United States.

In March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, which, among other things, includes changes to the coverage and payment for pharmaceutical products under government healthcare programs. Other legislative changes have been proposed and adopted since the PPACA 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. These Medicare sequester reductions were suspended and reduced through the end of June 2022, with the full 2% cut resuming thereafter.

Since enactment of the PPACA, 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 and Jobs Act of 2017, or the Tax Act, which was signed by President Trump on December 22, 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. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the PPACA is an essential and inseverable feature of the PPACA, and therefore because the mandate was repealed as part of the Tax Act, the remaining provisions of the PPACA 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 PPACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to undermine or delay implementation of the PPACA, including directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA 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 rescinded those orders and issued a new executive order that directs federal agencies to reconsider rules and other policies that limit access to healthcare, 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 PPACA 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 under the PPACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

Pharmaceutical prices

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, 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, the 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 products 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 products 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 implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which has been delayed by the Biden administration until January 1, 2026 by the Infrastructure Investment and Jobs Act.

On July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The Order directs the 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 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 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 Part D drugs in 2027, 15 additional Part B or Part D drugs in 2028, and 20 additional Part B or Part D drugs 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. 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.

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. A number of states, for example, require pharmaceutical manufacturers and other entities in the supply chain, including health carriers, pharmacy benefit managers, wholesale distributors, to disclose information about pricing of pharmaceuticals. 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 pharmaceutical 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.

Federal and state data privacy laws

There are multiple privacy and data security laws that may impact our business activities, in the United States and in other countries where we conduct trials or where we may do business in the future. These laws are evolving and may increase both our obligations and our regulatory risks in the future. In the health care industry generally, under HIPAA, the HHS has issued regulations to protect the privacy and security of protected health information, or PHI, used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. HIPAA may apply to us in certain circumstances and may also apply to our business partners in ways that may impact our relationships with them. Our clinical trials are regulated by the Common Rule, which also includes specific privacy-related provisions. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that may be applicable to our business. In addition to possible federal civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. State attorneys general also have authority to enforce state privacy and security laws. New laws and regulations governing privacy and security may be adopted in the future as well.

At the state level, California has enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA went into effect on January 1, 2020 and requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. Additionally, effective starting on January 1, 2023, the California Privacy Rights Act, or CPRA, significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. The CCPA and CPRA could impact our business activities depending on how it is interpreted and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and individually identifiable health information. These provisions may apply to some of our business activities. In addition, other states, including Virginia and Colorado, already have passed state privacy laws and other states will likely be considering similar laws in the near future.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more of such privacy and data security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and/or reporting requirements in multiple jurisdictions could increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any of the privacy or data security laws or regulations described above that are applicable to us, or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a consent decree or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any product candidates we may develop, once approved, are sold in a foreign country, we may be subject to similar foreign laws.

Approval and regulation of medical products in the European Union

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products outside of the United States. Whether or not we obtain FDA approval for a product candidate, we must obtain approval by the comparable regulatory authorities of foreign countries or economic areas, such as the 27-member European Union, before we may commence clinical trials or market products in those countries or areas. In the European Union, our product candidates also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls.

With the exception of the European Union and European Economic Area, or EEA, applying the harmonized regulatory rules for medicinal products, the approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly between countries and jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Clinical trials

On January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014, or the Clinical Trials Regulation, became effective in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC. The new regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one Member State of the European Union, or EU Member State, will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU Member States and the public. Beyond streamlining the process, the Clinical Trials Regulation includes a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors, and a harmonized procedure for the assessment of applications for clinical trials,

which is divided into two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted where EU Member States are concerned. Part II is assessed separately by each EU Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation.

The new regulation did not change the preexisting requirement that a sponsor must obtain prior approval from the competent national authority of the EU Member State in which the clinical trial is to be conducted. If the clinical trial is conducted in different EU Member States, the competent authorities in each of these EU Member States must provide their approval for the conduct of the clinical trial. Furthermore, the sponsor may only start a clinical trial at a specific clinical site after the applicable ethics committee has issued a favorable opinion.

Parties conducting certain clinical trials must, as in the United States, post clinical trial information in the European Union at the EudraCT website: https://eudract.ema.europa.eu.

Marketing authorization in the European Union

Marketing authorization applications, or MAAs, can be filed either under the so-called centralized or national authorization procedures, albeit through the mutual recognition or decentralized procedure for a product to be authorized in more than one EU Member State.

The centralized procedure provides for the grant of a single marketing authorization following a favorable opinion by the European Medicines Agency, or EMA, that is valid in all EU Member States, as well as Iceland, Liechtenstein and Norway, which are part of the EEA. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced-therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of specified diseases, such as HIV/ AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions and viral diseases. The centralized procedure is optional for products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the sponsor in response to questions asked by the Committee for Medicinal Products for Human Use, or the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is of 150 days, excluding stop-clocks.

There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

- *Decentralized procedure*. Using the decentralized procedure, a sponsor may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. The sponsor may choose a member state as the reference member State to lead the scientific evaluation of the application.

- *Mutual recognition procedure*. In the mutual recognition procedure, a medicine is first authorized in one EU Member State (which acts as the reference member state), in accordance with the national procedures of that country. Following this, further marketing authorizations can be progressively sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization produced by the reference member state.

Under the above-described procedures, before granting the marketing authorization, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Conditional approval

In particular circumstances, EU legislation (Article 14–a Regulation (EC) No 726/2004 (as amended by Regulation (EU) 2019/5 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables sponsors to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for

an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the product candidate is intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases; (2) the product candidate is intended to meet unmet medical needs of patients; (3) a marketing authorization may be granted prior to submission of comprehensive clinical data provided that the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required; (4) the risk-benefit balance of the product candidate is positive, and (5) it is likely that the sponsor will be in a position to provide the required comprehensive clinical trial data. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new clinical trials and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Pediatric trials

Prior to obtaining a marketing authorization in the European Union, sponsors have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate because (a) the product is likely to be ineffective or unsafe in part or all of the pediatric population; (b) the disease or condition occurs only in adult population; or (c) the product does not represent a significant therapeutic benefit over existing treatments for pediatric population. Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

PRIME designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority MEdicines, or PRIME, scheme is intended to encourage product development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises, or SMEs, may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated agency contact and rapporteur from the CHMP or Committee for Advanced Therapies are appointed early in the PRIME scheme, facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance to the sponsor on the overall development and regulatory strategies.

Periods of authorization and renewals

A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the product on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Regulatory requirements after marketing authorization

As in the United States, both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual EU Member States both before and after grant of the manufacturing and marketing authorizations. The holder of an EU marketing authorization for a medicinal product must, for example, comply with EU pharmacovigilance legislation and its related regulations and guidelines which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. The manufacturing process for medicinal products in the European Union is also highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, including compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients.

In the European Union, the advertising and promotion of approved products are subject to EU Member States' laws governing promotion of medicinal products, interactions with clinicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual EU Member States may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion, which is prohibited in the European Union.

Regulatory exclusivity

In the European Union, new products authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic sponsors from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic marketing authorization in the European Union during a period of eight years from the date on which the reference product was first authorized in the European Union. The market exclusivity period prevents a successful generic sponsor from commercializing its product in the European Union until ten years have elapsed from the initial authorization of the reference product in the European Union. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Orphan drug designation and exclusivity

The criteria for designating an orphan medicinal product in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition, (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition. The term 'significant benefit' is defined in Regulation (EC) 847/2000 to mean a clinically relevant advantage or a major contribution to patient care.

Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten year market exclusivity period, the EMA or the competent authorities of the Member States of the EEA, cannot accept an application for a marketing authorization for a similar medicinal product for the same indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The sponsor will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the European Union may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently

profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if: (1) the second sponsor can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (2) the sponsor consents to a second orphan medicinal product application; or (3) the sponsor cannot supply enough orphan medicinal product.

Pediatric exclusivity

If a sponsor obtains a marketing authorization in all EU Member States, or a marketing authorization granted in the centralized procedure by the European Commission, and the trial results for the pediatric population are included in the product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of the Supplementary Protection Certificate, or SPC, or alternatively a one year extension of the regulatory market exclusivity from ten to eleven years, as selected by the marketing authorization holder.

Patent term extensions

The European Union also provides for patent term extension through Supplementary Protection Certificates, or SPCs. The rules and requirements for obtaining a SPC are similar to those in the United States. An SPC may extend the term of a patent for up to five years after its originally scheduled expiration date and can provide up to a maximum of fifteen years of marketing exclusivity for a product. In certain circumstances, these periods may be extended for six additional months if pediatric exclusivity is obtained. Although SPCs are available throughout the European Union, sponsors must apply on a country-by-country basis. Similar patent term extension rights exist in certain other foreign jurisdictions outside the European Union.

Reimbursement and pricing of prescription pharmaceuticals

In the European Union, similar political, economic and regulatory developments to those in the United States 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, pharmaceutical firms may be required to conduct a clinical trial that compares the cost-effectiveness of the product to other available therapies.

Approval of companion diagnostic devices

In the European Union, medical devices such as companion diagnostics must comply with the General Safety and Performance Requirements, or SPRs, detailed in Annex I of the EU Medical Devices Regulation (Regulation (EU) 2017/745), or MDR which came into force on May 26, 2021 and replaced the previously applicable EU Medical Devices Directive (Council Directive 93/42/EEC). Compliance with SPRs and additional requirements applicable to companion medical devices is a prerequisite to be able to affix the CE Mark of Conformity to medical devices, without which they cannot be marketed or sold. To demonstrate compliance with the SPRs, a manufacturer must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. The MDR is meant to establish a uniform, transparent, predictable, and sustainable regulatory framework across the European Union for medical devices.

Separately, the regulatory authorities in the European Union also adopted a new In Vitro Diagnostic Regulation, or IVDR, (EU) 2017/746, which became effective in May 2022. The new regulation replaces the In Vitro Diagnostics Directive (IVDD) 98/79/EC. Manufacturers wishing to apply to a notified body for a conformity assessment of their in vitro diagnostic medical device had until May 2022 to update their Technical Documentation to meet the requirements and comply with the new, more stringent Regulation. The regulation, among other things, strengthens the rules on placing devices on the market and reinforce surveillance once they are available; establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance, and safety of devices placed on the market; improves the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number; sets up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union; and strengthens rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

General Data Protection Regulation

Many countries outside of the United States maintain rigorous laws governing the privacy and security of personal information. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the EEA, and the processing of personal data that takes place in the EEA, is subject to the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, and it imposes heightened requirements on companies that process health and other sensitive data, such as requiring in many situations that a company obtain the consent of the individuals to whom the sensitive personal data relate before processing such data. Examples of obligations imposed by the GDPR on companies processing personal data that fall within the scope of the GDPR include providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, appointing a data protection officer, providing notification of data breaches and taking certain measures when engaging third-party processors.

The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield framework, 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. Following the withdrawal of the United Kingdom from the European Union, the U.K. Data Protection Act 2018 applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-U.S. Privacy Shield. The European Commission initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022. It is unclear if and when the framework will be finalized and whether it will be challenged in court. The uncertainty around this issue may further impact our business operations in the European Union.

Brexit and the regulatory framework in the United Kingdom

The United Kingdom's withdrawal from the European Union took place on January 31, 2020. The European Union and the United Kingdom reached an agreement on their new partnership in the Trade and Cooperation Agreement, or the Agreement, which was applied provisionally beginning on January 1, 2021 and which became effective on May 1, 2021. The Agreement focuses primarily on free trade by ensuring no tariffs or quotas on trade in goods, including healthcare products such as medicinal products. Thereafter, the European Union and the United Kingdom will form two separate markets governed by two distinct regulatory and legal regimes. As such, the Agreement seeks to minimize barriers to trade in goods while accepting that border checks will become inevitable as a consequence that the United Kingdom is no longer part of the single market. 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 continues 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 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 United Kingdom. However, until December 31, 2023, it is possible for the MHRA to rely on a decision taken by the European Commission and EMA's CHMP on the approval of MAA or variations via the centralized procedure, or the so called "Reliance Procedure."

Intellectual property

We actively seek to protect the proprietary technology that we consider important to our business, including pursuing patents that cover our ADC platforms, proprietary compositions of matter, ADC product candidates and methods of using and manufacturing the same, as well as any other relevant inventions and improvements that are considered commercially important to the development of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

Our commercial success will depend significantly on our ability to obtain and maintain patents and other proprietary protection for the technology, inventions and improvements we consider important to our business, and to defend our patents, preserve the confidentiality of our trade secrets and operate without infringing the patents and proprietary rights of third parties. Our policy is to seek to protect our proprietary and intellectual property position by, among other methods, filing U.S., international (under Patent Cooperation Treaty, or PCT) and foreign patent applications related to our proprietary technology, inventions and improvements that we consider to be important to the development and implementation of our business. We also believe in protecting our unpatented trade secrets and know-how and continuing our technological innovation to develop our business and to maintain our competitive position.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. In the future, if and when our drug candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those drugs, depending upon the length of the clinical trials for each drug and other factors. There can be no assurance that any of our pending patent applications will issue or that we will benefit from any patent term extension or favorable adjustments to the terms of any of our patents.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our drug candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending patent applications, and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Any issued patents that we may currently own or license or may receive in the future may be challenged, invalidated, circumvented or have the scope of their claims narrowed. For example, we cannot be certain of the priority of inventions covered by pending third party patent applications. If third parties prepare and file patent applications in the United States that also claim technology or therapeutics to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention, which could result in substantial costs to us, even if the eventual outcome is favorable to us, which is highly unpredictable. In addition, because of the extensive time required for clinical development and regulatory review of a drug candidate we may develop, it is possible that, before any of our drug candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide. For more information regarding the risks related to our intellectual property, please see "Risk factors—Risks related to our intellectual property."

As of December 31, 2022, we owned, in all of our patent portfolios, 24 issued U.S. patents, 18 pending non-provisional U.S. patent applications (including two allowed U.S. patent applications), seven pending provisional U.S. patent applications, 131 issued foreign patents, three pending PCT patent applications and 209 pending foreign patent applications (including three allowed foreign patent applications), in a number of foreign jurisdictions, including, but not limited to, Algeria, Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Europe, Eurasia, Egypt, Gulf Cooperation Council, Hong Kong, India, Indonesia, Israel, Japan, Mexico, Macau, Malaysia, Nigeria, Pakistan, New Zealand, Philippines, Russia, Saudi Arabia, Singapore, South Korea, South Africa, Taiwan, Thailand, United Arab Emirates and Vietnam. Our 10 issued U.S. patents covering our Fleximer ADC platform are projected to expire in 2032, excluding any additional term for patent term adjustments or patent term extensions; our two issued U.S. patents covering our Dolaflexin ADC platform are projected to expire in 2034 and 2038, excluding any additional term for patent term adjustments or patent term extensions; our two issued U.S. patents covering UpRi are projected to expire in 2037 and 2039, excluding any additional term for patent term adjustments or patent term extensions; our one issued U.S. patent covering our Dolasynthen ADC platform is projected to expire in 2037, excluding any additional term for patent term adjustments or patent term extensions; our three issued U.S. patents covering our novel HER2 antibody are projected to expire in 2035, excluding any additional term for patent term adjustments or patent term

extensions; our one issued U.S. patent covering our STING agonist payload is projected to expire in 2040, excluding any additional term for patent term adjustments or patent term extensions; our additional five issued U.S. patents are projected to expire between 2033 and 2037, excluding any additional term for patent term adjustments or patent term extensions; and any patent that may issue from our pending U.S. applications are projected to expire between 2032 and 2043, in each case, excluding any additional term for patent term adjustments or patent term extensions. In addition, we have exclusively in-licensed four issued U.S. patents and one issued European patent for the NaPi2b antibody from Recepta, which Recepta licensed from the Ludwig Institute for Cancer Research. These in-licensed issued U.S. and European patents are projected to expire in 2029, excluding any additional term for patent term adjustments or patent term extensions. Recepta still owns one pending Brazilian patent application for the NaPi2b antibody, which is not licensed to us. A patent issuing from this Brazilian patent application is projected to expire in 2029, excluding any additional term for patent term adjustments or patent term extensions. We have also non-exclusively in-licensed from Synaffix certain patents and patent applications for their proprietary site-specific conjugation technology. These in-licensed Synaffix patents and patent applications are eight issued US patents, three pending non-provisional U.S. patent applications, thirteen issued foreign patents, and 14 pending foreign patent applications, in a number of foreign jurisdictions, including, but not limited to, China, Europe, India, Japan, and Netherlands These in-licensed issued U.S. and European patents are projected to expire from 2031 to 2040, excluding any additional term for patent term adjustments or patent term extensions. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before they are granted. Finally, the grant proceeding of each national or regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted by others. It is also quite common that depending on the country, various scopes of patent protection may be granted on the same product candidate or technology.

The intellectual property portfolio of our ADC platforms, our ADC product candidates and components thereof, and companion or complementary diagnostics are summarized below. Some of these portfolios are in very early stages, and prosecution has yet to commence on some of the pending patent applications. Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO may be narrowed (sometimes significantly) by the time they issue, if they issue at all. We expect this to be the case with respect to our pending patent applications referred to below.

Fleximer ADC platform

The intellectual property portfolio for our Fleximer ADC platform is directed to compositions of matter for the Fleximer ADCs, as well as methods of using and making these novel conjugates, compositions of matter for Fleximer drug conjugates prior to conjugation with the antibody or antibody fragment and methods of making the same, and compositions of matter for our proprietary auristatin DolaLock compounds and conjugates thereof (e.g., to Fleximer and/or an antibody or antibody fragment). As of December 31, 2022, we owned 10 issued U.S. patents, one pending non-provisional U.S. patent application, 50 issued foreign patents and two pending foreign patent applications, in a number of foreign jurisdictions, including, but not limited to, Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Macau, Mexico, Russia, South Korea, and Taiwan. Any U.S. or foreign patent issuing from the pending applications covering the Fleximer ADC platform is projected to expire in 2032, excluding any additional term for patent term adjustments or patent term extensions.

Dolaflexin ADC platform

The intellectual property portfolio for our Dolaflexin ADC platform is directed to compositions of matter for the Dolaflexin ADCs, as well as methods of using and making these novel conjugates, compositions of matter for Dolaflexin drug conjugates prior to conjugation with the antibody or antibody fragment and methods of making the same. As of December 31, 2022, we owned two issued U.S. patents, 36 issued foreign patents, and nine pending foreign patent applications, in a number of foreign jurisdictions, including, but not limited to, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Israel, India, Japan, South Korea, Mexico, South Africa and Taiwan. Any U.S. or foreign patent issuing from the pending applications covering Dolaflexin ADC platform is projected to expire in 2034, excluding any additional term for patent term adjustments or patent term extensions, and any U.S. or foreign patent issuing from the pending applications covering the method of making the Dolaflexin ADC is projected to expire in 2038, excluding any additional term for patent term adjustments or patent term extensions.

UpRi ADC

The intellectual property portfolio for UpRi, our leading NaPi2b ADC product candidate is directed to compositions of matter for our novel ADC based on exclusively in-licensed NaPi2b antibody and our Dolaflexin platform, as well as methods of using and making these novel conjugates, methods of administration and companion or complementary diagnostics. As of December 31, 2022, we owned two issued U.S. patents, five pending non-provisional U.S. patent applications (including one allowed U.S. patent application), two pending provisional U.S. patent applications, five issued foreign patents, 52 pending foreign patent applications (including two allowed foreign patent applications), in a number of foreign jurisdictions, including, but not limited

to, Argentina, Australia, Brazil, Canada, China, Eurasia, Europe, Japan, Gulf Cooperation Council, Israel, India, Mexico, New Zealand, Pakistan, South Africa, South Korea, Macau, Hong Kong, Taiwan, and two pending PCT applications directed to the composition of matter for UpRi, methods of using and making same, companion or complementary diagnostics for the UpRi ADC and UpRi dosing regimens. We also intend to enter the national/regional phase of the pending PCT patent applications in foreign jurisdictions, including, but not limited to, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Israel, India, Japan, Saudi Arabia, Singapore, South Korea, Macau, Mexico, New Zealand, South Africa and United Arab Emirates. Any U.S. or foreign patent issuing from the pending applications covering the composition of matter of UpRi is projected to expire in 2037, excluding any additional term for patent term adjustments or patent term extensions, and any U.S. or foreign patent issuing from the pending applications covering UpRi companion or complementary diagnostics is projected to expire in 2038, excluding any additional term for patent term adjustments or patent term extensions, and any U.S. or foreign patent issuing from the pending applications covering the UpRi dosing regimens is projected to expire in 2039, 2042, and 2043, excluding any additional term for patent term adjustments or patent term extensions.

In addition, as mentioned above, we have exclusively in-licensed four issued U.S. patents and one issued European patent for the novel NaPi2b antibody from Recepta, which Recepta licensed from the Ludwig Institute for Cancer Research. These in-licensed issued U.S. and European patents are projected to expire in 2029, excluding any additional term for patent term adjustments or patent term extensions. Recepta still owns one pending Brazilian patent application for the NaPi2b antibody, which is not licensed to us. A patent issuing from this Brazilian patent application is projected to expire in 2029, excluding any additional term for patent term adjustments or patent term extensions.

Dolasynthen ADC platform

The intellectual property portfolio for our novel Dolasynthen platform is directed to compositions of matter for the novel scaffold and ADCs thereof, as well as methods of using and making these novel conjugates and scaffolds. As of December 31, 2022, we owned one issued U.S. patent, three pending non-provisional U.S. patent applications and 51 pending foreign patent applications, in a number of foreign jurisdictions, including, but not limited to, Argentina, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Israel, India, Japan, Mexico, New Zealand, Pakistan, Saudi Arabia, Singapore, South Korea, Taiwan, and United Arab Emirates. Any U.S. or foreign patent issuing from the pending applications covering the novel Dolasynthen platform is projected to expire between 2037 and 2041, excluding any additional term for patent term adjustments or patent term extensions.

XMT-1660 ADC

The intellectual property portfolio for XMT-1660, our site-specific B7-H4 ADC product candidate is directed to compositions of matter for our novel ADC based on our novel B7-H4 antibody and our Dolasynthen platform, as well as methods of using, making these novel conjugates and administration of these novel conjugates. As of December 31, 2022, we owned one pending non-provisional U.S. patent application, two pending provisional applications, three pending foreign patent applications in a number of foreign jurisdictions including, but not limited to, Taiwan, Argentina, and Pakistan, and one pending PCT patent application. We intend to enter the national/regional phase of the PCT patent application in a number of foreign jurisdictions, including, but not limited to, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Israel, India, Japan, Macau, Mexico, South Korea, New Zealand, Singapore, South Africa, Saudi Arabia, and United Arab Emirates. Any U.S. or foreign patent issuing from the pending applications covering XMT-1660 is projected to expire in 2042 and 2043, excluding any additional term for patent term adjustments or patent term extensions.

Immunosynthen ADC platform

The intellectual property portfolio for our novel Immunosynthen platform is directed to compositions of matter for the novel STING agonists and ADCs thereof, as well as methods of using and methods of making these novel payloads and ADCs. As of December 31, 2022, we owned one issued U.S. patent, one pending non-provisional U.S. patent applications, 19 pending foreign patent applications in a number of foreign jurisdictions, including, but not limited to, Argentina, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Israel, India, Japan, Mexico, New Zealand, Saudi Arabia, South Korea, South Africa, Taiwan and United Arab Emirates related to our novel STING agonists, and two pending non-provisional U.S. patent applications and 29 pending foreign patent applications in a number of foreign jurisdictions, including, but not limited to, Algeria, Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Europe, Eurasia, Egypt, India, Indonesia, Israel, Japan, Mexico, Malaysia, Nigeria, Pakistan, New Zealand, Philippines, Saudi Arabia, Singapore, South Korea, South Africa, Taiwan, Thailand, United Arab Emirates and Vietnam, related to our Immunosynthen platform. Any U.S. or foreign patent issuing from the pending applications covering the novel STING agonists is projected to expire in 2040, excluding any additional term for patent term adjustments or patent term extensions, and any U.S. or foreign patent issuing from the pending applications covering the Immunosynthen platform is projected to expire in 2041, excluding any additional term for patent term adjustments or patent term extensions.

XMT-2056 ADC

The intellectual property portfolio for XMT-2056, our HER2-targeted novel Immunosynthen ADC, is directed to the compositions of matter for our novel ADC based on our novel HER2 antibody and our Immunosynthen platform, as well as methods of using, making these novel conjugates, combination comprising XMT-2056 and administration of XMT-2056. As of December 31, 2022, we owned one pending non-provisional U.S. patent application, three pending provisional U.S. patent applications and 23 pending foreign patent applications in a number of foreign jurisdictions, including, but not limited to, Argentina, Australia, Brazil, Chile, Colombia, Europe, Eurasia, Egypt, India, Indonesia, Israel, Japan, Mexico, Malaysia, Nigeria, Pakistan, New Zealand, Philippines, Saudi Arabia, South Korea, South Africa, Taiwan and United Arab Emirates. Any U.S. or foreign patent issuing from the pending applications covering the composition of matter of XMT-2056 is projected to expire in 2041, excluding any additional term for patent term adjustments or patent term extensions, any U.S. or foreign patent issuing from the pending applications covering combinations comprising XMT-2056 is projected to expire in 2043, excluding any additional term for patent term adjustments or patent term extensions, and any U.S. or foreign patent issuing from the pending applications covering the XMT-2056 dosing regimens is projected to expire in 2043, excluding any additional term for patent term adjustments or patent term extensions.

In addition to the above with respect to XMT-2056, as of December 31, 2022, we owned three issued U.S. patents, one pending non-provisional U.S. patent application, 19 issued foreign patents and seven pending foreign patent applications (including one allowed foreign patent application), in a number of foreign jurisdictions, including, but not limited to, Argentina, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Israel, India, Japan, Macau, Mexico, South Korea, New Zealand and Taiwan, directed to the novel HER2 antibody. Any U.S. or foreign patent issuing from the pending applications covering the novel HER2 antibody is projected to expire in 2035, excluding any additional term for patent term adjustments or patent term extensions.

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, by executing confidentiality and assignment of inventions agreements with our employees and consultants, which agreements may also include appropriate non-competition and non-solicit agreements depending on level and role, as well as confidentiality agreements with our collaborators and scientific advisors. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that we will have executed such agreements with all applicable employees and contractors, or that these agreements will afford us adequate protection of our intellectual property and proprietary information rights. Trade secrets and know-how can be difficult to protect. In particular, we anticipate that with respect to our technology platforms, trade secrets and know-how will over time be disseminated within the industry through independent development and public presentations describing the methodology. For more information regarding the risks associated with our trade secrets, please see “Risk factors—Risks related to our intellectual property—Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.”

Competition

The biotechnology and biopharmaceutical industries, and the oncology subsector, are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. While we believe that our proprietary ADC platforms and scientific expertise provide us with competitive advantages, a wide variety of institutions, including large biopharmaceutical companies, specialty biotechnology companies, academic research departments and public and private research institutions, are actively developing potentially competitive products and technologies. These competitors generally fall within the following categories:

New cancer treatments: Many global pharmaceutical companies, as well as medium and small biotechnology companies, are pursuing new cancer treatments whether small molecules, biologics or ADCs. Any of these treatments could prove to be superior clinically to our products.

ADC platforms: Although Dolaflexin, Dolasynthen, Immunosynthen and certain initiatives we have underway are highly differentiated and proprietary, many companies continue to invest in innovation in the ADC field including new payload classes, new conjugation approaches and new targeting moieties. Any of these initiatives could lead to a platform that has superior properties to ours. 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, 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.

Ovarian cancer: The first indication that we are targeting for UpRi, our most advanced clinical candidate, is ovarian cancer. There are multiple therapies currently available to treat both newly diagnosed and relapsed ovarian cancer, including platinum agents, non-platinum chemotherapy, PARP inhibitors, bevacizumab and mirvetuximab soravtansine. In addition, multiple investigational product candidates are in development to treat these ovarian cancer patients, including MORAb-202 (Eisai Co., Ltd. and BMS) and STRO-002 (Sutro Biopharma, Inc.), which are investigational ADCs. There are also ongoing Phase 3 clinical trials of agents and treatment modalities including Tumor Treating Fields (Novocure GmbH) and AVB-500 (Aravive, Inc.), which, if successful, could alter the treatment landscape for platinum resistant ovarian cancer. Our ability to compete effectively with these and other emerging ovarian cancer treatments will depend on our ability to differentiate UpRi from these other therapies based on target patient selection, efficacy and tolerability. If we are unable to effectively differentiate UpRi, this will negatively impact our ability to compete in ovarian cancer.

Breast Cancer: We are planning to evaluate two of our product candidates currently in clinical development, XMT-2056 and XMT-1660, in patients with breast cancer indications. Multiple therapies are currently available to treat metastatic breast cancer across newly diagnosed and relapsed settings, including but not limited to aromatase inhibitors, CDK 4/6 inhibitors, HER2-targeted therapies, anti-PD-1 inhibitors, PI3K inhibitors and ADCs targeting HER2 and Trop-2. Additional classes of therapies currently in development include oral selective estrogen receptor degraders (known as SERDs), Akt inhibitors, and ADCs, among others. The metastatic breast cancer treatment paradigm is evolving with the introduction of a newly defined subset of HER2-low breast cancer, following the FDA approval of trastuzumab deruxtecan. Our ability to compete effectively in the breast cancer market will depend on evolving standards of care across patient subsets (based on HER2 and hormone receptor status), and our ability to differentiate XMT-2056 and XMT-1660 from other available therapies based on efficacy and tolerability.

Many of our competitors, either alone or with strategic partners, have substantially greater financial, technical and human resources than we do. Accordingly, our competitors may be more successful than us in obtaining approval for treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive. Accelerated merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity could be substantially limited in the event that our competitors develop and commercialize products that are more effective, safer, more convenient or less expensive than our comparable products. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of our products' entry. We believe the factors determining the success of our programs will be the efficacy, safety and tolerability of our product candidates.

Employees and Human Capital

As of December 31, 2022, we had 228 full time employees, including 151 with M.D., Ph.D. or other advanced degrees. Of these employees, 171 are engaged in research and development and 57 are engaged in general and administrative activities. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. Our human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees, and focusing on employee well-being and workplace safety. We provide our employees with competitive salaries and bonuses, opportunity for equity ownership, development programs that enable continued learning and growth, and a robust employment package that promotes wellness across all aspects of their lives, including healthcare, retirement planning, and paid time off.

We also believe that fostering diversity, equity, and inclusion is a key element to discovering, developing and bringing therapies to patients with cancer. As of December 31, 2022, 57% of our global workforce identified as female. We strive to

build a workforce representative of the communities and patients we serve and to nurture an inclusive culture where all voices are welcomed, heard, and respected.

Facilities

Our corporate headquarters are located in Cambridge, Massachusetts. We occupy approximately 45,000 square feet of office and laboratory space that we lease in the multi-tenant building in which our corporate headquarters are located. The lease for the substantial majority of this space expires in March 2026. We have an option to extend the lease term for an additional five years thereafter. We believe that this office and laboratory space is sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Corporate Information

We were incorporated in 2001 as a Delaware corporation. Our principal executive offices are located at 840 Memorial Drive, Cambridge, MA 02139, and our telephone number is 617-498-0020. Our internet site is www.mersana.com. We routinely make available important information free of charge, including copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the SEC. We recognize our website as a key channel of distribution to reach public investors and as a means of disclosing material non-public information to comply with our disclosure obligations under SEC Regulation FD. Information contained on our website shall not be deemed incorporated into, or to be part of this Annual Report on Form 10-K, and any website references are not intended to be made through active hyperlinks.

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 Annual Report on Form 10-K, 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.

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 serious adverse events, or SAEs, including, without limitation, death, pneumonitis, renal impairment, abdominal pain, fatigue, vomiting, sepsis and pyrexia. We expect that certain patients in our ongoing clinical trials of UpRi, XMT-1660 and XMT-2056 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 U.S. Food and Drug Administration, or 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. 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 UpRi, XMT-1660 or XMT-2056 or of any other current or 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. 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, XMT-2056 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. 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 determined to focus development on patients with ovarian cancer. As a result, we may have missed an opportunity to have allocated the resources originally used to develop 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 candidate, we may relinquish valuable rights to 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 $204.2 million, $170.1 million, and $88.0 million, respectively, for the years ended December 31, 2022, 2021, and 2020, respectively. As of December 31, 2022, we had an accumulated deficit of $654.7 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 and 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, SVB 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 $280.7 million as of December 31, 2022. 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. We believe that our current cash, cash equivalents and marketable securities, which reflects the receipt in 2023 of a $30 million up-front payment from Merck KGaA related to our December 2022 collaboration, 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 manufacturers 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 manufacturers 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 manufacture our product candidates may be unique 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 appropriate our trade secrets or other proprietary information.

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, XMT-1660 and XMT-2056, 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, or complying with current good laboratory practices or current good clinical practices, as applicable, resulting in the 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 Dolaflexin 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 do not prioritize and commit sufficient resources to programs associated with our product candidates or collaboration product candidates, we or 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 candidate is delayed or sales of an approved product are disappointing. Any delay in entering into strategic collaboration agreements related to our 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 diagnosis criteria included in the final label for UpRi, acceptance by the medical community, the approval and availability of a commercial 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 or is 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 foreign markets, which may adversely affect our future profitability.

In some 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 of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of 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 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 research 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 the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations 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 patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects.

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 Janssen, the license for the rights covering the Dolasynthen platform; in the case of our agreement with Recepta, the license for the rights covering the NaPi2b antibody in UpRi; and, 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 in-licensed 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 portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our 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 or the use or manufacture of 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 jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business,

could put our patents at risk of being 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 and proprietary 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 could be disclosed to our competitors or others may independently develop substantially equivalent or superior 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 know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's 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.

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 United Kingdom. Until 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 Pre-approval 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.

Separately, in response to 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. As of May 26, 2021, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities.

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 soon issue a Federal Register notice describing how the termination of the public health emergency will impact the agency's COVID-19 related guidance, including the clinical trial guidance and updates thereto. At this point, it is unclear how, if at all, these developments will impact our efforts to develop and commercialize our product candidates. 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 time-consuming 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.

Furthermore, 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.

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 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 Food and Drug Omnibus Reform Act, or 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 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 could delay or prevent approval or limit 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. We may not be able to enter into arrangements with another or additional diagnostic company to obtain supplies of additional or an alternative 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. 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 implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price

reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which has been delayed under January 1, 2026, by the Infrastructure Investment and Jobs Act.

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 business partners.

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 operations, any of which could adversely affect our ability to operate our business and our results of operations.

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 coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. In such instance, 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 February 24, 2020 to February 24, 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;
- 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 anti-takeover 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, 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 pre-change 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 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our corporate headquarters are located in Cambridge, Massachusetts. We occupy approximately 45,000 square feet of office and laboratory space that we lease in a multi-tenant building in which our corporate headquarters are located. The lease for the substantial majority of this space expires in March 2026. We have an option to extend the lease term for an additional five years thereafter. We believe that this office and laboratory space is sufficient to meet our current needs and that suitable additional space will be available as and when needed.

ITEM 3. 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 Annual Report on Form 10-K, 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 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol "MRSN" on the Nasdaq Global Select Market. As of February 24, 2023, there were 19 holders of record of shares of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

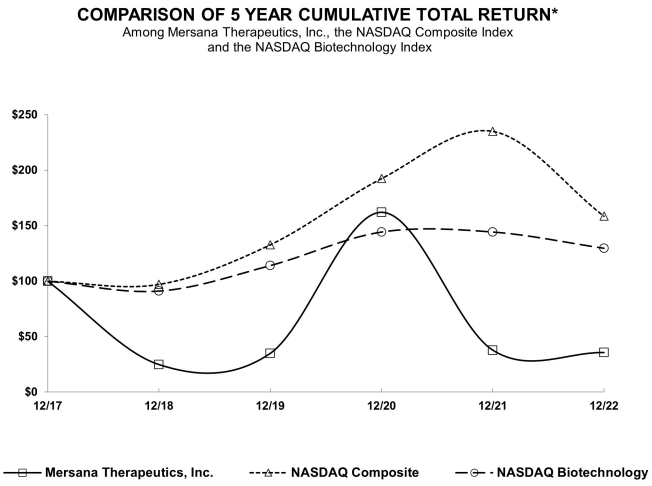
Dividend Policy

We have never declared nor paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends in respect of our common stock in the foreseeable future. In addition, our current credit facility contains restrictive covenants that prohibit us, subject to certain exceptions, from paying dividends on our common stock. Any future determination to pay cash dividends will be made at the discretion of our board of directors and will depend on restrictions and other factors our board of directors may deem relevant. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Stock Performance Graph

The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the Securities and Exchange Commission, or SEC, for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, nor shall such information be incorporated by reference into any future filing under the Exchange Act or Securities Act of 1933, as amended, or the Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the performance of our common stock to the Nasdaq Composite Index and to the Nasdaq Biotechnology Index from December 31, 2017 through December 31, 2022, which was the last trading day of the year. The comparison assumes $100 was invested in our common stock and in each of the foregoing indices after the market closed on December 31, 2017, and it assumes reinvestment of dividends, if any. The stock price performance included in this graph is not necessarily indicative of future stock price performance.



*$100 invested on 12/31/17 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliates Purchasers

Neither we nor any affiliated purchaser or anyone acting on behalf of us or an affiliated purchaser made any purchases of shares of our common stock during the fourth quarter of 2022.

ITEM 6. [RESERVED]

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our audited financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking 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 Annual 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 Annual 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 Annual Report on Form 10-K, 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 Securities and Exchange Commission, or 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.

For our discussion and analysis of the year ended December 31, 2021 compared to the year ended December 31, 2020, please refer to "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on February 28, 2022.

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 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-treated to those in earlier lines of the disease.

We are investigating two additional ADCs, XMT-1660 and XMT-2056, in Phase 1 clinical trials. 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, for which trial we began dosing patients in August 2022. 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.

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

In May 2022, we made the decision to discontinue the development of XMT-1592, a Dolasynthen ADC that had been in a Phase 1 dose exploration trial in patients with ovarian cancer and NSCLC, and to close this company-sponsored trial, which was completed in September 2022.

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. Our net losses were $204.2 million and $170.1 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $654.7 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, XMT-1660 and XMT-2056;
- prepare for a potential BLA submission for UpRi 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. We did not recognize revenue related to the 2022 Merck KGaA Agreement during the year ended December 31, 2022.

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 year ended December 31, 2022, we recognized $2.0 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 year ended December 31, 2022, we recognized $24.2 million of collaboration revenue related to performance under the Janssen Agreement and an associated development milestone.

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 years ended December 31, 2022 and 2021, we recognized an immaterial amount of revenue related to the 2014 Merck KGaA Agreement and Merck KGaA Supply Agreement.

During the year ended December 31, 2022, we recognized $0.3 million of revenue related to services provided to Asana BioSciences, LLC, or Asana Biosciences. We did not recognize revenue related to Asana Biosciences during the year ended December 31, 2021.

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 in the second quarter of 2022, all costs associated with our Dolasynthen platform were prospectively re-allocated 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 years ended December 31, 2022, 2021, and 2020.

(in thousands)	Year Ended December 31, 2022	2021	2020
UpRi external costs	$ 66,119	$ 45,511	$ 18,689
XMT-1660 external costs	15,032	—	—
XMT-2056 external costs	4,981	—	—
XMT-1592 external costs	3,802	9,126	7,180
Preclinical and discovery costs	14,991	28,464	9,883
Internal research and development costs	68,460	48,912	31,284
Total research and development costs	$ 173,385	$ 132,013	$ 67,036

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, XMT-1660 and 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 Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021, together with the changes in those items:

(in thousands)	Year Ended December 31, 2022	2021	Dollar Change
Collaboration revenue	$ 26,581	$ 43	$ 26,538
Operating expenses:			
Research and development	173,385	132,013	41,372
General and administrative	56,963	36,888	20,075
Total operating expenses	230,348	168,901	61,447
Other income (expense):			
Interest income	2,883	65	2,818
Interest expense	(3,328)	(1,267)	(2,061)
Total other expense, net	(445)	(1,202)	757
Net loss	$ (204,212)	$ (170,060)	$ (34,152)

Collaboration Revenue

Collaboration revenue increased by $26.5 million during the year ended December 31, 2022 as compared to the year ended December 31, 2021, primarily due to collaboration revenue of $24.2 million recognized under the Janssen Agreement and $2.0 million recognized under the GSK Agreement.

Research and Development Expense

Research and development expense increased by $41.4 million from $132.0 million for the year ended December 31, 2021 to $173.4 million for the year ended December 31, 2022.

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

- an increase of $21.6 million related to manufacturing and clinical development activities for UpRi;
- an increase of $14.5 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 $2.3 million related to clinical development activities for XMT-1660;
- an increase of $2.2 million related to manufacturing activities for XMT-1660 and the Dolasynthen platform;
- an increase of $1.5 million related to manufacturing and clinical development activities for XMT-2056; and
- an increase of $1.4 million related to consulting and professional fees.

These increased costs were partially offset by a decrease of $3.4 million related to manufacturing and clinical development activities for XMT-1592.

Stock-based compensation expense included in research and development expenses increased by $1.4 million primarily as a result of increased headcount.

General and Administrative Expense

General and administrative expense increased by $20.1 million from $36.9 million for the year ended December 31, 2021 to $57.0 million for the year ended December 31, 2022. The increase in general and administrative expense was primarily due to an increase of $11.1 million related to consulting and professional fees and an increase of $7.1 million related to employee compensation (excluding stock-based compensation) due to an increase in headcount. Stock-based compensation increased by $1.7 million, also primarily as a result of increased headcount.

Total Other Expense, Net

Total other expense, net was $0.4 million and $1.2 million for the years ended December 31, 2022 and 2021, respectively. The increase to the net balance was primarily due to an increase in interest income earned on marketable securities partially offsetting an increase in interest expense related to borrowings under the New Credit Facility, as defined below.

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 year ended December 31, 2021, we sold approximately 4.0 million shares of common stock under the 2020 ATM, resulting in net proceeds of $43.1 million. During the year ended December 31, 2022, we sold approximately 11.7 million shares of common stock under the 2020 ATM, resulting in gross proceeds and net proceeds of $55.9 million and $54.8 million, respectively. No shares were sold under the 2020 ATM during the quarter ended December 31, 2022. As of December 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 quarter ended December 31, 2022, we sold approximately 6.0 million shares of common stock under the February 2022 ATM, resulting in gross proceeds and net proceeds of $40.7 million and $39.9 million, respectively. During the year ended December 31, 2022, we sold approximately 18.8 million shares of common stock under the February 2022 ATM, resulting in gross proceeds and net proceeds of $98.4 million and $96.4 million, respectively. Approximately $1.6 million remained unsold and available for sale under the February 2022 ATM as of December 31, 2022.

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. As of December 31, 2022, we had not sold any shares of common stock under the November 2022 ATM.

On May 8, 2019, we entered into a loan and security agreement, or the Prior Credit Facility, with Silicon Valley Bank, or 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, SVB as a lender, and the other lenders from time to time a party thereto, or together the Lenders. The New Credit Facility, as amended on February 17, 2022, October 17, 2022, and December 27, 2022, 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 in one principal advance, if we reach certain development milestone events, through September 30, 2023 and (iii) an additional tranche of $20 million, subject to conditional approval from the Lenders. On May 8, 2019, we drew $25 million from the facility, of which $5.5 million was used to repay in full the existing balance and satisfy our existing obligations to SVB under the Prior Credit Facility. 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 SVB to extend further credit under the Prior Credit Facility and all guarantees and security interests granted by us to SVB under the Prior Credit Facility.

As of December 31, 2022, we had cash and cash equivalents and marketable securities of $280.7 million. In February 2023, we received the $30 million upfront payment due to us from MRKDG. In addition to our existing cash and 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 years ended December 31, 2022, 2021 and 2020:

	Year Ended December 31,		
(in thousands)	**2022**	**2021**	**2020**
Net cash used in operating activities	$ (49,363)	$ (139,988)	$ (74,696)
Net cash (used in) provided by investing activities	(152,716)	(648)	37,027
Net cash provided by financing activities	153,017	63,646	230,412
Increase (decrease) in cash, cash equivalents and restricted cash	$ (49,062)	$ (76,990)	$ 192,743

Net Cash Used in Operating Activities

Net cash used in operating activities was $49.4 million for the year ended December 31, 2022 and primarily consisted of a net loss of $204.2 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 $21.5 million. Net cash used in operating activities was $140.0 million for the year ended December 31, 2021 and primarily consisted of a net loss of $170.1 million adjusted for changes in our net working capital and other non-cash items including stock-based compensation of $18.4 million and depreciation of $0.9 million.

Net Cash Used in Investing Activities

Net cash used in investing activities was $152.7 million during the year ended December 31, 2022 as compared to net cash used in investing activities of $0.6 million during the year ended December 31, 2021. During the year ended December 31, 2022, net cash used in investing activities consisted primarily of purchases of marketable securities, partially offset by maturities of marketable securities. Net cash used in investing activities for the year ended December 31, 2021 consisted primarily of the purchase of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $153.0 million during the year ended December 31, 2022 as compared to $63.6 million during the year ended December 31, 2021. During the year ended December 31, 2022 net cash provided by financing activities consisted primarily of proceeds from the use of our 2020 ATM and February 2022 ATM of $150.9 million. During the year ended December 31, 2021, cash provided by financing activities consisted primarily of the proceeds from the use of the 2020 ATM of $43.1 million and issuance of debt, net of issuance costs, of $24.0 million under the New Credit Facility, as well as proceeds from exercise of stock options of $1.8 million, partially offset by repayment of debt of $5.5 million to repay the Prior Credit Facility.

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 December 31, 2022, we had cash, cash equivalents and marketable securities of $280.7 million, and we subsequently received the $30 million up-front payment from MRKDG under the 2022 Merck KGaA Agreement. In addition, we currently have the option to borrow $15 million under the New Credit Facility. 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

Our material cash requirements from known contractual obligations as of December 31, 2022 primarily consist of operating and finance lease liabilities and principal and interest payments under our New Credit Facility. Our total future minimum lease payments for our finance and operating leases are included in Note 12, *Leases,* in the Notes to Consolidated Financial Statements. The total future undiscounted minimum lease payments, including operating and finance leases, were $14.0 million as of December 31, 2022. Our total future minimum principal payments under our New Credit Facility are included in Note 8, *Debt,* in the Notes to Consolidated Financial Statements. The total future minimum principal payments under our New Credit Facility were $25.0 million as of December 31, 2022.

We enter into agreements in the normal course of business with third parties to assist us with preclinical, clinical, manufacturing, and other products and services for operating purposes. These agreements are generally cancellable at any time by us upon reasonable notice, and certain of these agreements include termination rights subject to termination fees or wind down costs. The exact amounts of such obligations are dependent on the timing of termination and the exact terms of the relevant agreement and cannot be reasonably estimated.

We also have obligations to make future payments to third parties that become due and payable on the achievement of certain milestones, including future payments to third parties with whom we have entered into license agreements. We have not included these commitments on our balance sheet because the achievement and timing of these milestones is not fixed and determinable.

In July 2015, we entered into a license agreement with Recepta Biopharma S.A., or Recepta, for the NaPi2b antibody. We refer to this license agreement, as amended, as the Recepta License. Under the Recepta License, we paid Recepta an upfront payment of $1.0 million and are obligated to pay Recepta up to $65.5 million in development, regulatory and commercial milestones and tiered royalties in the low-single digit percentages on net sales of products outside of Brazil until the expiration of the royalty term. Upon the expiration of each royalty term in each country for each applicable product, the exclusive licenses granted to each party under the Recepta License will become fully-paid up and royalty-free. We have incurred and paid $4.0 million in development milestone payments under the Recepta License.

In January 2019, we entered into a commercial license agreement with Synaffix B.V., or Synaffix, which we amended and restated in November 2021 and February 2022 to expand our relationship with Synaffix. We refer to the amended and restated agreement as the Synaffix License. Under the Synaffix License, we have the right to develop, manufacture and commercialize ADCs directed to targets using Synaffix's proprietary site-specific conjugation technology. We have licensed five targets in connection with our development programs and collaborations, and we have the right to license up to six additional targets. We have paid $6.8 million related to the Synaffix License, comprised of $4.0 million in reservation and license fees, $1.8 million in milestone payments and $1.0 million which may be applied to future reservation and license fees, as well as certain portions of potential future development milestones. We will be obligated to pay in the range of $48.0 million to $132.0 million for issuance, development, regulatory and commercial milestones. Upon commencement of commercial sales of any ADC product directed to a licensed target, if any, we are required to pay to Synaffix tiered royalties in the low-single digit percentages on net sales of the respective products. The Synaffix License remains in effect on a country-by-country and licensed product-by-licensed product basis until the expiration of the last-to-expire valid claim in a patent licensed under the Synaffix License covering such product in such country. Upon the expiration of the Synaffix License for each licensed product in each country, the licenses granted to us for such product in such country will become fully paid-up and perpetual. We may terminate the Synaffix License in its entirety or on a licensed product-by-licensed product basis at any time. Either party may terminate the Synaffix License, subject to a specified notice and cure period, for a breach by the other party of a material provision of the agreement or upon an insolvency-related event experienced by the other party.

Critical Accounting Policies and Significant Judgements and 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.

We believe that our most critical accounting policies are those relating to revenue recognition and accrued research and development expenses as discussed in the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K.

Revenue Recognition

We enter into collaboration agreements which are within the scope of Accounting Standards Update 2014-09, *Revenue from Contracts with Customers*, or ASC 606, under which we license rights to our technology and certain of our product candidates and perform research and development services for third parties. The terms of these arrangements typically include payment of one or more of the following: non-refundable, up-front fees; reimbursement of research and development costs; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of contract(s) with a customer; (ii) determination of whether the promised goods or services are performance obligations; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The promised good or services in our arrangements typically consist of license rights to our intellectual property and research and development services. We also have optional additional items in contracts, which are considered marketing offers and are accounted for as separate contracts with the customer if such option is elected by the customer, unless the option provides a material right which would not be provided without entering into the contract. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources or (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own or whether the required expertise is readily available.

We estimate the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration and at each reporting period, we evaluate the amount of potential payment and the likelihood that the payments will be received. We utilize either the most likely amount method or expected amount method to estimate the amount expected to be received based on which method better predicts the amount expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

Our contracts often include development and regulatory milestone payments. At contract inception and at each reporting period, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is not probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are not included in the transaction price. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

We allocate the transaction price based on the estimated standalone selling price of the underlying performance obligations or in the case of certain variable consideration to one or more performance obligations. We must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs to complete the respective performance obligation. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable

consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts we would expect to receive for each performance obligation.

For performance obligations consisting of licenses and other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

Collaborative Arrangements

We record the elements of our collaboration agreements that represent joint operating activities in accordance with ASC 808, *Collaborative Arrangements*. Accordingly, the elements of the collaboration agreements that represent activities in which both parties are active participants and to which both parties are exposed to the significant risks and rewards that are dependent on the commercial success of the activities, are recorded as collaborative arrangements. We consider the guidance in ASC 606 in determining the appropriate treatment for the transactions between us and our collaborators and the transactions between us and third parties. Generally, the classification of transactions under the collaborative arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. To the extent revenue is generated from a collaboration, we will recognize our share of the net sales on a gross basis if we are deemed to be the principal in the transactions with customers, or on a net basis if we are instead deemed to be the agent in the transactions with customers, consistent with the guidance in ASC 606.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We record our expenses related to research and development activities based upon our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed, enrollment of subjects, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrued or prepaid expense balance accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. To date, there have been no material differences from our estimates to the amounts actually incurred. Significant judgement is involved in making the above estimates.

Recent accounting pronouncements

See Note 2, *Recently Issued Accounting Pronouncements,* in the Notes to Consolidated Financial Statements for a description of recent accounting pronouncements applicable to our business.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risks

We are exposed to market risk related to changes in interest rates. As of December 31, 2022, we had cash, cash equivalents and marketable securities of $280.7 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 December 31, 2022, 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Mersana Therapeutics, Inc.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Mersana Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Mersana Therapeutics, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, consolidated statement of stockholders' equity, and consolidated statement of cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued & Prepaid Clinical Expenses

Description of the Matter

As summarized in Note 7 to the consolidated financial statements, the Company's accrual for clinical expenses totaled $14.8 million as of December 31, 2022. In addition, the Company's Prepaid Expenses and Other Current Assets totaled $8.5 million, which included amounts that were paid in advance of services pursuant to clinical trials as of December 31, 2022. As discussed in Note 2 to the consolidated financial statements, the Company is required to estimate clinical costs incurred and related accruals or remaining prepaid expenses based on certain information, including actual costs incurred or level of effort expended, as provided by its vendors. Payments for such activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred.

Auditing the Company's accrued and prepaid clinical expenses was complex and judgmental, as the amounts are based on various estimates from third-party vendors, as well as other inputs estimated by members of management, such as, actual costs incurred but not yet billed, estimated project timelines, and the costs associated with these services. Furthermore, due to the duration of the Company's ongoing research and development activities and the timing of invoicing received from third parties, the actual amounts incurred are not typically known by the date the financial statements are issued.

How We Addressed the Matter in Our Audit

To test the accrued and prepaid clinical expenses, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used to estimate the amounts recorded. We corroborated the progress of research and development activities through discussion with the Company's research and development personnel that oversee the research and development projects. We also inspected the Company's contracts with third parties and any pending change orders to assess the impact on amounts recorded. Additionally, we independently confirmed and/or reviewed information received by the Company directly from certain sites and other third parties, which included third parties' estimates of costs incurred to date. We also performed analytical procedures over fluctuations in accrued and prepaid clinical expenses by vendor, study, or other significant work order throughout the period subject to audit and inspected subsequent invoices received from third parties to assess the impact to the accrued and prepaid balances.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.
Boston, Massachusetts
February 28, 2023

Mersana Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 128,885	$ 177,947
Short-term marketable securities	151,827	—
Accounts receivable	30,000	—
Prepaid expenses and other current assets	8,507	10,951
Total current assets	319,219	188,898
Property and equipment, net	3,985	1,968
Operating lease right-of-use assets	10,475	12,889
Other assets, noncurrent	661	2,356
Total assets	$ 334,340	$ 206,111
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 13,951	$ 12,321
Accrued expenses	43,184	28,716
Deferred revenue	30,610	3,944
Operating lease liabilities	2,798	2,303
Other current liabilities	990	239
Total current liabilities	91,533	47,523
Operating lease liabilities, noncurrent	8,575	11,247
Long-term debt, net	24,929	24,626
Deferred revenue, noncurrent	117,043	—
Other liabilities, noncurrent	203	974
Total liabilities	242,283	84,370
Commitments (Note 15)		
Stockholders' equity		
Preferred stock, $0.0001 par value; 25,000,000 shares authorized; 0 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.0001 par value; 350,000,000 and 175,000,000 shares authorized at December 31, 2022 and December 31, 2021, respectively; 105,144,864 and 73,709,056 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	11	7
Additional paid-in capital	746,889	572,213
Accumulated other comprehensive loss	(152)	—
Accumulated deficit	(654,691)	(450,479)
Total stockholders' equity	92,057	121,741
Total liabilities and stockholders' equity	$ 334,340	$ 206,111

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

Mersana Therapeutics, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Year ended December 31,		
	2022	2021	2020
Collaboration revenue	$ 26,581	$ 43	$ 828
Operating expenses:			
Research and development	173,385	132,013	67,036
General and administrative	56,963	36,888	21,902
Total operating expenses	230,348	168,901	88,938
Other income (expense):			
Interest income	2,883	65	424
Interest expense	(3,328)	(1,267)	(359)
Total other income (expense), net	(445)	(1,202)	65
Net loss	$ (204,212)	$ (170,060)	$ (88,045)
Other comprehensive loss:			
Unrealized loss on marketable securities	(152)	—	(25)
Comprehensive loss	$ (204,364)	$ (170,060)	$ (88,070)
Net loss attributable to common stockholders — basic and diluted	$ (204,212)	$ (170,060)	$ (88,045)
Net loss per share attributable to common stockholders — basic and diluted	$ (2.18)	$ (2.41)	$ (1.43)
Weighted-average number of shares of common stock used in net loss per share attributable to common stockholders — basic and diluted	93,654,243	70,580,949	61,485,205

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

Mersana Therapeutics, Inc.

Consolidated Statements of Stockholders' Equity

(in thousands, except share and per share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	45,388,023	$ 5	$ 270,662	$ 25	$ (192,374)	$ 78,318
Issuance of common stock from at-the-market transactions, net of issuance costs of $2,176	10,900,599	1	62,976	—	—	62,977
Issuance of common stock under public offering, net of issuance costs of $10,809	9,200,000	1	163,990	—	—	163,991
Exercise of common stock warrant in exchange for common stock	2,574,971	—	—	—	—	—
Exercise of stock options	697,428	—	3,138	—	—	3,138
Purchase of common stock under ESPP	80,267	—	561	—	—	561
Stock-based compensation expense	—	—	7,172	—	—	7,172
Other comprehensive loss	—	—	—	(25)	—	(25)
Net loss	—	—	—	—	(88,045)	(88,045)
Balance at December 31, 2020	68,841,288	$ 7	$ 508,499	$ —	$ (280,419)	$ 228,087
Issuance of common stock from at-the-market transactions, net of issuance costs of $988	3,961,074	—	43,087	—	—	43,087
Exercise of stock options	421,381	—	1,837	—	—	1,837
Vesting of restricted stock units, net of employee tax obligation	407,060	—	(259)	—	—	(259)
Purchase of common stock under ESPP	78,253	—	640	—	—	640
Stock-based compensation expense	—	—	18,409	—	—	18,409
Net loss	—	—	—	—	(170,060)	(170,060)
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 $3,476	30,497,875	4	150,758	—	—	150,762
Exercise of stock options	414,914	—	1,331	—	—	1,331
Exercise of common stock warrant	16,654	—	—	—	—	—
Vesting of restricted stock units	235,591	—	—	—	—	—
Purchase of common stock under ESPP	270,774	—	1,065	—	—	1,065
Stock-based compensation expense	—	—	21,522	—	—	21,522
Other comprehensive loss	—	—	—	(152)	—	(152)
Net loss	—	—	—	—	(204,212)	(204,212)
Balance at December 31, 2022	105,144,864	$ 11	$ 746,889	$ (152)	$ (654,691)	$ 92,057

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

Mersana Therapeutics, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	Year ended December 31,		
	2022	**2021**	**2020**
Cash flows from operating activities			
Net loss	$ (204,212)	$ (170,060)	$ (88,045)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	927	855	1,010
Net amortization of premiums and discounts on marketable securities	(1,462)	—	(86)
Stock-based compensation	21,522	18,409	7,172
Other non-cash items	763	723	148
Changes in operating assets and liabilities:			
Accounts receivable	(30,000)	—	—
Prepaid expenses and other current assets	3,863	(2,734)	(1,950)
Other assets	—	(718)	(700)
Accounts payable	947	483	942
Accrued expenses	13,594	12,570	7,280
Operating lease right-of-use assets	2,777	1,829	1,642
Operating lease liabilities	(2,539)	(1,827)	(1,281)
Deferred revenue	143,709	(43)	(828)
Other liabilities	748	525	—
Net cash used in operating activities	(49,363)	(139,988)	(74,696)
Cash flows from investing activities			
Maturities of marketable securities	97,000	—	37,500
Purchase of marketable securities	(247,519)	—	—
Purchase of property and equipment	(2,197)	(648)	(473)
Net cash used in investing activities	(152,716)	(648)	37,027
Cash flows from financing activities			
Net proceeds from public offering of common stock	—	—	163,990
Net proceeds from at-the-market facilities	150,893	43,087	63,036
Proceeds from exercise of stock options	1,331	1,837	3,138
Proceeds from purchases of common stock under ESPP	1,065	640	561
Payment of employee tax obligations related to vesting of restricted stock units	—	(259)	—
Proceeds from issuance of debt, net of issuance costs	—	24,042	(197)
Repayment of debt	—	(5,486)	—
Payments under finance lease obligations	(272)	(215)	(116)
Net cash provided by financing activities	153,017	63,646	230,412
Increase (decrease) in cash, cash equivalents and restricted cash	(49,062)	(76,990)	192,743
Cash, cash equivalents and restricted cash, beginning of period	178,425	255,415	62,672
Cash, cash equivalents and restricted cash, end of period	$ 129,363	$ 178,425	$ 255,415
Supplemental disclosures of non-cash activities:			
Purchases of property and equipment in accounts payable and accrued expenses	$ 753	$ —	$ 102
Debt financing costs in accrued expenses	$ 150	$ —	$ —
Common stock issuance costs in accounts payable and accrued expenses	$ 131	$ —	$ —
Cash paid for interest	$ 2,463	$ 429	$ 234
Right-of-use assets obtained in exchange for operating lease liabilities	$ 298	$ 3,783	$ 9,980
Right-of-use assets obtained in exchange for financing lease liabilities	$ —	$ 609	$ —

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

Mersana Therapeutics, Inc.
Notes to 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, and XMT-2056, an Immunosynthen STING-agonist ADC that is designed to target a novel epitope of human epidermal growth factor receptor 2 ("HER2"), in a Phase 1 clinical trial enrolling previously treated patients with advanced/recurrent solid tumors expressing HER2, including breast, gastric, colorectal and non-small cell lung cancers. 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. The Company's net loss was $204.2 million, $170.1 million and $88.0 million for the years ended December 31, 2022, 2021 and 2020, respectively. The Company expects to continue to incur operating losses for at least the next several years. As of December 31, 2022, the Company had an accumulated deficit of $654.7 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 Annual Report on Form 10-K. 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 accompanying 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").

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying 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 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.

Research and Development

Research and development costs are expensed as incurred and include:

- employee-related expenses, including salaries, bonuses, benefits, travel and stock-based compensation expense;
- fees and expenses incurred under agreements with contract research organizations, investigative sites and other entities in connection with the conduct of preclinical studies, clinical trials and related services;
- the cost of acquiring, developing and manufacturing ADC product candidates, clinical trial materials and other research and development materials;
- fees and costs related to regulatory filings and activities;
- costs associated with collaboration agreements and license fees and milestone payments related to license agreements;
- costs associated with creating and obtaining approval for the NaPi2b companion or complementary diagnostic biomarker;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent, utilities, maintenance of facilities, insurance and other supplies; and
- other costs associated with clinical, preclinical, discovery and other research activities.

Costs for certain development activities, such as preclinical studies, clinical trials and manufacturing development activities, 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 the Company by its vendors on their actual costs incurred or level of effort expended. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheets as prepaid or accrued preclinical, manufacturing and clinical expenses.

Revenue Recognition

The Company enters into collaboration agreements which are within the scope of ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), under which the Company licenses rights to its technology and certain of the Company's product candidates and performs research and development services for third parties. The terms of these arrangements typically include payment of one or more of the following: non-refundable, up-front fees; reimbursement of research and development costs; development, regulatory and commercial milestone payments; and royalties on net sales of licensed products.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of contract(s) with a customer; (ii) determination of whether the promised goods or services are performance obligations; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

The promised good or services in the Company's arrangements typically consist of license rights to the Company's intellectual property and research and development services. The Company also has optional additional items in contracts, which are considered marketing offers and are accounted for as separate contracts with the customer if such option is elected by the customer, unless the option provides a material right which would not be provided without entering into the contract. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources or (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on their own and the availability of the required expertise.

The Company estimates the transaction price based on the amount expected to be received for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration and at each reporting period, the Company evaluates the amount of potential payment and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate the amount expected to be received based on which method better predicts the amount of consideration to which the Company will be entitled. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price. We assessed each of our revenue generating arrangements in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist in any of our arrangements because: (a) the promised consideration approximates the cash selling price of the promised goods and services; and (b) timing of payment approximates the transfer of goods and services and performance is over a relatively short period of time within the context of the entire term of the contract.

The Company's contracts often include development and regulatory milestone payments. At contract inception and at each reporting period, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not included in the transaction price. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration and other revenues and earnings in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of the Company's collaboration arrangements.

The Company allocates the transaction price based on the estimated standalone selling price of the underlying performance obligations or in the case of certain variable consideration to one or more performance obligations. The Company must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction and the estimated costs to complete the respective performance obligation. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts the Company would expect to receive for each performance obligation.

For performance obligations consisting of licenses and other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company will recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license.

The Company receives payments from its customers based on billing schedules established in each contract. Such billings generally have 30-day terms. Up-front payments and fees are recorded as a contract liability (deferred revenue) upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the right to consideration is unconditional and only the passage of time is required before payment is due. If the right to consideration is subject to a condition other than the passage of time, then the amount is recorded as a contract asset until the right to payment becomes unconditional. In accordance with ASC 606, the Company presents contract assets and contract liabilities on a net basis by customer contract.

Collaborative Arrangements

The Company records the elements of its collaboration agreements that represent joint operating activities in accordance with ASC 808, *Collaborative Arrangements* ("ASC 808"). Accordingly, the elements of the collaboration agreements that represent activities in which both parties are active participants and to which both parties are exposed to the significant risks and rewards that are dependent on the commercial success of the activities, are recorded as collaborative arrangements. The Company also considers the guidance in ASC 606 by analogy in determining the appropriate treatment for the transactions between the Company and its collaborators and the transactions between the Company and third parties. Generally, the classification of transactions under the collaborative arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. To the extent revenue is generated from a collaboration, the Company will recognize its share of the net sales on a gross basis if it is deemed to be the principal in the transactions with customers, or on a net basis if it is instead deemed to be the agent in the transactions with customers, consistent with the guidance in ASC 606.

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.

Marketable Securities

The Company's investment strategy is focused on capital preservation. The Company invests in instruments that meet the credit quality standards outlined in the Company's investment policy. Short-term marketable securities consist of investments in debt securities with maturities greater than three months and less than one year from the balance sheet date. The Company classifies all of its marketable securities as available-for-sale. Accordingly, these investments are recorded at fair value. Fair value is determined based on quoted market prices. Amortization and accretion of discounts and premiums are recorded as interest income within other income (expense), net. Realized gains and losses are included in other income (expense), net.

The Company assesses its available-for-sale debt securities under the available-for-sale debt security impairment model in ASC 326, *Financial Instruments - Credit Losses*, as of each reporting date in order to determine if a portion of any decline in fair value below carrying value recognized on its available-for-sale debt securities is the result of a credit loss. The Company records credit losses in the consolidated statements of operations and comprehensive loss as a component of other income (expense), net, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale debt securities.

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. These investments are subject to minimal credit and market risks. Cash and cash equivalents are stated at cost, which approximates market value.

Accounting for Stock-based Compensation

The Company accounts for its stock-based compensation in accordance with ASC 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments to employees, directors and non-employees to be recognized as expense in the statements of operations based on their grant date fair values. The Company estimates the fair value of options granted using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. The expected stock price volatility is calculated based on a period of time commensurate with the expected term assumption. Historically, due to the lack of a public market for the Company's common stock prior to completion of its initial public offering and a lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. During 2022, the Company began to estimate its volatility by using a blend of its stock price history for the length of time it has market data for its stock and the historical volatility of similar public companies for the expected term of each grant. For option grants with an expected term for which sufficient stock price history for the Company exists, expected stock price volatility is calculated using the average of volatilities for the period of the expected term prior to the grant date. For options granted to non-employees, the Company utilizes the contractual term of the option arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to do so.

The Company determines the fair value of each restricted stock unit ("RSU") at its grant date based on the closing market price of the Company’s common stock on that date or, if the date of grant is not a day on which the Company's primary trading market was open, the immediately preceding trading day. For stock-based compensation subject to service-based vesting conditions, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock-based compensation on a straight-line basis over the requisite service period.

The Company records forfeitures as a cumulative adjustment in the period in which they occur.

Property and Equipment

Property and equipment is stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful life of each asset as follows:

Computer equipment, office equipment and software	3 years
Laboratory equipment	5 years
Leasehold improvements	Shorter of useful life or life of lease

Upon retirement or sale, the cost of the disposed assets and the related accumulated depreciation are eliminated from the balance sheet, and related gains or losses are reflected in the statement of operations. There were no material sales of assets during the years ended December 31, 2022, 2021 and 2020.

The Company reviews its long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. If the Company performs an impairment review to evaluate an asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the asset to its carrying value. If the carrying amount of the asset exceeds its estimated undiscounted future net cash flows, the Company recognizes an impairment charge in the amount by which the carrying amount of the asset exceeds the fair value of the asset. The Company did not recognize impairment charges during the years ended December 31, 2022, 2021 and 2020.

Leases

Consistent with ASC 842, *Leases*, the Company determines if an arrangement is a lease at inception. Operating leases are included in right-of-use lease assets ("ROU assets"), current portion of lease obligations and long-term lease obligations on the Company's consolidated balance sheets. Assets subject to finance leases are included in property and equipment, and the related lease obligation is included in other current liabilities and other long-term liabilities on the Company's consolidated balance sheets. Lease assets are tested for impairment in the same manner as long-lived assets used in operations. Lease expense for operating leases is recognized on a straight-line basis over the lease term as an operating expense while expense for financing leases is recognized as depreciation expense and interest expense using the effective interest method. The Company has elected the short-term lease recognition exemption for short-term leases, which allows the Company not to recognize lease liabilities and ROU assets on the consolidated balance sheets for leases with an original term of twelve months or less.

ROU assets represent the Company's right to use an underlying asset for the lease term, and lease obligations represent the Company's obligation to make lease payments arising from the lease. Operating lease liabilities and their corresponding ROU assets are initially recorded based on the present value of lease payments over the expected remaining lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the option will be exercised. Certain adjustments to the ROU asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments. The incremental borrowing rate reflects the fixed rate at which the Company could borrow, on a collateralized basis, the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Prospectively, the Company will adjust the ROU assets for straight-line rent expense, or any incentives received and remeasure the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date.

The Company accounts for lease agreements with lease and non-lease components separately.

Patent Costs

The Company expenses patent application and related legal costs as incurred and classifies such costs as general and administrative expenses in the accompanying consolidated statements of operations.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, *Accounting for Income Taxes*, which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. The Company determines its deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company recognizes the effect of income tax positions only if those positions are more likely than not to be sustained. Recognized income tax positions are measured at the largest amount that is more likely than not to be realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs.

Comprehensive Income (Loss)

Comprehensive income (loss) comprises net loss and other comprehensive loss. For the years ended December 31, 2022 and 2020, other comprehensive income (loss) consisted of changes in unrealized income and loss on marketable securities. For the year ended December 31, 2021, comprehensive loss equaled net loss.

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.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard-setting bodies, and the Company adopts such pronouncements as of the specified effective date. Unless otherwise discussed below, the Company does not believe that the adoption of recently issued standards has had or may have a material impact on the Company's 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 co-develop 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. After the GSK Option Exercise, if any, GSK may elect to manufacture XMT-2056, and GSK and the Company will co-develop XMT-2056 aimed at the approval of Licensed Product(s) in the United States and the European Union, with GSK being responsible for the majority of the development costs. GSK will be responsible for all development costs aimed solely at gaining approval outside the United States and European Union.

Pursuant to the GSK Agreement, following the GSK Option Exercise and subject to certain exceptions and specified payment obligations, the Company’s aggregate shared development costs are capped at a fixed amount, with any amounts in excess to be borne by GSK unless and until the Company exercises its option to receive (or bear) a specified share of U.S. profits (or losses) for any Licensed Products (“Profit Share Election”). The excess development costs will accrue interest as specified in the GSK Agreement and will later either be repaid by the Company or offset against future regulatory and sales milestones or royalty payments that may become due to the Company. If the Company exercises its Profit Share Election, the cap on the Company’s share of development costs shall no longer apply, and the Company must pay any then-outstanding excess plus accrued interest costs. Additionally, if the Company exercises its Profit Share Election, it may also simultaneously elect to co-promote any Licensed Products in the United States.

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 Company is eligible to receive future development, regulatory, and commercial milestone payments up to approximately $1.3 billion and, if the Company does not exercise its Profit Share Election, tiered royalties up to the mid-twenty percent range based on global sales of Licensed Products. Included in the aggregate milestone payments amount is $30 million that the Company is eligible to earn upon the satisfaction of early clinical development milestones that may occur prior to the GSK Option Exercise. If the Company exercises its Profit Share Election, the Company will be eligible to receive reduced development, regulatory, and commercial milestone payments and reduced royalty rates on sales outside of the United States. Whether or not the Company exercises its Profit Share Election, GSK will be responsible for certain milestone payments or royalties due to specified third parties with which the Company currently has agreements that relate to the XMT-2056 program.

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 concluded that the Development Activities are one distinct performance obligation, as the underlying activities are not distinguishable in the context of the contract and are inputs to an integrated development program that will generate data and information providing value to GSK in determining whether to exercise the Option. The License Option is considered a material right as the value of the license exceeds the Option Payment, and is therefore a distinct performance obligation.

In accordance with ASC 606, the Company determined that the initial transaction price under the GSK Agreement equals $100.0 million, consisting of the upfront, non-refundable and non-creditable payment paid by GSK. None of the early clinical development milestones that may occur prior to the GSK Option Exercise have been included in the initial transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including stage of development and the remaining risks associated with the development required to achieve the milestones, as well as whether the achievement of the milestones is outside the control of the Company or GSK. The GSK Option payment is excluded from the initial transaction price at contract inception along with any future development, regulatory, and commercial milestone payments (including royalties) following the GSK Option Exercise.

Consistent with the allocation objective under ASC 606, the Company allocated the $100.0 million fixed upfront payment in the transaction price to the Development Activities and the License Option based on each performance obligation’s relative standalone selling price. The standalone selling price for the Development Activities was calculated using a cost-plus margin approach for the estimated pre-option development timeline. For the standalone selling price of the License Option, the Company utilized an income-based approach which included the following key assumptions: post-option development timeline and costs, revenue forecast, discount rates and probabilities of technical and regulatory success.

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 will defer 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 year ended December 31, 2022, the Company recorded collaboration revenue of $2.0 million related to its efforts under the GSK Agreement. As of December 31, 2022, the Company had recorded $98.0 million 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. Pursuant to the Janssen Agreement, the Company granted Janssen two exclusive, nontransferable, worldwide licenses - a research license and a commercialization license (together, the "Janssen Licenses"). The research license that forms a part of the Janssen Licenses provides Janssen, on a target-by-target basis, rights under the Company's technology and the Company's interest in the technology developed jointly through the collaboration solely to conduct Janssen's activities under the research and Chemistry, Manufacturing and Controls ("CMC") plans with respect to each target. The commercialization license that forms a part of the Janssen Licenses is a royalty-bearing license granted on a target-by-target basis under the Company's technology and the Company's interest in the technology developed jointly through the collaboration to develop, manufacture, commercialize and otherwise exploit licensed ADCs and any licensed products containing licensed ADCs directed toward a target. 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. Janssen will have sole responsibility for IND-enabling studies, IND submission, clinical development, regulatory activities and commercialization of the licensed ADCs. Both the Company and Janssen will have equal representation on a Joint Research Committee and Joint Manufacturing Committee to oversee the research and CMC activities. 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. Assuming successful development and commercialization of all three targets by Janssen, the Company could receive up to an additional $505 million in development and regulatory milestones and $530 million in sales milestones as well as tiered mid single-digit to low double-digit royalties on aggregate net sales of the ADC products.

Unless earlier terminated, the Janssen Agreement will expire upon the expiration of the last royalty term for a product under the Janssen Agreement. The Janssen Agreement contains customary provisions for termination by either party, including in the event of breach of the Janssen Agreement, subject to cure, by Janssen for convenience and by Mersana upon a challenge of the licensed patents, and customary provisions regarding the effects of termination.

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 concluded that the Janssen Licenses and research activities are one combined performance obligation for each target as the Janssen Licenses are not capable of being distinct from the research activities given their proprietary nature. The CMC activities are considered a distinct performance obligation for each target as the activities could be performed by a third-party provider. The first target substitution right is considered a material right as there is no option exercise fee and, as such, is a distinct performance obligation.

In accordance with ASC 606, the Company determined that the initial transaction price under the Janssen Agreement equals $40.0 million, consisting of the upfront, non-refundable and non-creditable payment. None of the development and the regulatory milestones were included in the initial transaction price, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including stage of development and the remaining risks associated with the development required to achieve the milestones, as well as whether the achievement of the milestones is outside the control of the Company or Janssen. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as such milestones were determined to relate predominantly to the license granted to Janssen and therefore have also been excluded from the transaction price. As of December 31, 2022, the revised total transaction price for the Janssen Agreement was $42.0 million. During 2022, the Company revised the estimated transaction price by $2.0 million based on the reassessment of the constraint of certain development milestones and the remaining risks associated with the development required to achieve the milestones.

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.

Consistent with the allocation objective under ASC 606, the Company allocated the total transaction price to the Janssen Licenses and research activities and first substitution right based on each performance obligation's relative standalone selling price. Each of the standalone selling prices for the Janssen Licenses and research activities and for the first substitution right were estimated utilizing an income approach, along with the likelihood of exercise for the substitution right and included the following key assumptions: the development timeline, revenue forecast, discount rate and probabilities of technical and regulatory success.

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 will recognize 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 year ended December 31, 2022, the Company recorded collaboration revenue of $24.2 million related to its performance obligations under the Janssen Agreement. As of December 31, 2022, the Company had recorded $15.8 million 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 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. Within 45 days of execution of 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"). The research license that forms a part of the MRKDG Licenses provides MRKDG, on a target-by-target basis, rights under the Company's technology and the Company's interest in the technology developed jointly through the collaboration solely to conduct MRKDG's activities under the research and CMC plans with respect to each target. The commercialization license that forms a part of the MRKDG Licenses is a royalty-bearing license granted on a target-by-target basis under the Company's technology and the Company's interest in the technology developed jointly through the collaboration to develop, manufacture, commercialize and otherwise exploit licensed ADCs and any licensed products containing licensed ADCs directed toward a target.

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. MRKDG will have sole responsibility for IND-enabling studies, IND submission, clinical development, regulatory activities and commercialization of the licensed ADCs. Both the Company and MRKDG will have equal representation on a Joint Research Committee and Joint Manufacturing Committee to oversee the research and CMC activities. 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. Assuming successful development and commercialization of the two targets by MRKDG, the Company could receive up to an additional $200 million in development and regulatory milestones and $600 million in sales milestones as well as tiered single-digit to low double-digit royalties on aggregate net sales of the ADC products. To date, the Company has not achieved any of the specified milestones.

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. The 2022 Merck KGaA Agreement contains customary provisions for termination by either party, including in the event of breach of the 2022 Merck KGaA Agreement, subject to cure, by MRKDG for convenience and by Mersana upon a challenge of the licensed patents, and customary provisions regarding the effects of termination.

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 concluded that the MRKDG Licenses and research activities are one combined performance obligation for each target as the MRKDG Licenses are not capable of being distinct from the research activities given their proprietary nature. The CMC activities are considered a distinct performance obligation for each target as the activities could be performed by a third-party provider.

In accordance with ASC 606, the Company determined that the initial transaction price under the 2022 Merck KGaA Agreement equals $32.0 million, consisting of the $30.0 million upfront, non-refundable and non-creditable fee and certain near-term discovery milestones. As the $30.0 million upfront fee was not received by the Company as of December 31, 2022, the Company recorded an accounts receivable for $30.0 million with a corresponding deferred revenue liability. The Company subsequently received this payment in February 2023. The development and the regulatory milestones not included in the transaction price were constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including stage of development and the remaining risks associated with the development required to achieve the milestones, as well as whether the achievement of the milestones is outside the control of the Company or MRKDG. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as such milestones were determined to relate predominantly to the license granted to MRKDG and therefore have also been excluded from the transaction price.

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 either of the two 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.

Consistent with the allocation objective under ASC 606, the Company allocated the $32.0 million estimated transaction price to the MRKDG Licenses and research activities based on each performance obligation’s relative standalone selling price. Each of the standalone selling prices for the MRKDG Licenses and research activities were estimated utilizing an adjusted market assessment approach, which was established based on comparable transactions.

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.

The Company did not record collaboration revenue related to the 2022 Merck KGaA Agreement during the year ended December 31, 2022. As of December 31, 2022, the Company had recorded $30.0 million 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.

In addition to the payments received for research and development activities performed on behalf of Merck KGaA, the Company could be eligible to receive up to a total of $780.0 million in future milestones related to all targets under the 2014 Merck KGaA Agreement, plus low to mid-single digit royalties on the commercial sales of any resulting products during the applicable royalty term. The total milestones are categorized as follows: development milestones $84.0 million; regulatory milestones $264.0 million; and sales milestones $432.0 million. There are six individual development milestones per target, payable upon the completion of various activities, from the delivery of ADCs meeting defined specifications, through the dosing in a Phase 3 clinical trial. There are five regulatory milestones, which are payable upon regulatory approvals for a first indication in each of the U.S., European Union and Japanese markets and regulatory approvals for both a second and a third indication in the United States. There are three individual commercial milestones, which are payable upon the attainment of certain defined thresholds for annual net sales.

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 in the years ended December 31, 2022 or 2021.

Unless earlier terminated, the 2014 Merck KGaA Agreement will expire upon the expiration of the last royalty term for a product under the 2014 Merck KGaA Agreement, after which time, Merck KGaA will have a perpetual, royalty-free license, or if Merck KGaA does not designate any ADC product candidates produced by the Company under the 2014 Merck KGaA Agreement as preclinical development candidates, upon the expiration of the last to expire research program. Merck KGaA may terminate the 2014 Merck KGaA Agreement in its entirety or with respect to any target for convenience upon 60 days' prior written notice. Each party may terminate the 2014 Merck KGaA Agreement in its entirety upon bankruptcy or similar proceedings of the other party or upon an uncured material breach of the 2014 Merck KGaA Agreement by the other party. However, if such breach only relates to one target, the agreement may only be terminated with respect to such target.

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 has concluded that each license for a designated target is not distinct from the research services performed related to the designated target as Merck KGaA cannot obtain the benefit of the license without the related research services. Each license for a designated target and the related services performance obligation is considered distinct from every other license for a designated target and related services performance obligation as each research plan is pursued independent of every other research plan for other designated targets.

The Company utilizes the expected value approach to estimate the amount of consideration related to the payment of fees associated with development and research services. The Company utilizes the most likely amount approach to estimate any development and regulatory milestone payments to be received. As of the date of initial application of ASC 606, there were no milestones payments that had not already been received, included in the estimated transaction price. The Company considered the stage of development and the remaining risks associated with the remaining development required to achieve the milestone, as well as whether the achievement of the milestone is outside the control of the Company or Merck KGaA. The milestone payment amounts were fully constrained, as a result of the uncertainty whether any of the associated milestones would be achieved. The Company has determined that any commercial milestones and sales based royalties will be recognized when the related sales occur as they were determined to relate predominantly to the license granted and therefore have also been excluded from the transaction price.

The transaction price was allocated to the performance obligations based on the relative estimated standalone selling prices of each performance obligation or in the case of certain variable consideration to one or more performance obligations. The estimated standalone selling prices for performance obligations, that include a license and research services, were developed using the estimated selling price of the license and an estimate of the overall effort to perform the research service and an estimated market rate for research services. The estimated standalone selling price of the licenses was established based on comparable transactions. The estimated standalone selling price for the rights to future technological improvements was developed based on the estimated selling prices of a license or rights received, as well as considering the probability that additional technology would be made available or the probability the counterpart would utilize the technology. The estimated standalone selling price for the joint research committee services was developed using an estimate of the time and costs incurred to participate in the committees.

The Company re-evaluates the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. As of December 31, 2022 and 2021, the total estimated transaction price for the 2014 Merck KGaA Agreement was $21.3 million.

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 December 31, 2022, 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 years ended December 31, 2022 and 2021 was immaterial. During the year ended December, 31 2020, the Company recorded collaboration revenue of $0.8 million related to its efforts under the 2014 Merck KGaA Agreement. There was no collaboration revenue or corresponding research and development expense recognized during the years ended December 31, 2022, 2021, and 2020 related to the 2018 Merck KGaA Supply Agreement.

As of each of December 31, 2022 and 2021, 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
Year ended December 31, 2022				
Contract liabilities:				
Total deferred revenue	$ 3,944	$ 170,000	$ 26,291	$ 147,653
Year ended December 31, 2021				
Contract liabilities:				
Total deferred revenue	$ 3,987	$ —	$ 43	$ 3,944

The Company did not record any contract assets associated with its collaboration agreements as of December 31, 2022 and December 31, 2021.

During the years ended December 31, 2022 and 2021 the Company recognized the following revenues as a result of changes in the contract liability balances in the respective periods:

	Year ended December 31,	
	2022	2021
Revenue recognized in the period from:		
Amounts included in the contract liability at the beginning of the period	$ 43	$ 43
Performance obligations satisfied in previous periods	$ —	$ —

Other Revenue

The Company has provided limited services for a collaborator, Asana BioSciences, LLC ("Asana Biosciences"). During the year ended December 31, 2022, the Company recognized revenue of $0.3 million related to these services and did not recognize revenue related to these services during the years ended 2021 and 2020. The next potential milestone the Company is eligible to receive is $2.5 million upon dosing the fifth patient in a Phase 1 clinical trial by Asana BioSciences. While the first patient was dosed in April 2022, as of December 31, 2022, the Company considered this next milestone to be fully constrained as there was considerable judgment involved in determining whether it is probable that a significant revenue reversal would occur. As part of its evaluation of the constraint, the Company considered numerous factors, including the fact that achievement of the milestone is outside the control of the Company and there was a high level of uncertainty in achieving this milestone, as the collaborator continues to evaluate its candidate in the Phase 1 trial.

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. The Company had no marketable securities as of December 31, 2021.

	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 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 December 31, 2022 and 2021, the carrying value of the Company’s outstanding borrowing under the New Credit Facility (as defined in Note 8) 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 8, *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 December 31, 2022 and 2021.

(in thousands)	Year Ended December 31, 2022		Year ended December 31, 2021	
	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	$ 177,947	$ 128,885	$ 255,094	$ 177,947
Restricted cash included in other assets, noncurrent	478	478	321	478
Total cash, cash equivalents and restricted cash per statement of cash flows	$ 178,425	$ 129,363	$ 255,415	$ 178,425

Marketable securities

The following table summarizes the Company's marketable securities held at December 31, 2022. The Company had no marketable securities as of December 31, 2021.

	December 31, 2022			
(in thousands)	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
	$ 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 year ended December 31, 2022, and, as a result, the Company did not reclassify any amounts out of accumulated comprehensive loss.

As of December 31, 2022, the Company's debt security portfolio consisted of 17 securities that were in an unrealized loss position and had an aggregate fair value of $92.8 million. There were no securities in an unrealized loss position for greater than 12 months as of December 31, 2022. 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 securities during the year ended December 31, 2022.

6. Property and Equipment

Property and equipment consists of the following as of December 31, 2022 and 2021:

(in thousands)	December 31, 2022	December 31, 2021
Laboratory equipment	$ 7,960	$ 6,725
Leasehold improvements	1,943	1,906
Computers, software, and office equipment	1,824	1,019
Total property and equipment at cost	11,727	9,650
Less: Accumulated depreciation	(7,742)	(7,682)
	$ 3,985	$ 1,968

Depreciation expense for the years ended December 31, 2022, 2021 and 2020 was $0.9 million, $0.9 million and $1.0 million, respectively.

7. Accrued Expenses

Accrued expenses consist of the following as of December 31, 2022 and 2021:

(in thousands)	December 31, 2022	December 31, 2021
Accrued clinical expenses	$ 14,822	$ 7,879
Accrued manufacturing expenses	11,536	8,476
Accrued payroll and related expenses	11,558	7,319
Accrued research and non-clinical expenses	2,767	3,848
Accrued professional fees	1,865	909
Accrued other	636	285
	$ 43,184	$ 28,716

8. Debt

On May 8, 2019, the Company entered into a loan and security agreement (the "Prior Credit Facility") with Silicon Valley Bank ("SVB"), pursuant to which the Company borrowed $5.0 million. The Prior Credit Facility accrued interest at a floating per annum rate equal to the greater of (i) 4.0% and (ii) 1.50% below the Prime Rate. The Prior Credit Facility had an interest-only period through August 31, 2020.

On August 28, 2020, the Company entered into a second amendment (the "Second Amendment") to the Prior Credit Facility. Pursuant to the Second Amendment, the Company drew $5.2 million upon execution of the Second Amendment, the proceeds of which were used to repay the Company's existing balance under the Prior Credit Facility and satisfy its obligations to SVB. The Prior Credit Facility, as amended by the Second Amendment, accrued interest at a floating per annum rate equal to the greater of (i) 4.25% and (ii) 1.00% above the Prime Rate.

On October 29, 2021, the Company entered into a loan and security agreement (the "New Credit Facility") with SVB and Oxford ("Oxford" and, together with SVB and the other lenders from time to time a party thereto, the "Lenders"). Pursuant to the New Credit Facility, as amended on February 17, 2022, October 17, 2022, and December 27, 2022, 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 drew $25.0 million upon execution of the New Credit Facility, of which $5.5 million of the proceeds was used to repay the existing balance under the Prior Credit Facility and satisfy its obligations to SVB. Upon entering into the New Credit Facility, the Company terminated all commitments by SVB to extend further credit under the Prior Credit Facility and all guarantees and security interests granted by the Company to SVB under the Prior Credit Facility.

The New Credit Facility bears interest at a floating per annum rate equal to the greater of (i) 8.50% and (ii) 5.25% above the Prime Rate. Interest is payable monthly in arrears on the first day of each month. The Company is obligated to make interest-only payments through November 1, 2024, followed by equal monthly principal payments and applicable interest through the maturity date of October 1, 2026 (the Maturity Date). If certain development milestones are met, then the interest-only period will be extended to November 1, 2025.

The Company is also required to make a final payment to the Lenders equal to 4.25% of the principal amount of the term loans then extended to the Company. This final payment is accreted under the effective interest method over the life of each term loan. The term loans are secured by substantially all of the Company’s assets, except for its intellectual property which is subject to a negative pledge, and certain other customary exclusions.

At the Company’s option, it may prepay the outstanding principal balance of any term loans in whole but not in part, subject to a prepayment fee of: (a) 3.0% of the term loans then extended to the Company if the prepayment occurs on or prior to the first anniversary of the funding date of such term loan, (b) 2.0% of the term loans then extended to the Company if the prepayment occurs after the first anniversary of the funding date of such term loan but on or prior to the second anniversary of the funding date of such term loan, or (c) 1.0% of the term loans then extended to the Company if the prepayment occurs after the second anniversary of the funding date of such term loan but before the Maturity Date. The New Credit Facility includes customary affirmative and restrictive covenants applicable to the Company. Affirmative covenants include, among others, covenants requiring the Company to maintain its corporate existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. The restrictive covenants include, among others, requirements relating to the Company’s ability to transfer collateral, incur additional indebtedness, engage in mergers or acquisitions, pay dividends or make other distributions, make investments, create liens, sell assets and agree to a change in control, in each case subject to certain customary exceptions.

The Company’s payment obligations under the New Credit Facility are subject to acceleration upon the occurrence of specified events of default, which include, but are not limited to, the occurrence of a material adverse change in the Company’s business, operations, or financial or other condition. Amounts outstanding upon the occurrence of an event of default are payable upon the Lenders' demand and shall accrue interest at an additional rate of 5.0% per annum of the past due amount outstanding. As of December 31, 2022, the Company was in compliance with all covenants under the New Credit Facility. As such, as of December 31, 2022, the classification of the loan balance as stated on the balance sheet was based on the timing of defined future payment obligations.

The following is a summary of obligations under the New Credit Facility as of December 31, 2022:

(in thousands)	December 31, 2022
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	(324)
Accretion related to final payment	253
Long-term debt, net	$ 24,929

As of December 31, 2022, the estimated future principal payments due are as follows:

(in thousands)	
2023	$ —
2024	2,083
2025	12,500
2026	10,417
Total debt	$ 25,000

Interest expense related to the New Credit Facility for the year ended December 31, 2022 was $3.2 million. The Company did not recognize any interest expense related to the New Credit Facility during the year ended December 31, 2021. Interest expense related to the Prior Credit Facility for the year ended December 31, 2021 was $0.8 million. The Company did not recognize any interest expense related to the Prior Credit Facility during the year ended December 31, 2022.

9. Stockholders' Equity

Preferred stock

As of December 31, 2022, 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 year ended December 31, 2021, the Company sold 3,961,074 shares of common stock, resulting in net proceeds of $43.1 million. During the first quarter of 2022, the Company sold 11,740,210 shares of common stock resulting in net proceeds of $54.8 million under the 2020 ATM. 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 year ended December 31, 2022, the Company sold 18,757,665 shares of common stock, resulting in net proceeds of $96.4 million under the February 2022 ATM. As of December 31, 2022, approximately $1.6 million remained unsold and available for sale under the February 2022 ATM.

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. As of December 31, 2022, the Company had not sold any shares of common stock under the November 2022 ATM.

Follow-on offering

In June 2020, the Company sold 9,200,000 shares of common stock in an underwritten public offering at a price to the public of $19.00 per share. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were $164.0 million.

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 December 31, 2022 and 2021 there were outstanding warrants to purchase 22,590 and 39,474 shares of common stock, respectively. During the year ended December 31, 2022, the Company issued 16,654 shares of common stock upon the net exercise of warrants.

Exchange warrants

On November 26, 2019, the Company entered into an exchange agreement with entities affiliated with Biotechnology Value Fund, L.P. (the "Exchanging Stockholders"), pursuant to which the Exchanging Stockholders exchanged an aggregate of 2,575,000 shares of common stock for warrants (the "Exchange Warrants") to purchase an aggregate of 2,575,000 shares of common stock (subject to adjustment in the event of any stock dividends and splits, reverse stock split, merger or consolidation, change of control, reorganization or similar transaction, as described in the Exchange Warrants), with an exercise price of $0.0001 per share.

In accordance with ASC Topic 505, *Equity*, the Company recorded the retirement of the common stock exchanged as a reduction of common shares outstanding and a corresponding debit to additional paid-in-capital at the fair value of the Exchange Warrants on the issuance date. While outstanding, the Exchange Warrants were classified as equity in accordance with ASC Topic 480, *Distinguishing Liabilities from Equity*, and the fair value of the Exchange Warrants was recorded as a credit to additional paid-in capital and is not subject to remeasurement. The Company determined that the fair value of the Exchange Warrants is substantially similar to the fair value of the retired shares on the issuance date due to the negligible exercise price for the Exchange Warrants. On March 2, 2020, the Exchanging Stockholders exercised the Exchange Warrants in full on a net cashless exercise basis, resulting in the issuance of 2,574,971 shares of 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 December 31, 2022 and 2021 there were 11,944,664 and 9,199,512, respectively, shares of common stock reserved for the exercise of outstanding stock options, restricted stock units ("RSUs") and warrants.

	December 31, 2022	December 31, 2021
Stock options	10,051,283	8,342,429
Restricted stock units	1,870,791	817,609
Warrants	22,590	39,474
	11,944,664	9,199,512

10. Stock-based Compensation

Stock incentive plans

As of June 30, 2017, there were 3,141,625 stock options outstanding under 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 initially, up to 2,255,000 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, 2022, the number of shares of common stock issuable under the 2017 Plan was increased by 2,948,362 shares. During the year ended December 31, 2022, the Company granted 3,541,558 RSUs and options to purchase shares of common stock to employees and non-employee directors under the 2017 Plan. As of December 31, 2022 there were 1,501,829 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 year ended December 31, 2022, the Company granted 713,025 RSUs and options to purchase shares of common stock to newly hired employees under the Inducement Plan. As of December 31, 2022, there were 1,342,175 shares available for future issuance under the Inducement Plan.

As of December 31, 2022 there were options to purchase 757,500 shares of common stock outstanding which were granted as inducement awards prior to establishment of the Inducement Plan.

Stock option activity

A summary of stock option activity is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2022	8,342,429	$ 11.25	7.2	$ 8,458
Granted	2,793,659	$ 5.43		
Exercised	(414,914)	$ 3.21		
Cancelled	(669,891)	$ 13.09		
Outstanding at December 31, 2022	10,051,283	$ 9.84	7.2	$ 8,197
Exercisable at December 31, 2022	5,410,541	$ 9.45	6.1	$ 6,076

The weighted-average grant date fair value of options granted during the years ended December 31, 2022, 2021 and 2020, was $3.97, $11.71 and $7.99 per share, respectively. The total intrinsic value of options exercised during the years ended December 31, 2022, 2021 and 2020, was $1.5 million, $4.3 million, and $11.1 million, respectively. 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 $1.3 million, $1.8 million and $3.1 million for the years ended December 31, 2022, 2021 and 2020, respectively.

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	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2022	817,609	1.5	$ 5,086	$ 15.68
Granted	1,460,924	—		$ 5.70
Vested	(235,591)	—		$ 15.62
Forfeited	(172,151)	—		$ 8.54
Unvested at December 31, 2022	1,870,791	1.5	$ 10,963	$ 8.55

The total fair value of RSUs vested during the years ended December 31, 2022, 2021 was $1.5 million and $5.8 million, respectively. No RSUs vested during the year ended December 31, 2020.

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 Company initially reserved 225,000 shares of common stock for issuance under the 2017 ESPP, plus an annual increase, to be added as of January 1st of each year, equal to the least of (i) 450,000 shares of common stock; (ii) one percent of the number of shares of common stock outstanding as of the close of business on the immediately preceding December 31st; and (iii) the number of shares of common stock determined by the Board on or prior to such date for such year, up to maximum of 4,725,000 shares of common stock in the aggregate. On January 1, 2022, no shares were added to the 2017 ESPP. During the years ended December 31, 2022 and 2021 the Company issued 270,774 and 78,253 shares, respectively, under the 2017 ESPP. As of December 31, 2022, there were 295,791 shares available for issuance under the 2017 ESPP.

Stock-based compensation expense

The Company uses the provisions of ASC 718 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 consolidated statements of operations and comprehensive loss:

	Year ended December 31,		
(in thousands)	**2022**	**2021**	**2020**
Stock options	$ 15,814	$ 14,528	$ 5,725
Restricted stock units	5,175	3,522	1,187
Employee stock purchase plan	533	359	260
Stock-based compensation expense included in total operating expenses	$ 21,522	$ 18,409	$ 7,172

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

	Year ended December 31,		
(in thousands)	**2022**	**2021**	**2020**
Research and development	$ 11,386	$ 9,984	$ 3,841
General and administrative	10,136	8,425	3,331
Stock-based compensation expense included in total operating expenses	$ 21,522	$ 18,409	$ 7,172

As of December 31, 2022, there was $30.4 million and $11.6 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 2.0 years and 2.6 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:

	December 31,		
	2022	2021	2020
Risk-free interest rate	2.1 %	0.9 %	1.2 %
Expected dividend yield	— %	— %	— %
Expected term (years)	5.99	6.06	6.05
Expected stock price volatility	88 %	82 %	74 %

Expected volatility for the Company's common stock is determined based on a blended rate of its historical volatility combined with the historical volatility of comparable publicly traded companies. 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.

11. 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):

	Year ended December 31,		
	2022	2021	2020
Stock options	10,051,283	8,342,429	6,112,948
Unvested restricted stock units	1,870,791	817,609	716,767
Warrants	22,590	39,474	39,474
	11,944,664	9,199,512	6,869,189

12. Leases

The Company has an operating lease for its office and lab space in Cambridge, Massachusetts and operating and finance leases for certain equipment. In March 2020, the Company entered into the Seventh Amendment to the office and lab space lease ("the Office Lease") to extend the term of the lease through March 2026. The Company has an option to extend the lease term of the Office Lease for an additional five years.

On April 5, 2021, the Company entered into an Eighth Amendment to the Office Lease, which granted the Company additional office space in its existing building for five years, beginning July 1, 2021, and committed the Company to lease payments of $5.0 million over that period (the "Expansion Lease"). Independent from the option under the Office Lease, the Company has an option to extend the lease term of the Expansion Lease for an additional five years. The Company's exercise of the options to extend the lease terms of both the Office Lease and Expansion Lease were not considered reasonably certain as of December 31, 2022.

The Expansion Agreement is a lease modification accounted for as a separate contract, because it expands the scope of the Office Lease and the additional lease payments are commensurate with market rents. The Company assessed the lease classification of the Expansion Lease as of the date of signing and determined that the Expansion Lease should be accounted for as an operating lease. The right-of-use asset and corresponding operating lease liability have been calculated based on the present value of lease payments over the lease term. The Company determined the appropriate incremental borrowing rate to utilize as a discount rate by using a synthetic credit rating which was estimated based on an analysis of outstanding debt of companies with similar credit and financial profiles. Since the operating lease is a net lease, as the non-lease components (i.e., common area maintenance) are paid separately from rent based on actual costs incurred, such non-lease components were not included in the ROU asset and liability and are reflected as an expense in the period incurred.

The Company had a standby letter of credit agreement for the benefit of its landlord in the amount of $0.5 million in connection with the Office Lease and Expansion Lease as of December 31, 2022 and 2021.

The Company has remaining finance lease terms of one year to five years for certain equipment, some of which include options to purchase at fair value.

Mersana Therapeutics, Inc.
Notes to consolidated financial statements
(continued)

The components of lease expense included in research and development and general and administrative expenses in the statement of operations were as follows:

	Years ended December 31,		
(in thousands)	**2022**	**2021**	**2020**
Operating lease cost	$ 3,793	$ 3,502	$ 2,755
Finance lease cost:			
Amortization of right-of-use assets	$ 194	$ 169	$ 101
Interest on lease liabilities	28	28	21
	$ 222	$ 197	$ 122

Supplemental balance sheet information related to leases was as follows:

	Year ended December 31,	
	2022	**2021**
Operating leases:		
Operating lease right-of-use assets	$ 10,475	$ 12,889
Operating lease liabilities, current	$ 2,798	$ 2,303
Operating lease liabilities	$ 8,575	$ 11,247
Finance leases:		
Property and equipment, gross	$ 1,038	$ 1,038
Property and equipment, accumulated depreciation	$ (539)	$ (345)
Other liabilities, current	$ 240	$ 239
Other liabilities	$ 203	$ 449
Weighted-average remaining lease term:		
Operating leases	3.3 years	4.3 years
Finance leases	2.0 years	4.0 years
Weighted-average discount rate:		
Operating leases	10.8 %	10.8 %
Finance leases	5.4 %	5.4 %

Supplemental cash flow information related to leases was as follows:

	Year ended December 31,	
(in thousands)	**2022**	**2021**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 3,865	$ 3,241
Operating cash flows from finance leases	$ 28	$ 28
Financing cash flows from finance leases	$ 272	$ 215

Future minimum lease payments under non-cancellable leases as of December 31, 2022 were as follows:

(in thousands)	Operating leases	Finance leases
2023	$ 3,857	$ 262
2024	4,146	141
2025	4,187	48
2026	1,310	8
2027 and thereafter	—	—
Total lease payments	13,500	459
Present value adjustment	(2,127)	(15)
Present value of lease liabilities	$ 11,373	$ 444

13. Income Taxes

For the years ended December 31, 2022, 2021 and 2020, the Company recorded no income tax benefit for the net operating losses ("NOLs") incurred in each year, due to the Company's operating losses and a full valuation allowance on deferred tax assets.

A reconciliation of the effective tax rate for the years ended December 31, 2022 and 2021 is as follows:

	2022	2021
Statutory US Federal Rate	21.0 %	21.0 %
State taxes, net of federal benefit	5.7 %	6.3 %
Permanent differences	(0.1)%	(0.2)%
General business credits	4.4 %	3.8 %
Stock compensation	(1.4)%	0.1 %
Change in valuation allowance	(29.6)%	(31.0)%
	— %	— %

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets as of December 31, 2022 and 2021 are as follows:

(in thousands)	2022	2021
Deferred tax assets:		
Net operating losses	$ 113,981	$ 106,055
R&D capitalization	40,380	—
Tax credit carryforwards	21,429	12,424
Stock-based compensation	6,522	5,018
Accrued expenses	3,340	1,874
Lease liabilities	3,096	3,698
Capitalized licenses	3,077	2,775
Deferred revenue	1,062	1,076
Depreciation	437	493
Other	116	71
Total gross deferred tax assets	193,440	133,484
Valuation allowance	(190,588)	(130,051)
Net deferred tax assets less valuation allowance	2,852	3,433
Deferred tax liabilities		
Right-of-use assets	(2,852)	(3,433)
Total gross deferred tax liabilities	(2,852)	(3,433)
Net deferred taxes	$ —	$ —

The Company has incurred NOLs since inception. At December 31, 2022, the Company had federal and state NOL carryforwards of approximately $432.8 million and $365.3 million, respectively. Of the $432.8 million of federal NOL carryforwards, $34.1 million expire at various dates through 2037. The remaining $398.7 million of federal NOL carryforwards do not expire. The state NOL carryforwards expire at various dates through 2042. At December 31, 2022, the Company 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.

As required by ASC 740, management of the Company has evaluated the evidence bearing upon the reliability of its deferred tax assets. Based on the weight of available evidence, both positive and negative, management has determined that it is more likely than not that the Company will not realize the benefits of all of these assets. Accordingly, the Company recorded a valuation allowance of $190.6 million and $130.1 million at December 31, 2022 and December 31, 2021, respectively. The valuation allowance increased by $60.5 million during the year ended December 31, 2022, primarily a result of the Company's current year NOL.

Utilization of the NOLs and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382, as well as similar state provisions. These ownership changes may limit the amount of NOLs and research and development tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. If a change in control as defined by Section 382 has occurred at any time since the Company's formation, utilization of its NOLs or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, which could then be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the NOLs or research and development tax carryforwards before their utilization. The Company has determined that ownership changes have occurred in the past and that certain NOLs and research and development tax credit carryforwards will be subject to limitation. The amounts presented do not include NOLs or research and development tax credit carryforwards that will expire unused due to ownership changes.

The Company applies the accounting guidance in ASC 740 related to accounting for uncertainty in income taxes. The Company's reserves related to taxes are based on a determination of whether, and how much of, a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. As of December 31, 2022 and 2021, the Company had no unrecognized tax benefits.

The Company has not conducted a study of its research and development credit carryforwards. This study may result in an adjustment to research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheets or statements of operations if an adjustment were required.

Interest and penalties related to uncertain tax positions would be classified as income tax expense in the accompanying statements of operations. As of December 31, 2022 and 2021, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company files income tax returns in the United States federal tax jurisdiction and eight state jurisdictions. The Company did not have any foreign operations during the years ended December 31, 2022, 2021 and 2020. The statute of limitations for assessment by the Internal Revenue Service and state tax authorities is closed for tax years prior to 2018, although carryforward attributes that were generated prior to tax year 2018 may still be adjusted upon examination to the extent utilized in a future period. There are no federal or state audits currently in progress.

14. Employee Benefit Plan

The Company has a defined contribution plan established under Section 401(k) of the Internal Revenue Code ("401(k) Plan"), which covers substantially all employees. Employees who have attained the age of 21 and have worked more than 1,000 hours are eligible to participate in the 401(k) Plan. Employees may contribute up to 95% of eligible pay on a pre–tax basis up to the federal annual limits. For the years ended December 2022, 2021, and 2020, the Company made matching contributions equal to 100% of the employee's contributions, subject to a maximum of 4% of eligible compensation. For the years ended December 31, 2022, 2021 and 2020, the Company recorded expense of $1.1 million, $0.8 million and $0.5 million, respectively, related to its contribution to its 401(k) Plan.

15. Commitments

License agreements

During the years ended December 31, 2022, 2021 and 2020, the Company recorded research and development expense related to non-refundable license payments of $1.5 million, $3.1 million, and $0.3 million, respectively.

During the years ended December 31, 2022, 2021 and 2020, the Company recorded research and development expense related to development milestones of $0.7 million, $2.1 million and $0.8 million, respectively. The 2022, 2021, and 2020 development milestones were associated with XMT-1660, UpRi, and XMT-1592, respectively.

See Note 12, *Leases,* for the Company's future obligations related to leases as of December 31, 2022.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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 (1) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial officer, 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 disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

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 December 31, 2022, the end of the period covered by this Annual Report on Form 10-K. 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.

Internal Control Over Financial Reporting

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles, or GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control — Integrated Framework. Based on our assessment, our management has concluded that, as of December 31, 2022, our internal control over financial reporting is effective based on those criteria.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Other than as noted below, the information required by this item is incorporated by reference to the information set forth in the sections titled "Proposal No. 1 – Election of Directors," "Executive Officers," and "Information Regarding the Board of Directors and Corporate Governance" and "Delinquent Section 16(a) Reports," if any, in our definitive proxy statement for our 2023 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the end of our fiscal year ended December 31, 2022, or the 2023 Proxy Statement.

We post our Code of Business Conduct and Ethics, which applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, in the “Corporate Governance” sub-section of the “Investors & Media” section (https://ir.mersana.com) of our corporate website https://mersana.com/. We intend to disclose on our website any amendments to, or waivers from, the Code of Business Conduct and Ethics that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item (other than the information required by Item 402(v) of Regulation S-K) is incorporated by reference to the information set forth in the sections titled "Executive Compensation" and "Information Regarding the Board of Directors and Corporate Governance - Compensation Committee Interlocks and Insider Participation" in our 2023 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to the information set forth in the sections titled "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans" in our 2023 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to the information set forth in the sections titled "Certain Relationships and Related Party Transactions" and "Information Regarding the Board of Directors and Corporate Governance – Director Independence" in our 2023 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to the information set forth in the section titled "Principal Accountant Fees and Services" in our 2023 Proxy Statement.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

Our consolidated financial statements are listed in the "Index to Consolidated Financial Statements" under Part II, Item 8 of this Annual Report on Form 10-K.

(a)(2) Financial Statement Schedules

All schedules are omitted because they are not required or are not applicable or because the information required is included in the consolidated financial statements or the notes thereto.

(a)(3) Exhibits

Exhibit Number	Description of Exhibit
3.1	Fifth Amended and Restated Certificate of Incorporation, as amended, as of June 9, 2022 (incorporated by reference to Exhibit 5.03 to the Current Report on Form 8-K (File No. 001-38129) filed with the Securities and Exchange Commission (the "SEC") on June 10, 2022).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K (File No. 001-38129) filed with the SEC on July 10, 2017).
4.1	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 1, 2017).
4.2	Form of Exchange Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K (File No. 001-38129) filed with the SEC on November 27, 2019).
4.3*	Description of Securities.
10.1†	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 16, 2017).
10.2	Commercial Lease, dated February 24, 2009, between Mersana Therapeutics, Inc. and Rivertech Associates II, LLC (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 1, 2017).
10.3	Seventh Lease Extension and Modification Agreement to the Lease Between Rivertech Associates II LLC and Mersana Therapeutics, Inc., dated March 10, 2020, by and between Mersana Therapeutics, Inc. and Rivertech Associates II LLC (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 001-38129) filed with the SEC on May 8, 2020).
10.4	Eighth Lease Modification Agreement to the Lease Between Rivertech Associates II LLC and Mersana Therapeutics, Inc., effective as of April 5, 2021, by and between Mersana Therapeutics, Inc. and Rivertech Associates II LLC (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 001-38129) filed with the SEC on May 10, 2021).
10.5+	Collaboration and Commercial License Agreement, dated June 23, 2014, by and between Mersana Therapeutics, Inc. and Merck KGaA (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 1, 2017).
10.6+	Amendment 1 to the Collaboration and Commercial License Agreement, dated June 1, 2016, by and between Mersana Therapeutics, Inc. and Merck KGaA (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 1, 2017).
10.7+	Amendment 2 to the Collaboration and Commercial License Agreement, dated August 12, 2016, by and between Mersana Therapeutics, Inc. and Merck KGaA (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 1, 2017).

10.8+	Amendment 3 to the Collaboration and Commercial License Agreement, dated February 28, 2017, by and between Mersana Therapeutics, Inc. and Merck KGaA (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 1, 2017).
10.9	Amendment 4 to Collaboration and Commercial License Agreement dated May 15, 2018, by and between Mersana Therapeutics, Inc. and Merck KGaA (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 001-38129) filed with the SEC on August 14, 2018).
10.10+	License, Development and Commercialization Agreement, dated July 9, 2015, by and between Mersana Therapeutics, Inc. and Recepta Biopharma S.A. (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 1, 2017).
10.11	First Amendment to the License, Development and Commercialization Agreement, dated August 19, 2019, by and between Mersana Therapeutics, Inc. and Recepta Biopharma S.A. (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 001-38129) filed with the SEC on November 6, 2019).
10.12+	Second Amendment to the License, Development and Commercialization Agreement, dated September 28, 2021, by and between Mersana Therapeutics, Inc. and Recepta Biopharma S.A. (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 001-38129) filed with the SEC on November 9, 2021).
10.13+	Agreement Regarding LICR Technology, dated July 9, 2015, by and between Ludwig Institute for Cancer Research, Recepta Biopharma S.A. and Mersana Therapeutics, Inc. (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 1, 2017).
10.14+	Amended and Restated Commercial License and Option Agreement, dated November 23, 2021, by and between Synaffix B.V. and Mersana Therapeutics, Inc. (incorporated by reference to Exhibit 10.15 to Annual Report on Form 10-K (File No. 001-38129) filed with the SEC on February 28, 2022).
10.15+	Amendment No. 1 to the Amended and Restated Commercial License and Option Agreement, dated February 2, 2022, between Mersana Therapeutics, Inc. and Synaffix B.V. (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q (File No. 001-38129) filed with the SEC on May 9, 2022).
10.16+	Research Collaboration and License Agreement, dated February 2, 2022, between Mersana Therapeutics, Inc. and Janssen Biotech, Inc. (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q (File No. 001-38129) filed with the SEC on May 9, 2022).
10.17+	Collaboration, Option and License Agreement, dated August 6, 2022, between Mersana Therapeutics, Inc. and GlaxoSmithKline Intellectual Property (No. 4) Limited (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 001-38129) filed with the SEC on November 7, 2022).
10.18*+	Collaboration and Commercial License Agreement, dated December 22, 2022, between Mersana Therapeutics, Inc. and Ares Trading S.A.
10.19+	Loan and Security Agreement, dated October 29, 2021, by and between Oxford Finance LLC, Silicon Valley Bank and Mersana Therapeutics, Inc. (incorporated by reference to Exhibit 10.14 to Annual Report on Form 10-K (File No. 001-38129) filed with the SEC on February 28, 2022).
10.20+	First Amendment to Loan and Security Agreement, dated February 17, 2022, between Oxford Finance LLC, the Lenders named therein including Silicon Valley Bank, and Mersana Therapeutics, Inc. (incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q (File No. 001-38129) filed with the SEC on May 9, 2022).
10.21*+	Second Amendment to Loan and Security Agreement, dated October 17, 2022, between Oxford Finance LLC, the Lenders named therein including Silicon Valley Bank, and Mersana Therapeutics, Inc.
10.22*	Third Amendment to Loan and Security Agreement, dated December 27, 2022, between Oxford Finance LLC, the Lenders named therein including Silicon Valley Bank, and Mersana Therapeutics, Inc.

10.23	Sales Agreement, dated November 7, 2022, between Mersana Therapeutics, Inc. and Cowen and Company, LLC (incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K (File No. 001-38129) filed with the SEC on November 7, 2022).
10.24†	Amended and Restated Offer Letter, by and between Mersana Therapeutics, Inc. and Anna Protopapas, dated March 17, 2017 (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 1, 2017).
10.25†	Amended and Restated Offer Letter, by and between Mersana Therapeutics, Inc. and Timothy B. Lowinger, dated March 8, 2017 (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 1, 2017).
10.26†	Offer Letter, by and between Mersana Therapeutics, Inc. and Brian DeSchuytner, dated June 10, 2019 (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q (File No. 001-38129) filed with the SEC on May 8, 2020).
10.27†	Offer Letter, by and between Mersana Therapeutics, Inc. and Arvin Yang, dated November 5, 2020 (incorporate by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q (File No. 001-38129) filed with the SEC on May 10, 2021).
10.28†	Offer Letter, dated March 5, 2021, by and between Mersana Therapeutics, Inc. and Alejandra Carvajal (incorporated by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q (File No. 001-38129) filed with the SEC on May 9, 2022).
10.29†	Offer Letter, dated June 15, 2021, between Mersana Therapeutics, Inc. and Tushar Misra (incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q (File No. 001-38129) filed with the SEC on May 9, 2022).
10.30†	2007 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.19 to the Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 1, 2017).
10.31†	Form of Incentive Stock Option under the 2007 Stock Incentive Plan (incorporated by reference to Exhibit 10.20 to the the Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 1, 2017).
10.32†	Form of Nonqualified Stock Option under the 2007 Stock Incentive Plan (incorporated by reference to Exhibit 10.21 to the the Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 1, 2017).
10.33†	2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.22 to Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 16, 2017).
10.34†	Form of Incentive Stock Option under the 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.23 to Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 16, 2017).
10.35†	Form of Nonqualified Stock Option under the 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.24 to Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 16, 2017).
10.36†	Form of Restricted Stock Unit under the 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 333-38129) filed with the SEC on August 6, 2021).
10.37†	2022 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 10.28 to the Annual Report on Form 10-K (File No. 001-38129) filed with the SEC on February 28, 2022).
10.38†	Form of Inducement Restricted Stock Unit under the 2022 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 10.29 to the Annual Report on Form 10-K (File No. 001-38129) filed with the SEC on February 28, 2022).
10.39†	Form of Non-statutory Stock Option under the 2022 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 10.30 to the Annual Report on Form 10-K (File No. 001-38129) filed with the SEC on February 28, 2022).
10.40*†	2017 Employee Stock Purchase Plan, as amended

10.41†	2017 Cash Bonus Plan (incorporated by reference to Exhibit 10.26 to Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-218412) filed with the SEC on June 16, 2017).
10.42*†	Non-Employee Director Compensation Policy, effective as of December 1, 2022.
21.1*	Subsidiaries of Mersana Therapeutics, Inc.
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm.
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97*†	Clawback Policy
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.

** The certification attached as Exhibit 32.1 accompanying this Annual Report on Form 10-K 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 Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

† Indicates a management contract or compensatory plan.

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

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Mersana Therapeutics, Inc.

Date: February 28, 2023

/s/ Anna Protopapas

Anna Protopapas
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on dates indicated.

Signature	Title	Date
/s/ ANNA PROTOPAPAS Anna Protopapas	President, Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2023
/s/ BRIAN DESCHUYTNER Brian DeSchuytner	Senior Vice President, Chief Financial Officer (Principal Financial Officer)	February 28, 2023
/s/ ASHISH MANDELIA Ashish Mandelia	Vice President, Controller (Principal Accounting Officer)	February 28, 2023
/s/ DAVID MOTT David Mott	Chairman of the Board	February 28, 2023
/s/ LAWRENCE M. ALLEVA Lawrence M. Alleva	Director	February 28, 2023
/s/ WILLARD H. DERE, M.D. Willard H. Dere, M.D.	Director	February 28, 2023
/s/ ALLENE M. DIAZ Allene M. Diaz	Director	February 28, 2023
/s/ ANDREW A. F. HACK Andrew A. F. Hack, M.D., Ph.D.	Director	February 28, 2023
/s/ KRISTEN HEGE Kristen Hege, M.D.	Director	February 28, 2023
/s/ MARTIN H. HUBER, M.D. Martin H. Huber, M.D.	Director	February 28, 2023

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description summarizes selected information regarding our capital stock, as well as relevant provisions of: (i) our fifth amended and restated certificate of incorporation, as amended, or the Restated Certificate, (ii) our amended and restated bylaws, or Bylaws, and (iii) the General Corporation Law of the State of Delaware, or DGCL. The following summary is qualified in its entirety by, and should be read in conjunction with, the Restated Certificate and the Bylaws, copies of which have been filed as exhibits to the Annual Report on Form 10-K to which this Description of Securities is an exhibit, and the applicable provisions of the DGCL.

General

Our authorized capital consists of 375,000,000 shares, all with a par value of $0.0001 per share, of which 350,000,000 shares are designated as common stock ("Common Stock"), and 25,000,000 shares are designated as preferred stock. Our Common Stock is registered under Section 12 of the Securities Exchange Act of 1934, as amended, and listed on the Nasdaq Global Select Market under the symbol "MRSN."

Common Stock

Each holder of our Common Stock shall be entitled to one vote for each share of Common Stock held of record by such holder on all matters on which stockholders generally are entitled to vote and does not have cumulative voting rights. A contested election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election; otherwise, a nominee is elected if the votes properly cast for such nominee exceed the votes properly cast against such nominee.

Dividends of cash or property may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by our board of directors and subject to any preferential dividend rights of any then outstanding preferred stock. The holders of the Common Stock shall have no preemptive rights to subscribe for any shares of any class of stock of the Corporation whether now or hereafter authorized. The Common Stock shall not be convertible into, or exchangeable for, shares of any other class or classes or of any other series of the same class of the Corporation's capital stock. Upon the dissolution, liquidation or winding up of the affairs of the Corporation, whether voluntary or involuntary, after payment or provision for payment of the debts and liabilities of the Corporation and of the preferential and other amounts, if any, to which the holders of preferred stock shall be entitled, holders of Common Stock shall be entitled to receive all assets of the Corporation available for distribution to its stockholders, ratably in proportion to the number of shares held by each such stockholder.

Additional shares of authorized common stock may be issued, as authorized by our board of directors from time to time, without stockholder approval, except as may be required by applicable stock exchange requirements.

Anti-Takeover Effects of our Restated Certificate, Bylaws and the DGCL

Authorized but Unissued Shares.

Our authorized but unissued shares of Common Stock and preferred stock are available for future issuance without stockholder approval. Our board of directors has the authority under our Restated Certificate to issue preferred stock with rights superior to the rights of the holders of Common Stock. As a result, the issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control of the Corporation without further action by the stockholders and may adversely affect the voting and other rights of the holders of Common Stock.

Classified Board

Our Restated Certificate provides for our board of directors to be divided into three classes, with staggered three-year terms. As a result, only one class of directors is elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our Restated Certificate also provides that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors.

Removal of Directors

Our Restated Certificate provides that our directors may be removed only for cause by the affirmative vote of at least 75% of the voting power of our outstanding shares of capital stock, voting together as a single class. This

requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board of directors.

Action by Written Consent; Special Meeting of Stockholders

Our Restated Certificate also requires that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of the stockholders and cannot be taken by written consent in lieu of a meeting. A special meeting of the stockholders may be called only by or at the direction of our board of directors pursuant to a written resolution adopted by a majority of the total number of directors which the Corporation would have if there were no vacancies. These provisions may have the effect of delaying, deferring or preventing a change in control and may also delay or prevent changes in management of the Corporation.

Advance Notice Procedures

Our Bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting are only able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although our Bylaws do not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, our Bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Super Majority Approval Requirements

Our Restated Certificate and Bylaws provide that the affirmative vote of holders of at least 75% of the total votes eligible to be cast in the election of directors is required to amend, alter, change or repeal specified provisions. This requirement of a supermajority vote to approve amendments to our Restated Certificate and Bylaws could enable a minority of our stockholders to exercise veto power over any such amendments.

Exclusive Forum

Our Restated Certificate requires, to the fullest extent permitted by law, that derivative actions brought in the name of the Corporation, actions against directors, officers and employees for breach of a fiduciary duty and other similar actions may be brought only in specified courts in the State of Delaware. Although we believe this provision benefits us by providing increased consistency in the application of Delaware law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers.

These and other provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and to discourage certain types of transactions that may involve an actual or threatened change of control. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, such provisions also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts.

Section 203 of the General Corporation Law of the State of Delaware

We are subject to Section 203 of the DGCL which regulates acquisitions of some Delaware corporations. In general, Section 203 prohibits, with some exceptions, a publicly held Delaware corporation such as us from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time that the stockholder became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock

outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or by-laws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Exhibit 10.18

CONFIDENTIAL

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

ARES TRADING S.A.

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COLLABORATION AND COMMERCIAL LICENSE AGREEMENT

This Collaboration and Commercial License Agreement, effective as of December 22, 2022 ("**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**"), Ares Trading S.A. (a wholly-owned subsidiary of Merck KGaA, Darmstadt, Germany, a corporation with General Partners and having its principal place of business in Frankfurter Straße 250, 64293 Darmstadt, Germany ("**MRKDG**")), having its principal place of business at Rue de l'Ouriette 151, Zone industrielle de l'Ouriettez, CH-1170 Aubonne, Switzerland ("**ATSA**"). Mersana and ATSA 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, ATSA is engaged in the Development and Commercialization of pharmaceutical products;

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

WHEREAS, ATSA desires to license from Mersana and Mersana wishes to license to ATSA, 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:

ARTICLE 1

DEFINITIONS AND INTERPRETATION.

Section 1.1. **Definitions**. For the purposes of this Agreement the following words and phrases will have the following meanings:

1.1.1. "**Accounting Standards**" means, with respect to each Party, the IFRS (International Financial Reporting Standards), or the US GAAP (Generally Accepted Accounting Principles) as generally and consistently applied throughout such Party's organization.

1.1.2. "**ADC**" means any Antibody-drug conjugate containing an ATSA Antibody Directed to a Designated Target that is conjugated, using Mersana's Technology, to Mersana's proprietary STING Agonist, which ADC is created under a Research Program under this Agreement.

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 [**].

1.1.6. "**Antigen**" means [**].

1.1.7. "**Applicable Laws**" 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. "**ATSA**" is defined in the introduction to this Agreement.

1.1.9. "**ATSA Antibody**" means an Antibody Controlled by ATSA that is Directed to a Designated Target, and that is provided by or on behalf of ATSA to Mersana for inclusion in an ADC under a Research Program. [**].

1.1.10. "**ATSA Antibody Conditions**" means the [**].

1.1.11. "**ATSA Background IP**" means all Background IP Controlled by ATSA relating to the ATSA Technology.

1.1.12. "**ATSA Foreground IP**" means all Foreground IP that is (a) an improvement to, or related to, ATSA Background IP or (b) solely relating to any ADC (including the Licensed ADCs) and Licensed Products arising under this Agreement, including without limitation all ATSA ADC Patents and ATSA Product Patents.

1.1.13. **"ATSA ADC Patent(s)"** means all Patent Rights in the Foreground IP solely related to the composition of matter of the Licensed ADC(s), excluding any Patent Rights in the Mersana Foreground IP.

1.1.14. **"ATSA Product Patent(s)"** means all Patent Rights in the Foreground IP solely related to the Licensed Product(s), excluding the ATSA ADC Patents and any Patent Rights in the Mersana Foreground IP.

1.1.15. "**ATSA Know-How**" means Know-How relating to ATSA Technology, that is Controlled by ATSA or any Affiliate of ATSA as of the Effective Date or at any time [**].

1.1.16. "**ATSA Patents**" means all Patent Rights in ATSA Background IP or ATSA Foreground IP [**].

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

1.1.18. **"ATSA Technology"** means ATSA's proprietary technology relating to Antibodies, including but not limited to their screening, identification, development, manufacturing, formulation, combination and use, but excluding any Mersana Technology**.**

1.1.19. **"ATSA IP"** means ATSA Foreground IP and ATSA Background IP. [**].

1.1.20. "**Available**" is defined in Section 2.7.2(a).

1.1.21. **"Background IP"** means any IP that (a) is owned, Controlled, acquired or developed by either Party or any of its Affiliates either (i) prior to or on the Effective Date of the Agreement or (ii) after the Effective Date but outside of activities conducted under this Agreement (including, for clarity, IP Controlled through any Future Mersana In-License or Future ATSA In-License or IP related to Future ATSA Antibodies) and (b) is reasonably necessary or useful to Research, have Researched, Develop, have Developed, make, have made, manufacture, have manufactured, use, promote, sell, offer for sale, distribute or Commercialize the Licensed ADCs or Licensed Products.

1.1.22. "**Bankruptcy Code**" is defined in Section 12.6.

1.1.23. "**BLA**" is defined in the definition of Regulatory Approval.

1.1.24. "**Breaching Party**" is defined in Section 12.3.

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

1.1.26. "**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.

1.1.27. "**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.

1.1.28. "**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 immediately following such merger or consolidation; (b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction 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 (c) any "person" 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, other than pursuant to a bona fide financing.

1.1.29. "**Claim**" is defined in Section 13.1.1.

1.1.30. "**Clinical Supply Agreement**" is defined in Section 5.3.3.

1.1.31. "**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.

1.1.32. "**CMC**" means chemistry, manufacturing and controls.

1.1.33. "**CMC Budget**" is defined in Section 2.3.1.

1.1.34. "**CMC Costs**" means the (a) Out-of-Pocket Expenses, [**] and (b) FTE Costs, in each case ((a) and (b)), accrued or incurred by Mersana and its Affiliates in line with Mersana's Accounting Standards in conducting the CMC Development and Manufacturing activities (including the supply of ADCs under the CMC Plan) under this Agreement.

1.1.35. "**CMC Development**" means test method development and stability testing, process development, product characterization, method validation, process validation, process scale-up, formulation development, delivery system development, quality assurance and quality control development, technology transfer to a Third Party (other than to ATSA or any of its CMOs) and other related activities directed to establishing Manufacturing of a drug or biological product.

1.1.36. "**CMC Plan**" means, with respect to any Research Program, the written plan for CMC Development and Manufacturing activities in connection with such Research Program, as further described in Section 2.3.

1.1.37. "**CMC Term**" means, with respect to a Research Program, the period beginning on the approval of the CMC Plan by the JMC for such Research Program until the earlier of (a) the commencement of Manufacturing of Licensed Product supply by ATSA for the first Pivotal Clinical Trial for the first Licensed Product under such Research Program, or (b) the mutual agreement by the Parties to terminate the CMC Term for such Research Program.

1.1.38. "**CMO**" means a Third Party contract manufacturing organization.

1.1.39. "**[**]**" means [**].

1.1.40. "**[**]**" means [**].

1.1.41. "**[**]**" means [**].

1.1.42. "**Combination Product**" means a product that consists of a Licensed ADC and other pharmaceutical active compounds or active ingredients sold as a single formulation.

1.1.43. "**Commercialize**" or "**Commercializing**" means to (a) market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize a compound or product, (b) conduct activities, other than Research, Development and Manufacturing, in preparation for the foregoing activities, including obtaining Pricing Approval or (c) conduct post-Regulatory Approval studies (including Clinical Trials). When used as a noun, "Commercialization" means activities involved in Commercializing.

1.1.44. "**Commercially Reasonable Efforts**" means: (a) with respect to the efforts to be expended by a Party with respect to any objective, [**].

1.1.45. "**Compulsory License**" means a compulsory license obtained by a Third Party through the order, decree, or grant of a competent Governmental Authority or court, authorizing such Third Party to develop, make, have made, use, sell, offer to sell or import a Licensed Product in any country.

1.1.46. "**Confidential Information**" of a Party, means (i) 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 (ii) "Confidential Information" as defined in that certain Confidentiality Agreement dated [**] between Mersana and ATSA[**]; provided, that notwithstanding anything to the contrary, (a) Confidential Information constituting Mersana Know-How or Mersana Regulatory Documentation will be Confidential Information of Mersana (and Mersana will be deemed the disclosing Party and ATSA the receiving Party with respect thereto) and (b) Confidential Information constituting ATSA Know-How or ATSA Regulatory Documentation including ATSA Antibody Confidential Information will be Confidential Information of ATSA (and ATSA will be deemed the disclosing Party and Mersana the receiving Party with respect thereto).

1.1.47. "**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 ATSA Technology, Mersana Technology or any other Confidential Information of ATSA or Mersana (other than information or intellectual property Controlled by a Future Acquirer that would be excluded by clause (a) or (b)(i) of this Section 1.1.47).

1.1.48. "**Designated Target"** means the Primary Target or the Secondary Target, if any.

1.1.49. "**Development**" means, with respect to a compound or product, all clinical and non-clinical research and development activities conducted after filing of an IND for such compound or product, including but not limited to toxicology, pharmacology test method development and stability testing, process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, Clinical Trials (other than post-Regulatory Approval Clinical Trials), regulatory affairs, pharmacovigilance, Clinical Trial regulatory activities and obtaining and maintaining Regulatory Approval. When used as a verb, "Develop" or "Developing" means to engage in Development.

1.1.50. "**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 (a) for a Designated Target comprised of a single Antigen, an Antibody or Antibody-drug conjugate will not be deemed to be Directed to such Designated Target if it preferentially binds to a combination of two (2) or more Antigens, even if such combination of Antigens includes the Antigen that is the Designated Target, and (b) for a Designated Target comprised of a combination of two (2) or more Antigens, an Antibody or Antibody-drug conjugate will not be deemed to be Directed to such Designated Target if (i) such Antibody or Antibody-drug conjugate preferentially binds to a combination of Antigens that includes all of the Antigens included in the Designated Target as well as one (1) or more additional Antigens, or (ii) such Antibody or Antibody-drug conjugate preferentially binds to one or more Antigens that does not include all of the Antigens included in the Designated Target.

1.1.51. "**[**]**" means [**].

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

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

1.1.54. "**Estimated Pre-Payment**" is defined in Section 7.2.1(a).

1.1.55. "**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.

1.1.56. "**Event of Force Majeure**" is defined in Section 14.1.

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

1.1.58. "**Exclusive License**" is defined in Section 4.3.

1.1.59. "**Executive Officers**" means the [**] of Mersana and the [**] of ATSA, or any other executive vice president or senior executive officer designated by a Party who has the authority to resolve the applicable matter referred to the Executive Officers in accordance with this Agreement.

1.1.60. **"Exploit"** means make, have made, import, use, sell or offer for sale, including to Develop, have Developed, Commercialize, have Commercialized, 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.

1.1.61. "**Extensions**" is defined in Section 9.3.7.

1.1.62. "**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).

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

1.1.64. "**Field**" means all uses.

1.1.65. "**First Commercial Sale**" means, with respect to any Licensed Product and with respect to any country of the Territory, (a) if Regulatory Approval is required by Applicable Laws for a commercial transfer or disposition of such Licensed Product for value in such country, the first commercial transfer or disposition for value of such Licensed Product in such country by ATSA, its Affiliates or Sublicensees to a Third Party following Regulatory Approval of such Licensed Product in such country, or (b) if Regulatory Approval is not required by Applicable Laws for a commercial transfer or disposition of such Licensed Product for value in such country, the first commercial transfer or disposition for value of such Licensed Product in such country by ATSA, its Affiliates or Sublicensees to a Third Party, in each case ((a) and (b)), for use or consumption of such Licensed Product in such country by the general public. [**].

1.1.66. **"Foreground IP"** any IP arising during the Term of the Agreement from the activities conducted (i) 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 including under each Research Plan and CMC Plan or (ii) by or on behalf of any Sublicensee in the course of conducting activities under a permitted sublicense hereunder.

1.1.67. "**FTE**" means one person (or the equivalent of one person) working full time for a twelve (12) month period in a Research, Development (including CMC Development), Manufacturing, 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.

1.1.68. "**FTE Costs**" means, with respect to a given period, the actual FTE costs accrued or incurred by Mersana in line with Mersana's Accounting Standards (i.e., no mark-up) during such period, but not to exceed an effective FTE rate of [**] US Dollars ($[**]) per FTE; provided that such effective FTE rate cap will be adjusted annually, with the first adjustment effective as of January 1, 2025, based on the percentage increase or decrease in the Consumer Price Index (U.S. Bureau of Labor Statistics for all urban consumers, U.S. city average, all items) between the last day of the most recent completed Calendar Year and December 31, 2023.

1.1.69. "**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.

1.1.70. **"Future ATSA Antibodies"** means all Antibodies which are (a) generated or otherwise obtained by ATSA after the Effective Date that are Directed to a Designated Target and (b) which are provided by or on behalf of ATSA to Mersana for inclusion in an ADC under a Research Program.

1.1.71. "**Future ATSA In-License**" means an agreement between ATSA or an Affiliate of ATSA and a Third Party, entered into after the Effective Date (or solely with respect to the Secondary Target, entered into prior to or after the Effective Date), pursuant to which ATSA has, but for the second proviso of this Section 1.1.71, acquired Control of Product Blocking IP that is necessary to Research, Develop, Manufacture, Commercialize or otherwise Exploit a Licensed Product Directed to a Designated Target; [**].

1.1.72. "**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 1.1.72, acquired Control of Platform Blocking IP that is necessary to use the Mersana Technology to Research, Develop, Manufacture, Commercialize or otherwise Exploit a Licensed Product Directed to a Designated Target [**].

1.1.73. "**GAAP**" means the then-current generally accepted accounting principles in the United States as established by the Financial Accounting Standard Board or any successor entity or other entity generally recognized as having the right to establish such principles in the United States, in each case consistently applied.

1.1.74. "**Gatekeeper**" means [**], or such other Third Party as may be agreed by the Parties in writing from time to time.

1.1.75. "**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.

1.1.76. "**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.

1.1.77. "**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.

1.1.78. "**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.

1.1.79. "**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).

1.1.80. "**IFRS**" means the International Financial Reporting Standards, the set of accounting standards and interpretations and the framework in force on the Effective Date and adopted by the European Union as issued by the International Accounting Standards Board ("**IASB**") and the International Financial Reporting Interpretations Committee ("**IFRIC**"), as such accounting standards may be amended from time to time.

1.1.81. "**IND**" means (a) 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 (b) any foreign counterpart of the foregoing, including clinical trial applications.

1.1.82. "**Indemnitee**" is defined in Section 13.2.

1.1.83. "**Indemnitor**" is defined in Section 13.2.

1.1.84. "**Indication**" would mean [**].

1.1.85. "**Initiation of GLP Toxicology Study**" would mean the first dosing of a nonhuman primate (or other species appropriate for IND-enabling toxicology studies) with an ADC in a GLP Toxicology Study.

1.1.86. "**Intellectual Property**" or "**IP**" means Patents Rights, Know-How and any other intellectual property rights, including design rights and copyrights, and other similar proprietary rights (whether patentable or not), all rights of whatsoever nature in materials, computer programs, databases and all intangible rights and privileges of a nature similar to any of the foregoing whether or not registered and including all granted registrations, all applications for registrations and rights to apply for any of the foregoing, anywhere in the world.

1.1.87. "**JIPC Matters**" is defined in Section 3.4.4(c).

1.1.88. "**JMC Matters**" is defined in Section 3.3.4(c).

1.1.89. "**Joint Intellectual Property Committee**" or "**JIPC**" is defined in Section 3.4.1.

1.1.90. "**Joint IP**" means all Foreground IP other than Mersana Foreground IP and ATSA Foreground IP.

1.1.91. "**Joint Know-How**" means Know-How in the Joint IP.

1.1.92. "**Joint Manufacturing Committee**" or "**JMC**" is defined in Section 3.3.1.

1.1.93. "**Joint Patent**" means a Patent Right in the Joint IP.

1.1.94. "**Joint Research Committee**" or "**JRC**" is defined in Section 3.2.1.

1.1.95. "**JRC Matters**" is defined in Section 3.2.4(b).

1.1.96. "**Know-How**" means any: (i) scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, that is not in the

public domain or otherwise publicly known, including discoveries, inventions, trade secrets, devices, databases, practices, protocols, regulatory filings, methods, processes (including manufacturing processes, specification and techniques), techniques, concepts, ideas, specifications, formulations, formulae, data (including pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), case reports forms, medical records, data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), summaries and information contained in submissions to and information from ethical committees, or Regulatory Authorities, and manufacturing process and development information, results and data, whether or not patentable, all to the extent not claimed or disclosed in a patent or patent application; and (ii) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material, including drug substance samples, intermediates of drug substance samples, drug product samples and intermediates of drug product samples. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, or a development relating to the item, is (and remains) not known to the public. "Know-How" includes any rights including copyright, database or design rights protecting such Know-How. "Know-How" excludes information that is generally known.

1.1.97. "**Liability**" is defined in Section 13.1.1.

1.1.98. **"Licensed Antibody Drug Conjugate(s)" or "Licensed ADC(s)"** means any ADC that is designated as a Licensed ADC pursuant to Section 5.1.1.

1.1.99. "**Licensed Product**" means, with respect to a Designated Target, the pharmaceutical product in any form containing the Licensed ADC Directed to such Designated Target as an active ingredient, in any dosage form, formulation or method of delivery. Any pharmaceutical product that meets the above definition of "Licensed Product" and that includes the same Licensed ADC will be deemed to be the same Licensed Product for purposes of this Agreement.

1.1.100. "**Major European Countries**" means [**].

1.1.101. "**Manufacture**" or "**Manufacturing**" means to make, have made, 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.

1.1.102. "**Mersana**" is defined in the introduction to this Agreement

1.1.103. **"Mersana Background IP"** means all Background IP Controlled by Mersana relating to the Mersana Technology. The Patent Rights in the Mersana Background IP as of the Effective Date are set forth in Schedule 1.1.103.

1.1.104. **"Mersana Foreground IP"** means all Foreground IP that is an improvement to, or related to, Mersana Background IP.

1.1.105. **"Mersana IP"** means Mersana Background IP and Mersana Foreground IP.

1.1.106. "**Mersana Know-How**" means Know-How relating to Mersana Technology, that is Controlled by Mersana or any Affiliate of Mersana as of the Effective Date or at any time [**].

1.1.107. "**Mersana Patents**" means all Patent Rights in the Mersana Background IP or Mersana Foreground IP.

1.1.108. "**Mersana Regulatory Documentation**" means Regulatory Documentation owned or Controlled by Mersana or any of its Affiliates on or after the Effective Date specifically related to the [**] of the Mersana Technology, in each case, that is necessary or useful to Exploit a Licensed ADC or a Licensed Product.

1.1.109. "**Mersana Technology**" or "**Immunosynthen Platform**" means Mersana's proprietary technology relating to (a) Mersana's proprietary STING Agonist, (b) Mersana's proprietary [**], (c) the conjugation of a STING Agonist to an Antibody, and (d) the Manufacture of Antibody-drug conjugates created or developed using such proprietary technology.

1.1.110. "**Mersana Trademarks**" is defined in Section 9.6.3.

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

1.1.112. "**Net Sales**" means the gross amounts invoiced by or on behalf of ATSA, 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 as a deduction in accordance with IFRS, applied on a consistent basis, and are specifically attributable to actual sales of such Licensed Product

[**].

In the event that the Licensed Product is sold as a Combination Product, the Net Sales will be calculated on a country-by-country basis by multiplying the Net Sales of the Combination Product by the fraction, A/(A+B) where A is the weighted average sale price (by sales volume) in the prior calendar year in the relevant country of the Licensed Product containing the Licensed ADC as the sole active ingredient in finished form, and B is the weighted average sale price (by sales volume) in the prior calendar year that country of the product(s) containing the other component(s) as the sole active ingredient(s) in finished form. Regarding prices comprised in the weighted average price when sold separately referred to above, if these are available for different dosages from the dosages of Licensed ADC and other active ingredient components that are included in the Combination Product, then ATSA shall make a proportional adjustment to such prices in calculating the Net Sales of the Combination Product. If the weighted average sale price in the prior calendar year cannot be determined for the Licensed Product or other product(s) containing the single Licensed ADC or component(s), the calculation of Net Sales for Combination Products will be agreed by the Parties based on the relative value contributed by each component (each Party's agreement not to be unreasonably withheld or delayed). Discussions to reach agreement should be started no later than [**] prior to the anticipated commercial launch of the Combination Product. 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, with the cost of such independent expert

determination to be shared equally by the Parties. In the event such determination is not made prior to the commercial launch of the Combination Product, then ATSA shall in any event make payment to Mersana attributing not less than [**] percent ([**]%) 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 determination has been made. If the agreed attributed value percentage is not equal to [**] percent ([**]%), the reconciliation between the Parties shall be made within [**] 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 country-by-country basis by multiplying the Net Sales of the Product Bundle by the fraction, A/(A+B) where A is the weighted average sale price (by sales volume) in the prior calendar year in the relevant country of the Licensed Product if sold individually, and B is the weighted average sale price (by sales volume) in the prior calendar year in that country of the product(s) if sold individually. If the weighted average sale price in the prior calendar year cannot be determined for the Licensed Product or other product(s) containing the single Licensed ADCs or component(s), the calculation of Net Sales for such Product Bundle will be agreed by the Parties based on the relative value contributed by each product in such Product Bundle (each Party's agreement not to be unreasonably withheld or delayed). Discussions to reach agreement should be started no later than [**] prior to the anticipated commercial launch of the Product Bundle. 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, with the cost of such independent expert determination to be shared equally by the Parties. In the event such determination is not made prior to the commercial launch of the Product Bundle, then ATSA shall in any event make payment to Mersana attributing not less than [**] percent ([**]%) 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 determination has been made. If the agreed attributed value percentage is not equal to [**] percent ([**]%), the reconciliation between the Parties shall be made within [**] 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 ATSA, 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 ATSA, 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) [**], (ii) [**], (iii) for preclinical, clinical, regulatory or governmental purposes, [**], or (iv) for use in any tests or studies reasonably necessary to comply with any Applicable Laws, 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", as long as any reimbursement thereon is not included in net sales following ATSA's Accounting Standards.

1.1.113. "**Notice of Dispute**" is defined in Section 14.6.1.

1.1.114. "**Notice Period**" is defined in Section 12.3.

1.1.115. "**Out-of-Pocket Expenses**" means the amounts actually paid by or on account of Mersana to [**].

1.1.116. "**Overage**" is defined in Section 7.2.1(b).

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

1.1.118. "**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, 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.

1.1.119. "**Pharmacovigilance Agreement**" is defined in Section 6.3.

1.1.120. "**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).

1.1.121. "**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. [**].

1.1.122. "**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.

1.1.123. "**Pivotal Clinical Trial**" means a Clinical Trial of a product on a sufficient number of subjects that, prior to commencement of the trial, satisfies both of the following:

(a) [**]; and

(b) [**].

For clarity, a Pivotal Clinical Trial need not be designated a "Phase III Clinical Trial."

1.1.124. "**Pre-Clinical Development Candidate Designation**" is defined in Section 7.5.

1.1.125. "**Platform Blocking IP**" means Third Party Know-How or Patent Rights that are necessary in order to practice the Mersana Technology to Research, Develop, Manufacture, Commercialize or otherwise Exploit any Antibody-drug conjugate, including the Licensed ADCs and Licensed Products.

1.1.126. "**Pricing Approval**" means (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, or (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.

1.1.127. "**Primary Target**" is defined in Section 2.7.1(b).

1.1.128. "**Product Blocking IP**" means Third Party Know-How or Patent Rights, other than Platform Blocking IP, that are necessary to use the Designated Target or the ATSA Antibody in the manner contemplated by this Agreement, or that are necessary for the Research, Development, Manufacture, Commercialization or other Exploitation of any Licensed ADC or Licensed Product.

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

1.1.130. "**Product Trademarks**" is defined in Section 9.6.1.

1.1.131. "**Publication**" is defined in Section 8.5.

1.1.132. "**Regulatory Approval**" means final regulatory 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.

1.1.133. "**Regulatory Assistance Costs**" means the (a) Out-of-Pocket Expenses, [**] and (b) FTE Costs, in each case ((a) and (b)), accrued or incurred by Mersana and its Affiliates in line with Mersana's Accounting Standards in conducting the regulatory assistance activities under Section 6.1.

1.1.134. "**Regulatory Authority**" means, with respect to a country in the Territory, any national (e.g., the FDA), supra-national (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.

1.1.135. "**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.

1.1.136. "**Regulatory Exclusivity**" means, [**].

1.1.137. "**Reimbursed Costs**" is defined in Section7.12.2(c).

1.1.138. "**Research**" means conducting research activities to discover, design, optimize, deliver and advance compounds or products, including pre-clinical studies and optimization, but specifically excluding Development, Manufacture and Commercialization. When used as a verb, "Researching" means to engage in Research.

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

1.1.140. "**Research Program**" means each research program conducted pursuant to Article 2.

1.1.141. "**Research Program Materials**" means any ADCs or other reagents and reference standards delivered by or on behalf of Mersana to ATSA in connection with the performance of the Research Plan activities.

1.1.142. "**Research Program Term**" is defined in Section 2.6.

1.1.143. "**Royalty Report**" is defined in Section 7.12.1(a).

1.1.144. "**Royalty Term**" is defined in Section 7.3.3.

1.1.145. "**Secondary Target**" is defined in Section 2.7.1(b).

1.1.146. "**STING**" means the protein "stimulator of interferon genes," also known as TMEM173 (transmembrane protein 173), encoded by the TMEM173 gene.

1.1.147. "**STING Agonist**" means Mersana's proprietary compound [**].

1.1.148. "**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 of Licensed ADC and Licensed Product 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 3.4.2.

1.1.149. "**Sublicensee**" means a person or entity that is granted a sublicense by ATSA or any direct or indirect sublicensees of ATSA under any rights granted to ATSA under the Exclusive License.

1.1.150. "**Target Designation Date**" is defined in Section 2.7.2(d).

1.1.151. **"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.

1.1.152. "**Technology Transfer Budget**" is defined in Section 5.3.6(c).

1.1.153. "**Technology Transfer Costs**" means the (a) Out-of-Pocket Expenses, [**] and (b) FTE Costs, in each case ((a) and (b)), accrued or incurred by Mersana and its Affiliates in line with Mersana's Accounting Standards in conducting the technology transfer activities allocated to it in a Technology Transfer Plan.

1.1.154. "**Technology Transfer Plan**" is defined in Section 5.3.6(c).

1.1.155. "**Term**" is defined in Section 12.1.

1.1.156. "**Territory**" means all countries in the world.

1.1.157. "**Third Party**" means a person or entity other than ATSA, Mersana and their respective Affiliates.

1.1.158. "**Third Party Action**" is defined in Section 10.1.1.

1.1.159. "**Upfront Fee**" is defined in Section 7.1.

1.1.160. "**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 1.1.160 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 1.1.160.

Section 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.

ARTICLE 2

RESEARCH PROGRAM.

Section 2.1. **Objective and Conduct of the Research Programs**. The Parties will conduct up to two (2) Research Programs, each with respect to a different Designated Target and in accordance with a Research Plan, the terms of this Agreement and Applicable Laws in good scientific manner. The purpose of each Research Program will be to identify, develop and evaluate ADCs to enable ATSA to make a Pre-Clinical Development Candidate Designation and subsequently Exploit Licensed ADCs designated pursuant to Section 5.1.1 under this Agreement.

Section 2.2. **Research Plans**.

2.2.1. **In General**. Each Research Program will have a separate Research Plan. Each Research Plan will set forth all of the Research activities (excluding CMC Development activities) to be conducted by the Parties under the Research Program for the applicable Designated Target during the Research Program Term through the filing of one or more INDs for one (1) Licensed Product Directed to the applicable Designated Target, including the deliverables, a timeline for the conduct of such activities, and any applicable biophysical characterization specifications for such Research Program. During the Research Program Term for a Research Program, 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. ATSA will promptly (but in any event, within [**]) notify Mersana in the event that (a) ATSA makes a Pre-Clinical Development Candidate Designation with respect to a particular ADC, or (b) ATSA makes a determination to not make a Pre-Clinical Development Candidate Designation with respect to a particular ADC.

2.2.2. **Research Plan Responsibilities**. Unless otherwise agreed by the Parties through the Joint Research Committee, the Parties acknowledge and agree that the responsibilities of the Parties in a Research Plan will generally be allocated as follows:

(a) ATSA will have primary responsibility for (i) providing [**] ATSA Antibodies in sufficient quantities and of sufficient quality for the conduct of the Research Plan activities, (ii) biological activities, (iii) in vitro and in vivo experimentation, (iv) management of Third Party relationships related to the Research and Development of the ATSA Antibodies, ADCs, Licensed ADCs and Licensed Products (but excluding the relationship with any Third Party related to the Mersana Technology), (v) pre-IND and IND-enabling studies, and (vi) preparation and submission of any INDs; and

(b) Mersana will have primary responsibility for the conjugation of [**] ATSA Antibodies using the Mersana Technology.

2.2.3. **Initial Research Plans**. The Research Plan for the Primary Target is attached as Schedule 2.2.3-1. Promptly following the Target Designation Date for the Secondary Target, the JRC will meet and prepare the initial Research Plan for the Research Program for the Secondary Target, and will use diligent efforts to approve such initial Research Plan within [**] of such Target Designation Date. The Research Plan approved by the JRC will be attached to this Agreement as an additional sequentially numbered schedule (i.e., Schedule 2.2.3-2), and, unless otherwise agreed by the Parties, will be substantially the same form as the Research Plan for the Primary Target, and include substantially the same final deliverables.

2.2.4. **Changes to Research Plans**. Each Party may, via the JRC, propose changes to a Research Plan, which will be subject to review and approval by the JRC as provided in Section 3.2.2.

2.2.5. **Research Program Records**. The Parties will maintain, in good scientific manner, complete and accurate books and records pertaining to its activities under each Research Plan.

2.2.6. **Costs of Research Plan Activities**. Each Party will bear all costs incurred by such Party and its Affiliates in conducting the activities allocated to it under the Research Plans, unless otherwise mutually agreed by the Parties in writing.

Section 2.3. **CMC Plans**.

2.3.1. **In General**. Each Research Program will have a separate CMC Plan. Each CMC Plan will set forth all of the CMC Development and Manufacturing activities to be conducted by the Parties in relation to a Research Program, including the CMC Development work required for Mersana to Manufacture (or have Manufactured) the ADCs that Mersana is obligated to supply under Section 5.3. Each CMC Plan shall be accompanied by a rolling budget for the CMC Costs to be accrued or incurred by Mersana and its Affiliates in conducting the CMC Plan activities that are scheduled to be commenced or conducted during each [**] during the [**] and a forecast of the CMC Costs to be accrued or incurred by Mersana and its Affiliate in conducting the CMC Plan activities that are scheduled to be commenced in the [**] (the "**CMC Budget**"). During the CMC Term for a Research Program, each Party will use Commercially Reasonable Efforts to perform activities assigned to it under each CMC Plan in accordance with the timelines set forth therein and the CMC Budget.

2.3.2. **CMC Plan Responsibilities**. Unless otherwise agreed by the Parties through the JMC, the Parties acknowledge and agree that the responsibilities of the Parties in each CMC Plan will be generally allocated as follows:

(a) ATSA will have primary responsibility for (i) supplying Mersana with ATSA Antibodies in sufficient quantities and of sufficient quality for the conduct of the CMC Development and Manufacturing activities allocated to Mersana under the CMC Plan, and (ii) performing all CMC Development and Manufacturing of Licensed Products not otherwise allocated to Mersana, to the extent necessary to conduct the Research Plan activities for the applicable Designated Target; and

(b) Mersana will have primary responsibility for (i) performing bioconjugation of the ATSA Antibody to the Immunosynthen Platform to create GLP bulk drug substance for the GLP Toxicology Studies solely as provided for in the CMC Plan; [**], and (ii) conducting analytical testing and stability testing of bulk drug substance and drug product for a reasonable period of time to be agreed upon by the Parties.

2.3.3. **Initial CMC Plan and CMC Budget**. Within [**] following the Pre-Clinical Development Candidate Designation of an ADC with respect to a Research Program, the JMC will meet and prepare the initial CMC Plan for such Research Program and the initial CMC Budget for such CMC Plan, and will thereafter use diligent efforts to approve such initial CMC Plan within [**] of such Pre-Clinical Development Candidate Designation. The CMC Plan and CMC Budget will not go into effect unless and until approved by the JMC. Notwithstanding anything to the contrary herein, Mersana shall not be obligated to perform any CMC Plan activities until the initial CMC Plan and the initial CMC Budget has been approved by the JMC.

2.3.4. **Changes to CMC Plans**. Each Party may, via the JMC, propose changes to a CMC Plan or CMC Budget, which will be subject to review and approval by the JMC as provided in Section 3.3.2; provided that any change to the CMC Plan approved by the JMC that will result in an increase to the CMC Costs will not become effective until a corresponding change to the CMC Budget is approved by the JMC.

2.3.5. **Costs of CMC Plan Activities**. ATSA shall pay Mersana's CMC Costs for CMC Plan activities performed by or on behalf Mersana, in accordance with Section 7.2.

Section 2.4. **Subcontracting**. Except as otherwise set forth in this Agreement [**], each Party may subcontract the performance of any activities allocated to it under the Research Plans and the CMC Plans; provided that any such subcontractor is bound to applicable provisions of this Agreement, including obligations of confidentiality and assignment of inventions comparable in scope to and consistent with those included herein. For activities relating to the CMC Plan, Mersana may subcontract to the entities set forth in Schedule 2.4; [**]. The Party subcontracting the performance of any of its activities under a Research Plan shall remain responsible for the performance of the activities by the subcontractor.

Section 2.5. **Restrictions on use of Materials**.

2.5.1. Mersana (a) will not use the ATSA Antibodies for any purpose other than exercising its rights and performing its obligations under the applicable Research Plan and CMC Plan, (b) will only use the ATSA Antibodies in compliance with all Applicable Laws and the ATSA Antibody Conditions, and (c) will not transfer the ATSA Antibodies or grant any rights thereto to any Third Party without the express prior written consent of ATSA. ATSA will

retain full ownership of, and all right, title and interest in and to, the ATSA Antibodies. At the later of (i) the end of the applicable Research Program Term and (ii) the end of the applicable CMC Term, or upon earlier termination of this Agreement, Mersana will at the instruction of ATSA either destroy or return any remaining ATSA Antibodies.

2.5.2. Prior to ATSA making a Pre-Clinical Development Candidate Designation with respect to an ADC, ATSA (a) will not use the applicable Research Program Materials provided by Mersana 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, other than to subcontractors in compliance with Section 2.4 to the extent such Research Program Material is needed for such subcontractor to perform activities under this Research Plan. Upon the earliest of (i) ATSA's election to not make a Pre-Clinical Development Candidate Designation with respect to an ADC, or (ii) termination of this Agreement, ATSA will at the instruction of Mersana either destroy or return any remaining Research Program Materials from the applicable Research Program. [**].

Section 2.6. **Term of a Research Program**. The term of the first Research Program, which covers the Primary Target, will commence upon the Effective Date, and the term of the Research Program for the Secondary Target will commence upon the applicable Target Designation Date. Each Research Program will continue until the earliest of (a) the completion of the Research Plan activities assigned to Mersana for such Research Program, (b) (i) with respect to the Research Program for the Primary Target, [**] from the Effective Date, or (ii) with respect to the Research Program for the Secondary Target, [**] from the applicable Target Designation Date, and (c) the termination of this Agreement with respect to the applicable Designated Target (the term of a Research Program, each, a "**Research Program Term**"); provided that the Parties may extend the Research Program Term upon mutual agreement of the Parties in writing. If a Research Program Term ends pursuant to clause (c) of this Section 2.6, then the Designated Target that is the subject of the applicable Research Program will no longer be deemed to be a Designated Target hereunder.

Section 2.7. **Availability of Targets; Approval of New Research Plans**.

2.7.1. Designated Targets. ATSA may designate up to two (2) Designated Targets (with each Designated Target consisting of one Antigen or a combination of two (2) or more Antigens) under this Agreement as follows:

(a) The first Designated Target is set forth on Schedule 2.7.1-1 (the "**Primary Target**").

(b) ATSA may designate a second Designated Target in accordance with this Section 2.7.1(b) and Section 2.7.2 at any time prior to the [**] anniversary of the Effective Date (the "**Secondary Target**"); ***provided*** that if ATSA fails to designate the Secondary Target prior to the [**] anniversary of the Effective Date, as may be extended in accordance with Section 2.7.2(b), then ATSA will be deemed to have forfeited its right to select a Secondary Target. Following the Target Designation Date, such Secondary Target will be set forth on Schedule 2.7.1-2.

2.7.2. Gatekeeper Process.

(a) In order to designate an Antigen (or combination of Antigens) as a new Designated Target under Section 2.7.1(b) (such one Antigen or combination of Antigens, the "**Proposed Antigen**"), ATSA will complete a Proposed Antigen proposal in the form attached hereto as Schedule 2.7.2 (which form Mersana may revise from time to time and notify ATSA of such revised form), which Proposed Antigen proposal will provide the Gatekeeper with a confidential written description of such Proposed Antigen (with a maximum of [**] being checked by the Gatekeeper at any given time), including to the extent available, the Name and UniProt/SwissProt number sequence for such Proposed Antigen; [**]. ATSA will notify Mersana promptly after each time that ATSA provides a Proposed Antigen proposal to the Gatekeeper. Within [**] following Gatekeeper's receipt of such Proposed Antigen proposal with respect to a particular Proposed Antigen, Mersana will cause the Gatekeeper to notify ATSA in writing whether such 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 ATSA as a Designated Target unless prior to the date of receipt of the written notice from ATSA to Gatekeeper (a) Mersana has granted, or [**] grant to a Third Party [**] a license or rights to acquire a license to Research, Develop or Commercialize an Antibody or an Antibody-drug conjugate using the Mersana Technology that is Directed to such Proposed Antigen, , (b) an agreement entered into would be breached by including such Proposed Antigen as a Designated Target under this Agreement, or (c) [**].

(b) For clarity, in the event that the Gatekeeper determines that a Proposed Antigen is not Available pursuant to the procedures set forth in this Section 2.7.2, the Gatekeeper will notify both Parties of such fact (but will not identify to Mersana the specific Proposed Antigen), and ATSA will not have exhausted its right to designate an Antigen as a new Designated Target hereunder within the applicable designation time period. Should an Antigen proposed by ATSA be rejected by the Gatekeeper, the applicable nomination period for such Antigen shall be automatically extended by [**] and ATSA may submit another Proposed Antigen in accordance with this Section 2.7.2 if the applicable nomination period under Section 2.7.1(b), as extended, has not already expired.

(c) The Parties acknowledge and agree that, as of the Effective Date, the Primary Target set forth on Schedule 2.7.1-1 is Available, and the procedures set forth in Section 2.7 will not apply to the Primary Target.

(d) If the Gatekeeper determines that the Proposed Antigen is Available, then the Proposed Antigen will automatically be deemed a Designated Target (which for clarity, will be the Secondary Target) hereunder upon Gatekeeper's written notice to the Parties that such Proposed Antigen is Available and has been designated as a Designated Target (such date, the "**Target Designation Date**"). Promptly thereafter, an initial Research Plan will be created and provided for approval by the JRC in accordance with Section 2.2.3 for such new Designated Target.

Section 2.8. **Target Exclusivity**.

2.8.1. From the Effective Date until the earliest of (a) the [**], (b) such date that [**]; (c) the date of [**], and (d) the date of [**], Mersana will not, itself or with or through any Affiliate or Third Party, Research, Develop, Manufacture or Commercialize any Antibody-drug conjugate product that utilizes the Immunosynthen Platform that is Directed to the Primary Target; provided that, if following the expiration of the Research Program Term with respect to

the Primary Target, upon Mersana's reasonable request (not to be made more than [**]), ATSA fails to provide reasonable evidence within [**] that it has conducted material Development activities with respect to the Licensed ADC or Licensed Product Directed to the Primary Target, within (i) the past [**] from such request date, if such request was made prior to [**] for such Licensed ADC or Licensed Product, or (ii) the past [**] from such request date, if such request was made following [**] for such Licensed ADC or Licensed Product, then the foregoing exclusivity obligations (to the extent such obligations are still ongoing at such time) with respect to the Primary Target shall automatically terminate and have not further effect. In addition, from the Target Designation Date for the Secondary Target until the earliest of w) the [**] for the Licensed ADC or Licensed Product Directed to the Secondary Target, (x) such date that [**] with respect to a ADC or Directed to such Secondary Target, (y) the date of [**], and (z) the date of [**] with respect to the Secondary Target, Mersana will not, itself or with or through any Affiliate or Third Party, Develop, Manufacture or Commercialize any Antibody-drug conjugate product that utilizes the Immunosynthen Platform that is Directed to the Secondary Target; provided that, if following [**] with respect to the Secondary Target, upon Mersana's reasonable request (not to be made more than [**]), ATSA fails to provide reasonable evidence within [**] that it has conducted material Development activities within the past [**] from such request date with respect to the Licensed ADC or Licensed Product Directed to the Secondary Target, within (i) the past [**] from such request date, if such request was made prior to [**] for such Licensed ADC or Licensed Product, or (ii) the [**] from such request date, if such request was made following [**] for such Licensed ADC or Licensed Product then the foregoing exclusivity obligations (to the extent such obligations are still ongoing at such time) with respect to the Secondary Target shall automatically terminate and have no further effect. For clarity, any dispute related to this Section 2.8.1 will be resolved pursuant to Section 14.6.

ARTICLE 3

GOVERNANCE OF RESEARCH PROGRAMS

Section 3.1. **Alliance Managers**. 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 JRC, JMC or JIPC. A Party may replace its alliance manager at any time by written notice to the other Party.

Section 3.2. **Joint Research Committee**.

3.2.1. **Formation and Composition**. Promptly after the Effective Date, the Parties will establish a joint research committee (the "**Joint Research Committee**" or "**JRC**") composed of [**] appointed representatives of each of ATSA and Mersana. Each JRC representative must be an employee of the appointing Party. A Party may change one or more of its representatives on the JRC at any time or elect to have one of its members represented by a delegate at a meeting of the JRC, provided that such delegate is an employee of such Party. The JRC will be chaired by an [**] representative selected by [**] from one of [**] members of the JRC. The Parties may allow additional representatives of each Party to attend meetings of the JRC subject to the confidentiality provisions of Article 8.

3.2.2. **Functions and Authority**. The JRC will be responsible for supervising and managing the Research Programs. Its functions will be:

(a) Overseeing and coordinating the progress, timelines and results of the Research Programs and Research Plans;

(b) Preparing, and approving, the initial Research Plan for the Secondary Target in accordance with Section 2.7.2(d) and reviewing and approving any proposed changes or amendments to the Research Plans in accordance with Section 5.2;

(c) Serving as a forum for the Parties to discuss the data and results arising from the activities under each Research Plan; and

(d) Such other matters as the Parties may mutually agree in writing or that are expressly delegated to the JRC in this Agreement.

3.2.3. **Meetings**. During the Research Program Term, the JRC will meet in person or by teleconference or videoconference at least [**]. The JRC also may choose to meet more frequently on an as needed basis and will meet upon the request of either Party. The chairperson of the JRC will coordinate and prepare the agenda (which agenda will include items requested by either Party), and ensure the orderly conduct of the meetings of the JRC. Each Party will bear its own expenses related to its JRC representatives' participation in and attendance at such meetings.

3.2.4. **Decisions**.

(a) A quorum of the JRC is required for any meeting of the JRC, which quorum will exist if at least one (1) JRC representative of each Party is present. No action taken at a meeting of the JRC shall be effective unless a quorum exists.

(b) The JRC will only have authority to determine, approve or resolve matters that the JRC is expressly authorized to determine, approve or resolve under this Agreement ("**JRC Matters**"). The JRC will determine, approve or resolve JRC Matters by consensus, with the representatives of each Party collectively having one (1) vote on behalf of such Party. In the event that the JRC does not reach consensus on a JRC Matter within [**] after the matter is first presented to the JRC, the JRC Matter may be referred by either Party to the Executive Officers, who will use reasonable efforts to meet promptly to discuss and resolve such matter. If such Executive Officers do not reach agreement with respect to a particular JRC Matter within [**] after the matter is first referred to such Executive Officers, ATSA will have final decision-making authority relating to such JRC Matter (including amendments to the Research Plan); provided that ATSA will not have the right to exercise its final decision-making authority:

(i) [**];

(ii) to approve the initial Research Plan for the Secondary Target; or

(iii) to amend or modify a Research Plan, if such amendment or modification (i) would result in an increase (as reasonably demonstrated by Mersana through written documentation) to Mersana's FTE Costs and Out-of-Pocket Expenses of [**], individually with respect to a proposed amendment or in the aggregate with respect to a proposed amendment and all previously approved amendments, as compared to the FTE Costs and Out-of-Pocket Expenses to conduct the activities in the initial Research

Plan, to conduct the activities allocated to Mersana under such Research Plan, (ii) would require Mersana to perform research activities beyond what is identified as Mersana's responsibility in Section 2.2.2, (iii) would require Mersana to perform research activities beyond the expiration of the applicable Research Program Term for such Research Plan, or (iv) could potentially require modifications to the use of the Mersana Technology in such Research Program.

(c) Neither the JRC nor ATSA (when exercising its final decision-making authority) has the authority to: (i) amend, modify or waive compliance with any term or condition of this Agreement; (ii) make any decision that is expressly stated in this Agreement to require the mutual agreement of the Parties or one Party's approval or consent; (iii) decide any issue in a manner that would conflict with the express terms and conditions of this Agreement; or (iv) resolve any dispute, including whether or in what amount a payment is owed under this Agreement or whether a Party is in breach of this Agreement.

3.2.5. **Minutes and Reports**. The JRC will maintain accurate minutes of its meetings, including all proposed decisions and recommended actions or decisions taken. Promptly after each meeting, either the chairperson of the JRC or another member of the JRC designated by the JRC will provide the Parties with draft minutes of the meeting, including any issues requiring decisions, any proposed decisions and recommended actions or decisions taken. Within [**] of each meeting, the JRC chair will provide final versions of the meeting minutes. Minutes will be deemed approved unless any member of the JRC objects to the accuracy of such minutes by providing written notice to the other members of the JRC prior to the next meeting of the JRC. In the event of any objection to the minutes that is not resolved by mutual agreement of the Parties, such minutes will be amended to reflect such unresolved dispute.

3.2.6. **Duration**. The JRC will be in existence only during, and will be automatically dissolved on the last day of, the last-to-expire Research Program Term.

Section 3.3. **Joint Manufacturing Committee**.

3.3.1. **Formation and Composition**. Within [**] after the Effective Date, the Parties will establish a joint manufacturing committee (the "**Joint Manufacturing Committee**" or "**JMC**") composed of [**] of each of ATSA and Mersana. Each JMC representative must be an employee of the appointing Party. A Party may change its representative on the JMC at any time or elect to have its member represented by a delegate at a meeting of the JMC, provided that such delegate is an employee of such Party. The JMC will be chaired by the [**] representative. The Parties may allow additional representatives of the Parties to attend meetings of the JMC subject to the confidentiality provisions of Article 8.

3.3.2. **Functions and Authority**. The JMC will be responsible for supervising and managing the CMC activities under the CMC Plan. Its functions will be:

(a) overseeing and coordinating the progress, timelines and results of the CMC Plans (but excluding, for clarity, activities under the Clinical Supply Agreement, if any);

(b) preparing and approving the initial CMC Plan and the initial CMC Budget for the Research Program for each Designated Target in accordance with Section

2.3.3, and reviewing or preparing, and approving, any proposed changes or amendments to the CMC Plan(s) or CMC Budget(s) in accordance with Section 2.3.4;

(c) coordinating ADC Manufacturing activities and supply matters under the CMC Plans;

(d) facilitating the exchange of information between the Parties, and coordinating resolution of issues, relevant to the Manufacturing and supply of ADCs by Mersana during the CMC Term;

(e) preparing and approving the initial Technology Transfer Plan and Technology Transfer Budget for the Research Program for each Designated Target in accordance with Section 5.3.6(d), and reviewing or preparing, and approving, any proposed changes or amendments to the Technology Transfer Plan or Technology Transfer Budget in accordance with Section 5.3.6(e);

(f) overseeing the technology transfer pursuant to Section 5.3.6;

(g) reviewing and approving the [**] portion of the CMC Budget prior to the start of each [**] during the CMC Term in accordance with Section 7.2.1(a); and

(h) Such other matters as the Parties may mutually agree in writing or that are expressly delegated to the JMC in this Agreement.

3.3.3. **Meetings**. During the CMC Term, the JMC will meet in person or by teleconference or videoconference at least [**]. The JMC also may choose to meet more frequently on an as needed basis and will meet upon the request of either Party. The chairperson of the JMC will coordinate and prepare the agenda (which agenda will include items requested by either Party) for, and ensure the orderly conduct of, the meetings of the JMC. Each Party will bear its own expenses related to its JMC representatives' participation in and attendance at such meetings.

3.3.4. **Decisions**.

(a) A quorum of the JMC is required for any meeting of the JMC, which quorum will exist only if the JMC representative of each Party is present. No action taken at a meeting of the JMC shall be effective unless a quorum exists.

(b) The JMC will only have authority to determine, approve or resolve matters that the JMC is expressly authorized to determine, approve or resolve under this Agreement ("**JMC Matters**"). The JMC will determine, approve or resolve JMC Matters by consensus, with the representatives of each Party collectively having one vote on behalf of such Party. In the event that the JMC does not reach consensus on a JMC Matter within [**] after the JMC Matter is first presented to the JMC, the JMC Matter may be referred by either Party to the Executive Officers, who will use reasonable efforts to meet promptly to discuss and resolve such matter. If such Executive Officers do not reach agreement with respect to a particular JMC Matter within [**] after the matter is first referred to such Executive Officers, ATSA will have final decision-making authority relating to such JMC Matter (including amendments to the CMC Plan); provided that, ATSA will not have the right to exercise its final decision-making authority:

(i) [**];

(ii) to approve the initial CMC Plan for the Primary Target or the Secondary Target;

(iii) to amend or modify a CMC Plan, if such amendment or modification (A) would result in an increase (as reasonably demonstrated by Mersana through written documentation) to Mersana's FTE Costs and Out-of-Pocket Expenses of [**], individually with respect to a proposed amendment or in the aggregate with respect to a proposed amendment and all previously approved amendments, as compared to the FTE Costs and Out-of-Pocket Expenses to conduct the activities in the initial CMC Plan, to conduct the activities allocated to Mersana under such CMC Plan, would require Mersana to perform Manufacturing activities beyond what is identified as Mersana's responsibility under Section 2.3.2 or beyond what is in Section 5.3, (B) would require Mersana to perform CMC activities beyond the expiration of the CMC Term for such Research Program, or (C) could potentially require modifications to the use of the Mersana Technology in such Research Program.

(iv) to approve the initial CMC Budget or any amendments to the CMC Budget for the Primary Target or the Secondary Target; or

(v) to approve the initial Technology Transfer Plan or Technology Transfer Budget or any amendments to the Technology Transfer Plan or Technology Transfer Budget for a Licensed Product for the Primary Target or the Secondary Target.

(c) Neither the JMC nor ATSA (when exercising its final decision-making authority) has the authority to: (i) amend, modify or waive compliance with any term or condition of this Agreement; (ii) make any decision that is expressly stated in this Agreement to require the mutual agreement of the Parties or one Party's approval or consent; (iii) decide any issue in a manner that would conflict with the express terms and conditions of this Agreement; or (iv) resolve any dispute, including whether or in what amount a payment is owed under this Agreement or whether a Party is in breach of this Agreement.

3.3.5. **Minutes and Reports**. The JMC will maintain accurate minutes of its meetings, including all proposed decisions and recommended actions or decisions taken. Promptly after each meeting, either the chairperson of the JMC or another member of the JMC designated by the JMC will provide the Parties with draft minutes of the meeting, including any issues requiring decisions, any proposed decisions and recommended actions or decisions taken. Within [**] of each meeting, the JMC chair will provide final versions of the meeting minutes. Minutes will be deemed approved unless any member of the JMC objects to the accuracy of such minutes by providing written notice to the other members of the JMC prior to the next meeting of the JMC. In the event of any objection to the minutes that is not resolved by mutual agreement of the Parties, such minutes will be amended to reflect such unresolved dispute.

3.3.6. **Duration**. Unless earlier terminated by mutual written consent of the Parties, the JMC will be in existence until, and will be automatically dissolved on, the last day of the last-to-expire CMC Term.

Section 3.4. **Joint Intellectual Property Committee**.

3.4.1. **Formation and Composition**. Within [**] after the Effective Date, the Parties will establish a joint intellectual property committee (the "**Joint Intellectual Property Committee**" or "**JIPC**") composed of [**] of each of ATSA and Mersana. Each JIPC representative must be an employee or outside patent counsel of the appointing Party. A Party may at any time, by written notice to the other Party's representative on the JIPC, change its representative on the JIPC or elect to be represented by a delegate at a meeting of the JIPC, provided that such delegate is an employee or outside patent counsel of such Party. The Parties may allow additional employees to attend meetings of the JIPC subject to the confidentiality provisions of Article 8.

3.4.2. **Functions and Authority**. The JIPC will be responsible for only the following:

(a) for each Research Program, draft and propose a Strategic IP Plan (and any amendments thereto) to the Parties, which Strategic IP Plan at a minimum needs to detail the countries of filing and a patent filing strategy, which strategy shall (i) be aligned between the Parties to secure the maximum protection of ATSA Foreground IP, Licensed ADC or Licensed Product and Mersana Foreground IP, (ii) include that in the case that any proposed filing with respect to an ATSA ADC Patent or ATSA Product Patent in the ATSA Foreground IP discloses a species generically covered by any potential Mersana Patent and ATSA Patent, ATSA and Mersana will use good faith efforts to coordinate filings with respect to such ATSA ADC Patent, ATSA Product Patent, ATSA Patent and Mersana Patent so that filings with respect to such ATSA ADC Patent, ATSA Product Patent, ATSA Patent and Mersana Patent are made no earlier than the same day and (iii) that any proposed filing of a Mersana Patent must not disclose unpublished ATSA Know-How and any proposed filing of an ATSA Patent must not disclose unpublished Mersana Know-How without the JIPC's prior written consent;

(b) oversee the drafting, filing, prosecution and maintenance of all ATSA ADC Patents and ATSA Product Patents generated from the activities under this Agreement in accordance with the Strategic IP Plan and Article 9, which shall include overseeing Mersana's reasonable opportunity to comment on all ATSA ADC Patent and ATSA Product Patent filings and ATSA's obligation to reasonably consider in good faith Mersana's comments with respect thereto;

(c) as necessary, take decisions relating to the drafting, filing, prosecution and maintenance of the resulting ATSA ADC Patents and ATSA Product Patents in accordance with the Strategic IP Plan and Article 9;

(d) report to the Parties on the drafting, filing, prosecution and maintenance of the ATSA ADC Patents and ATSA Product Patents;

(e) propose to the Parties 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;

(f) discussing and resolving any dispute over whether any Third Party Know-How or Patent Rights constitutes Platform Blocking IP or Product Blocking IP pursuant to Section 4.8.3.

(g) discussing whether it is necessary to enter into any license agreements with a Third Party in respect of a Designated Target; and

(h) such other matters as the Parties may mutually agree in writing or that are expressly delegated to the JIPC in this Agreement.

In the event of a conflict between the JIPC's authority under this Section 3.4.2 and a Party's rights under Section 9.3.3 or Section 9.3.4, as applicable, Mersana's and ATSA's respective rights under Section 9.3.3 and Section 9.3.4 shall prevail.

3.4.3. **Meetings**. During the Term, the JIPC will meet in person or by teleconference or videoconference [**]. Each Party will bear its own expenses related to its JIPC representative's participation in and attendance at such meetings.

3.4.4. **Decisions**.

(a) A quorum of the JIPC is required for any meeting of the JIPC, which quorum will exist if the JIPC representative for each Party is present. No action taken at a meeting of the JIPC shall be effective unless a quorum exists.

(b) The JIPC will only have authority to determine, approve or resolve matters that the JIPC is expressly authorized to determine, approve or resolve under this Agreement ("**JIPC Matters**"). The JIPC will determine, approve or resolve JIPC Matters by consensus, with the representative of each Party collectively having one (1) vote on behalf of such Party. In the event that the JIPC does not reach consensus on a JIPC Matter within [**] after the matter is first presented to the JIPC, the JIPC Matter may be referred by either Party to the Executive Officers, who will use reasonable efforts to meet promptly to discuss and resolve such matter. The JIPC shall however have no authority to amend any Strategic IP Plan or this Agreement.

(c) With respect to resolving a dispute over whether any Third Party Know-How or Patent Rights constitutes Platform Blocking IP or Product Blocking IP pursuant to Section 4.8.3, if, following escalation of the matter to the Executive Officers in accordance with Section 3.4.4(b), the Executive Officers are unable to resolve such matter after [**] from when the Executive Officers first meet, then either Party may refer such matter for resolution to an independent Third Party patent attorney agreed upon by the Parties. Such independent patent attorney will have no less than [**] of expertise in the pharmaceutical or biotechnology industry and relevant expertise in the specific matter at issue and, unless otherwise agreed in writing by the Parties, must not be a current or former employee, contractor, agent, or consultant of either Party or its Affiliates. The Parties will jointly engage such expert and the Parties will share equally the out-of-pocket costs incurred in connection with the engagement of such expert. No more than [**] after the engagement of such expert, such expert will deliver its written decision to the Parties as to whether or not such Third Party Know-How or Patent Rights constitutes Platform Blocking IP or Product Blocking IP as applicable (including a detailed report as to such expert's rationale for such decision), and such decision will be binding on the Parties.

3.4.5. **Minutes and Reports**. The JIPC will document their decisions regarding each Strategic IP Plan in the meeting minutes. The JIPC will draft, distribute and maintain accurate minutes of its meetings, including with respect to all matters discussed at such meeting, in accordance with policies to be agreed by the JIPC.

3.4.6. **Duration**. Unless earlier terminated by mutual written consent of the Parties, the JIPC will be in existence until the end of the Term.

ARTICLE 4

LICENSE GRANTS.

Section 4.1. **Research and CMC License to Mersana**. Subject to the terms and conditions of this Agreement, and for clarity, if applicable, ATSA Antibody Conditions, ATSA will, and hereby does, grant to Mersana and its Affiliates, a non-exclusive, transferrable (only to the extent set forth in Section 14.2 [**]), sublicensable (only to the extent set forth below in this Section 4.1 [**]), worldwide, royalty-free right and license to and under the ATSA IP solely to conduct (i) its activities under each Research Plan during the applicable Research Program Term, and (ii) its activities under each CMC Plan during the applicable CMC Term. Such license includes [**] the right to grant sublicenses through multiple tiers to Third Party subcontractors who conduct activities under the applicable Research Program on behalf, and under the direction of Mersana or its Affiliates, as applicable, subject to compliance with Section 2.4 and any applicable ATSA Antibody Conditions.

Section 4.2. **Research License to ATSA.** Subject to the terms and conditions of this Agreement, Mersana will, and hereby does, grant to ATSA and its Affiliates, a non-exclusive, transferrable (only to the extent set forth in Section 14.2), sublicensable (only to the extent set forth below in this Section 4.2), worldwide, royalty-free right and license to and under the Mersana IP solely to conduct its activities under each Research Plan during the applicable Research Program Term or research activities that are solely relating to the Licensed ADC or Licensed Product during the Term. Such license includes the right to grant sublicenses through multiple tiers to Third Party subcontractors who conduct activities under the applicable Research Program on behalf, and under the direction of ATSA or its Affiliates, as applicable, subject to compliance with Section 2.4.

Section 4.3. **Exclusive Licenses to ATSA**. With respect to each Designated Target, subject to the terms and conditions of this Agreement, Mersana will, and does hereby, grant to ATSA an exclusive (even as to Mersana, except to the extent required for Mersana to perform its obligations under this Agreement), irrevocable (except as provided in Section 12.7), transferrable (only to the extent set forth in Section 14.2), sublicensable (only to the extent set forth in Section 4.5), royalty-bearing (a) right and license to and under the Mersana IP and Mersana's interest to and under the Joint IP, necessary to Exploit (including to conduct its activities under each Research Plan during the applicable Research Program Term) the Licensed ADCs or the Licensed Products, and (b) right to reference to the Mersana Regulatory Documentation in accordance with Article 6, solely in connection with its exercise of its rights under clause (a) of this Section 4.3, in each case ((a) and (b)), solely to Exploit the Licensed ADCs or the Licensed Product Directed to such Designated Target in the Field in the Territory (collectively (a) and (b) with respect to such Designated Target, an "Exclusive License"). For clarity, the Exclusive License does not grant ATSA rights under the Mersana IP to Develop, Manufacture or Commercialize any active ingredient within a Licensed Product that is not the applicable Licensed ADC. Each Exclusive License will continue for the applicable Royalty Term and thereafter, as provided in Section 12.7.4, unless earlier terminated pursuant to Article 12.

Section 4.4. **Unblocking License Upon Termination of Exclusivity or Termination of Agreement**. Subject to the terms and conditions of this Agreement, on a Designated Target-by-Designated Target basis and effective upon the earlier of (i) termination of Mersana's exclusivity obligations under Section 2.8.1 with respect to such Designated Target, and (ii) termination of this Agreement with respect to such Designated Target, ATSA will, and hereby does, grant to Mersana and its Affiliates, a non-exclusive, perpetual, transferrable (only to the extent set forth in Section 14.2), sublicensable (through multiple tiers), worldwide, royalty-free

right and license to and under [**]; provided that, the license in this Section 4.4 does not grant Mersana or its Affiliates any right or license to and under (1) any ATSA Background IP or (2) any ATSA Foreground IP specifically related to or covering any ATSA Antibody.

Section 4.5. **Sublicensing**. Subject to Section 2.5.2, ATSA will have the right to grant sublicenses under each Exclusive License through multiple tiers to any Affiliate or any Third Party, subject to the applicable terms and conditions of any Future Mersana In-Licenses. As a condition to granting any sublicense hereunder, ATSA will require each Sublicensee to assign to ATSA all Know-How and Patent Rights invented, conceived, or developed by or on behalf of any such Sublicensee, whether alone or with ATSA or a Third Party, that would be Mersana IP if invented, conceived or developed by ATSA (alone or with ATSA) under this Agreement. ATSA 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. ATSA will promptly (but in any event, within [**]) notify Mersana after granting any sublicense to a Sublicensee under any rights granted to ATSA under the Exclusive License and will provide a copy of the sublicense agreement with such Sublicensee, which agreement may be redacted to remove information not relevant for the purposes of checking compliance with sublicense requirements hereunder. ATSA 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.

Section 4.6. **Compliance with the Mersana In-Licenses**. ATSA and its Affiliates will comply with, and ATSA shall cause its Sublicensees to comply with, all obligations, covenants and conditions of any Future Mersana In-Licenses, and any amendments thereto (following written disclosure and notice to ATSA of such Future Mersana In-Licenses), that apply under any Future Mersana In-Licenses to ATSA, its Affiliates or Sublicensees, as applicable.

Section 4.7. **Compliance with ATSA In-Licenses**. Mersana and its Affiliates will comply with, and Mersana shall cause its sublicensees to comply with, all obligations, covenants and conditions of any Future ATSA In-Licenses, and any amendments thereto (following written disclosure and notice to Mersana of such Future ATSA In-Licenses), that apply under any Future ATSA In-Licenses to Mersana, its Affiliates or Sublicensees, as applicable, [**].

Section 4.8. **New Third Party Agreements**.

4.8.1. Mersana will be responsible for obtaining, and will have the sole right to obtain, a license to any Platform Blocking IP, and will be responsible for any payment obligations and all other liabilities or costs under such license (but excluding, for clarity, liabilities or costs caused by breach of the agreement by ATSA or costs of ATSA's compliance with such agreement, which, in each case, shall be borne by ATSA) in accordance with Section 7.4.1. Each Party will notify the other Party when it becomes aware of any Platform Blocking IP necessary to use the Mersana Technology to Research, Develop, Manufacture or otherwise Exploit the Licensed ADCs or the Licensed Products. Upon entering a license for rights to such Platform Blocking IP, Mersana will provide ATSA with a summary of the terms of such license that would apply to ATSA as a sublicensee, as well as a copy of such license, which copy may be redacted with respect to terms that would not be applicable to ATSA. Upon ATSA's notice to Mersana that it agrees to comply with the terms of such license and provide any information necessary for Mersana to meet its payment obligations under any such license, which notice must be provided within [**] of receipt of such summary of terms by ATSA, and such license will be deemed a Future Mersana In-License under this Agreement, with such in-licensed rights under such agreement being subject to the license grants under Article 4.

4.8.2. ATSA will be responsible for obtaining, and will have the sole right to obtain, a license to any Product Blocking IP, and will be responsible for any payment obligations and all other liabilities or costs under such license (but excluding, for clarity, liabilities or costs caused by breach of the agreement by Mersana or costs of Mersana's compliance with such agreement, which, in each case, shall be borne by Mersana) in accordance with Section 7.4.2. Each Party will notify the other Party when it becomes aware of Product Blocking IP necessary to Exploit the Licensed ADCs or the Licensed Products. Upon entering a license for rights to such Product Blocking IP, ATSA will provide Mersana with a summary of the terms of such license that would apply to Mersana as a sublicensee, as well as a copy of such license, which copy may be redacted with respect to terms that would not be applicable to Mersana. Upon Mersana's notice to ATSA that it agrees to comply with the terms of such license and provide any information necessary for ATSA to meet its payment obligations under any such license, which notice must be provided within [**] of receipt of such summary of terms by Mersana, and such license will be deemed a Future ATSA In-License under this Agreement, with such in-licensed rights under such agreement being subject to the license grants under Article 4. To the extent that ATSA (a) fails to enter an agreement with an applicable Third Party to obtain rights to any Product Blocking IP necessary for Mersana to perform its obligations under this Agreement, or (b) amends a Future ATSA In-License in a manner that causes Mersana to reasonably believe it no longer has sufficient rights under Product Blocking IP necessary to perform its obligations under this Agreement, in each case (a) and (b) as determined by the JIPC under Section 3.4.2(f) (including, if necessary, the dispute resolution process in Section 3.4.4), then Mersana shall be excused from performing, and shall not have liability with respect to the failure to perform, such obligations under this Agreement until it has such rights under Product Blocking IP.

4.8.3. Any disputes concerning whether any Third Party intellectual property is Platform Blocking IP or Product Blocking IP shall be resolved by the JIPC in accordance with Section 3.4.4.

ARTICLE 5

DEVELOPMENT, COMMERCIALIZATION, SUPPLY AND MANUFACTURING.

Section 5.1. **In General**. Subject to Section 5.1.1, ATSA will have the sole right and responsibility, at its sole expense, for all aspects of the Exploitation of Licensed ADCs and Licensed Products, except with respect to those obligations of Mersana in support thereof as provided hereunder, including as set forth in (a) in the Research Plans during the Research Program Term and those activities of Mersana in support thereof in the CMC Plans, and (b) as set forth in Section 5.3 and Article 6.

5.1.1. **Designation of Licensed ADC**.

(a) The first ADC in a Research Program for which an IND is filed with the applicable Regulatory Authorities in any country in the Territory during the applicable Research Program Term shall be deemed the Licensed ADC for the Research Program for the applicable Designated Target, unless the Parties mutually agree in writing to designate a different ADC from such Research Program to be the Licensed ADC. Each Research Program may only have up to one (1) Licensed ADC, and such Licensed ADC must be designated prior to the end of the Research Program Term, either through the filing of an IND for the applicable ADC (or through mutual agreement of the Parties in writing). ATSA acknowledges and agrees that, following the Research Program Term for a Designated Target, the Exclusive License granted to ATSA is limited to Exploiting up to one (1) Licensed ADC and a Licensed Product containing such Licensed

ADC Directed to such Designated Target. ATSA will have the sole and exclusive right to decide which Licensed ADC it will file an IND for in each Research Program.

(b) [**].

5.1.2. **Diligence**. For each Designated Target, ATSA shall use Commercially Reasonable Efforts to (a) Develop and obtain Regulatory Approval (and, if necessary to Commercialize a Licensed Product in such country, Pricing Approval) for the [**] Directed to such Designated Target for [**], and (b) following receipt of Regulatory Approval in [**], Commercialize such Licensed Product in such country.

5.1.3. **Compliance**. ATSA will comply with all Applicable Laws (including Good Laboratory Practices, Good Clinical Practices, and Good Manufacturing Practices) in the Exploitation of each Licensed ADC or Licensed Products, and will require its Affiliates and Sublicensees to do the same.

5.1.4. **Right to Subcontract of ATSA.** Subject to Section 2.4 as applicable, ATSA may exercise any of its rights, or perform any of its obligations, under this Agreement (including any of the rights licensed in Section 4.3) by subcontracting the exercise or performance of all or any portion of such rights and obligations on ATSA's behalf; provided that any such subcontractor is bound to applicable provisions of this Agreement, including obligations of confidentiality and assignment of inventions comparable in scope to and consistent with those included herein. Any subcontract granted or entered into by ATSA as contemplated hereunder of the exercise or performance of all or any portion of the rights or obligations that ATSA may have under this Agreement shall not relieve ATSA from any of its obligations under this Agreement.

Section 5.2. **Funding and Progress Reports**. ATSA will be solely responsible for funding all costs of the Exploitation of each Licensed Product pursuant to each Exclusive License. ATSA will keep Mersana informed in a timely manner as to the progress of the Development of Licensed Products by delivering reports in accordance with this Section 5.2. After [**] following the expiration of the Research Program Term, on a Licensed Product-by-Licensed Product basis, ATSA will provide Mersana, through its alliance manager identified in accordance with Section 3.1, with written [**] reports that provide a summary of ATSA's significant 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 ATSA's Confidential Information for the purposes of Article 8.

Section 5.3. **Manufacturing**.

5.3.1. **Mersana Manufacturing Obligations**. Mersana shall (i) Manufacture and supply, and shall perform release, characterization and stability testing on, pre-clinical and, pursuant to a Clinical Supply Agreement, if any, clinical supplies of GLP bulk drug substance of ADCs, including for GLP Toxicology Studies and (ii) perform testing on Licensed Product containing ADCs for a reasonable period of time to be agreed upon by the Parties, in each case ((i) and (ii)), as set forth in the applicable CMC Plan or the Clinical Supply Agreement, as applicable, and in accordance with the terms of this Section 5.3. For clarity, whether under the CMC Plan or a Clinical Supply Agreement (and only during the applicable term thereof), Mersana shall only be obligated to perform (or have performed) Manufacture of the [**], and to conduct testing of such material containing ADCs for GLP Toxicology Studies and clinical

studies, and shall not be responsible for any further manufacturing or processing (*e.g.*, drug product or finished product manufacturing).

5.3.2. **Pre-Clinical Supplies of ADCs for Research Plan Activities**. In accordance with the applicable CMC Plan for a Designated Target, Mersana shall use Commercially Reasonable Efforts to Manufacture and supply each Party's requirements of pre-clinical supplies of bulk drug substance of ADCs for use in GLP Toxicology Studies under the Research Plan for such Designated Target, and shall perform release, characterization and stability testing on intermediates and ADCs (up to, but not including, drug product manufacturing, unless otherwise agreed by the Parties), and testing of such ADCs for an agreed period of time, in connection with such supplies. Mersana shall use Commercially Reasonable Efforts to Manufacture and supply such pre-clinical supplies in accordance with the timelines set forth in the CMC Plan.

5.3.3. **Clinical Trial Supplies of Licensed ADCs**. If, after Pre-Clinical Development Candidate Designation, ATSA desires for Mersana to continue the Manufacture and supply of Licensed ADCs Directed to Designated Targets for use in Clinical Trials for Licensed Products containing such Licensed ADCs (or testing of clinical supplies of Licensed Product containing Licensed ADCs as agreed by the Parties), then upon ATSA's request, the Parties will discuss and negotiate in good faith a supply agreement setting forth the terms and conditions applicable to the Manufacture and supply of clinical supplies of the Licensed ADCs (and testing of clinical supplies of Licensed Product containing Licensed ADCs) from Mersana to ATSA (the "**Clinical Supply Agreement**") and a related quality agreement. Each Clinical Supply Agreement shall be consistent with the terms of this Section 5.3, and shall contain reasonable and customary terms for agreements of its type and for this type of product and at such product's stage of development (including terms appropriate for the clinical studies the products will be used for, forecasting and ordering requirements, delivery, termination and indemnification). If ATSA Controls any Know-How or Patent Rights that are necessary to Manufacture clinical supplies of the applicable Licensed ADCs, the Clinical Supply Agreement will also include a license from ATSA to Mersana under Know-How and Patent Rights Controlled by ATSA that is necessary to perform such Manufacturing activities on ATSA's behalf. Until the Clinical Supply Agreement is executed, the terms set forth in this Section 5.3 shall apply to such clinical supply of Licensed ADCs. For clarity, the Manufacture, supply and testing of such clinical supplies by Mersana will not be included in the CMC Plan for the applicable Designated Target (and, instead, the Manufacture and supply of such clinical supplies will be governed by the Clinical Supply Agreement, if any), but any CMC Development activities necessary to support the Manufacture of such clinical supplies may be included in the CMC Plan for the applicable Designated Target.

5.3.4. **Supply of ATSA Antibodies**. All of Mersana's supply and testing obligations under this Section 5.3 will be subject to ATSA's delivery of sufficient quantities of the relevant ATSA Antibody that meet the applicable specifications and are otherwise of sufficient quality for use in the Research Program or Clinical Trials, as applicable.

5.3.5. **Costs of Supplies**. For preclinical supplies and Phase I Clinical Trial supplies (if the Parties enter into a Clinical Supply Agreement) of ADCs provided by Mersana to ATSA pursuant to this Section 5.3, ATSA will pay Mersana a supply price equal to [**]. The cost of supply for Clinical Trials other than the Phase I Clinical Trial will be set forth in the Clinical Supply Agreement.

5.3.6. **Technology Transfer**.

(a) Subject to the provisions of this Section 5.3.6, for each applicable Licensed ADC, upon ATSA's request following the initiation of a Phase I Clinical Trial for a Licensed Product containing such Licensed ADC, and in accordance with the applicable Technology Transfer Plan, Mersana shall conduct a technology transfer to ATSA, one of its Affiliates or a CMO that is designated by ATSA for the Manufacturing process for such ADC [**]; provided that ATSA may request such technology transfer prior to [**], Mersana shall, provide such technology transfer. As part of such technology transfer, Mersana shall: (i) [**]; and (ii) [**]. ATSA may delay the timing of such technology transfer services to help enable Manufacturing by ATSA, its Affiliate or its CMO, as applicable, until [**] or, if ATSA elects to have Mersana supply in accordance with Section 5.3.3, ADCs for Clinical Trials, until [**].

(b) Notwithstanding anything to the contrary in this Agreement, Mersana shall have no obligation to transfer to ATSA or its Affiliates or Sublicensees, and ATSA or its Affiliates or Sublicensees may not practice during the Term, any manufacturing Know-How under the Mersana IP specifically related to the synthesis of the scaffold-linker-payload, and ATSA or its Affiliates or Sublicensees shall only obtain access to such Know-How through Mersana or a Mersana's CMO under a supply agreement upon mutually agreed terms with Mersana.

(c) The technology transfer(s) described in this Section 5.3.6 will be conducted for each Designated Target in accordance with a technology transfer plan developed and approved by the JMC (the "**Technology Transfer Plan**"). Each Technology Transfer Plan will set forth the technology transfer activities to be conducted by the Parties in relation to the Licensed ADC Directed to the applicable Designated Target. Each Technology Transfer Plan shall be accompanied by a budget for the Technology Transfer Costs to be accrued or incurred by Mersana and its Affiliates in conducting the activities described in the Technology Transfer Plan (the "**Technology Transfer Budget**").

(d) Promptly following ATSA's request to commence a technology transfer with respect to a Designated Target, the initial Technology Transfer Plan for such Designated Target will be developed and approved by the JMC. Each Technology Transfer Plan will include all activities necessary to conduct a technology transfer as described in Section 5.3.6(a) (as limited by Section 5.3.6(b)). Mersana shall provide an initial Technology Transfer Budget proposal to ATSA for each initial Technology Transfer Plan promptly following JMC approval of an initial Technology Transfer Plan, and the JMC will review and discuss the initial Technology Transfer Budget proposal and make revisions as necessary. The Technology Transfer Budget will not go into effect unless and until approved by the JMC. Notwithstanding anything to the contrary herein, Mersana shall not be obligated to perform any Technology Transfer Plan activities until the initial Technology Transfer Plan and the initial Technology Transfer Budget have been approved by the JMC.

(e) Each Party may, via the JMC, propose changes to a Technology Transfer Plan or Technology Transfer Budget, which will be subject to review and approval by the JMC as provided in Section 3.3.2; provided that any change to the Technology Transfer Plan approved by the JMC that will result in an increase to the Technology Transfer Costs will not become effective until a corresponding change to the Technology Transfer Budget is approved by the JMC.

(f) ATSA shall reimburse the Technology Transfer Costs accrued or incurred by Mersana and its Affiliates in conducting the technology transfer activities allocated to it in the Technology Transfer Plan in accordance with Section 7.2.

5.3.7. **Use of CMOs**. Subject to Section 2.4, Mersana may perform its obligations set forth under this Section 5.3 itself or through a CMO.

5.3.8. **Other Manufacturing of Licensed Products**. Other than as expressly provided in this Section 5.3, ATSA shall be responsible for all Manufacturing of the Licensed Products at its cost with respect to activities under this Agreement. For clarity, ATSA will be responsible for the Manufacture of all clinical supplies of Licensed Products, unless otherwise agreed in a Clinical Supply Agreement, and for all commercial supplies of Licensed Products.

Section 5.4. **Commercialization**. ATSA will have the sole right to Commercialize the Licensed Products in the Field in the Territory under this Agreement, including 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, ATSA or its subcontractors 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. ATSA will notify Mersana within a reasonable period after commencing any recall of any Licensed Product wherein such recall may be related to Mersana Technology or Mersana's Manufacture and supply of such Licensed Product to ATSA.

ARTICLE 6

REGULATORY MATTERS.

Section 6.1. **Regulatory Assistance**.

6.1.1. **ATSA Rights and Obligations**. As between the Parties, ATSA 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 Laws. Promptly following ATSA making a Pre-Clinical Development Candidate Designation with respect to a Licensed Product, Mersana will, and does hereby, assign to ATSA or its designated Affiliate or Sublicensee all of its right, title and interest in and to all Regulatory Documentation, if any, solely and exclusively relating to any applicable Licensed ADC or such Licensed Product.

6.1.2. **Mersana Cooperation**. At ATSA's reasonable request [**], Mersana will consult and cooperate with ATSA 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 ATSA 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 ATSA's respective filings relating to a Licensed Product. ATSA will compensate Mersana for its Regulatory Assistance Costs in accordance with Section 7.2.

6.1.3. **ATSA Cooperation**. At Mersana's reasonable request [**], ATSA will reasonably assist Mersana in Mersana's preparation of filings and submissions necessary to obtain and maintain Regulatory Approval for other products Exploited by Mersana or its Affiliates or sublicensees utilizing the Mersana Technology; provided that ATSA shall not be obligated to assist Mersana in connection with any such products Directed to a Designated Target. Such assistance shall solely include providing rights of reference and necessary instruments effectuating such rights to the extent such rights of reference may be granted by ATSA without violating any agreement between ATSA and a Third Party and are necessary in Mersana's respective filings relating to such product and which rights of reference ATSA hereby grants to Mersana, its Affiliates and licensees upon request by Mersana.

Section 6.2. **Regulatory Participation**. ATSA will keep Mersana reasonably informed regarding the status and progress of seeking Regulatory Approval for each Licensed Product, including the following:

6.2.1. **Access to Applications**. ATSA will provide to Mersana copies of all Regulatory Documentation related to the Mersana Technology reasonably in advance of such filing or major submission to Regulatory Authorities for Mersana to have a reasonable opportunity to review such filing or submission (and in any event at least [**] in advance). Mersana will provide comments on such proposed Regulatory Documentation, if any, to ATSA as soon as practicable following receipt thereof, and ATSA will consider in good faith any timely comments provided by Mersana. ATSA will provide Mersana final copies of such Regulatory Documentation following such filing or submission to Regulatory Authorities.

6.2.2. **Correspondence**. With respect to material communications with Regulatory Authorities related to the Mersana Technology that do not constitute Regulatory Documentation, ATSA will provide Mersana with a reasonable opportunity to review any proposed written communications or discuss with Mersana any proposed oral communications prior to providing such communication or discussing with any Regulatory Authority. Mersana will provide comments on such proposed communications, if any, to ATSA as soon as practicable following receipt thereof, and ATSA will consider in good faith any timely comments provided by Mersana. ATSA will provide Mersana final copies of such written communications with the Regulatory Authorities, or will provide a summary of any oral communications with the Regulatory Authorities, to the extent related to the Licensed Products or the Mersana Technology.

Section 6.3. **Pharmacovigilance**. Prior to the clinical Development of the first Licensed Product Directed at a Designated Target, the Parties will discuss and execute a pharmacovigilance agreement (the "**Pharmacovigilance Agreement**"), which will set forth the responsibilities of each Party with respect to pharmacovigilance matters relating to such Licensed Product. If there is a Licensed Product for the other Designated Target, then the Parties will either amend the Pharmacovigilance Agreement or enter into a new one for that Licensed Product for the other Designated Target. The Pharmacovigilance Agreement will provide for (a) disclosure by ATSA to Mersana of safety data Controlled by ATSA or its Affiliates with respect to the Licensed Products, solely to the extent ATSA determines that such safety data relates to the Mersana Technology and solely for use by Mersana in complying with its regulatory obligations with respect to other Antibody-drug conjugate products that utilize the Mersana

Technology and (b) disclosure by Mersana to ATSA of safety data Controlled by Mersana or its Affiliates with respect to other Antibody-drug conjugate products that utilize the Mersana Technology, solely to the extent Mersana determines that such safety data relates to the Mersana Technology and solely for use by ATSA in complying with its regulatory obligations with respect to the Licensed Products. The Parties will update the Pharmacovigilance Agreement from time to time as needed to properly reflect the status of the marketing and sale of each Licensed Product and the relevant pharmacovigilance regulations in the Territory. ATSA will maintain the global safety database for each Licensed Product and will establish and maintain all necessary pharmacovigilance requirements for a Licensed Product in full compliance with all Applicable Laws and requirements of the Regulatory Authorities in the Territory. Mersana will establish and maintain appropriate pharmacovigilance systems to fulfill its responsibilities under the Pharmacovigilance Agreement.

ARTICLE 7

FEES, MILESTONES, AND ROYALTIES.

Section 7.1. **Upfront Fee**. After the Effective Date, within forty-five (45) days after receipt of the corresponding invoice from Mersana, ATSA will pay to Mersana, a one-time, non-refundable, non-creditable, upfront fee of Thirty Million Dollars ($30,000,000.00) (the "**Upfront Fee**").

Section 7.2. **CMC Costs; Technology Transfer Costs; Regulatory Costs**.

7.2.1. **CMC Costs**.

(a) [**] Estimated Pre-Payment. Within [**] of the approval of the [**] CMC Budget by the JMC, and prior to the start of each [**] thereafter during the CMC Term, Mersana will invoice ATSA for, an amount equal to [**] of the applicable CMC Budget amount for such [**] ("**Estimated Pre-Payment**"). ATSA will make the Estimated Pre-Payment within [**] of receipt of the corresponding invoice.

(b) Reconciliation. Within [**] after the end of each [**] during each CMC Term (including any partial [**] at the end of a CMC Term), Mersana will provide ATSA with a reasonably detailed reconciliation report evidencing (1) the CMC Costs actually accrued or incurred by Mersana during such [**], (2) the amounts pre-paid by ATSA for such [**] and (3) as the case may be ((i) or (ii)), (i) the amount by which the CMC Costs actually accrued or incurred by Mersana during such [**] exceed the amounts pre-paid by ATSA for such [**], or (ii) the Overage for such [**]. Such reconciliation report shall include reasonable supporting information and documentation (including related supporting third party invoices as applicable) concerning the CMC Costs actually accrued or incurred during such [**]. If such CMC Costs exceed amounts pre-paid by ATSA for such [**], they will be paid by ATSA within [**] following receipt of an invoice covering such amounts exceeding the pre-paid CMC Costs. Such invoice shall be provided to ATSA concurrently with the reconciliation report. Any amounts pre-paid by ATSA for such [**], that exceed the CMC Costs actually accrued or incurred by Mersana during such [**] (such excess amount, the "**Overage**"), will be refunded by Mersana to ATSA within [**] following the end of such [**]. Any disputes on accrued or incurred costs and significant discrepancies to the cost projections agreed upon in the CMC Plan and quarterly CMC Budget shall be discussed in the JMC.

7.2.2. **Technology Transfer Costs**. For each Designated Target, ATSA shall pay Mersana on a [**] basis in arrears for the Technology Transfer Costs actually accrued or incurred by Mersana and its Affiliates in line with Mersana's Accounting Standards during the foregoing [**]. Mersana shall invoice ATSA for such costs after the end of each [**], with each invoice accompanied by a reasonable supporting explanation and documentation for such invoiced amounts. Any disputes on accrued or incurred costs and significant discrepancies to the Technology Transfer Plan and Technology Transfer Budget shall be discussed in the JMC.

7.2.3. **Regulatory Costs**. Prior to Mersana's commencement of regulatory activities pursuant to Section 6.1, the Parties will meet to discuss the scope of activities that Mersana shall be required to perform and related cost projections. ATSA shall pay Mersana on a [**] basis in arrears for the Regulatory Assistance Costs actually accrued or incurred by Mersana and its Affiliates in line with Mersana's Accounting Standards during the foregoing [**]. Mersana shall invoice ATSA for such costs after the end of each [**], with each invoice accompanied by a reasonable supporting explanation and documentation for such invoiced amounts. Any disputes on accrued or incurred costs and significant discrepancies to the cost projection shall be discussed in the JRC.

7.2.4. **Payments**. ATSA will pay Mersana the undisputed amounts set forth in any invoice submitted pursuant to this Section 7.2 within [**] after receipt of the applicable invoice by ATSA. ATSA may request and Mersana shall provide reasonably available records and Third Party invoices to substantiate the invoiced costs and expenses. Mersana will not double charge ATSA for any costs or expenses subject to reimbursement under this Section 7.2.

Section 7.3. **Royalties Payable by ATSA**.

7.3.1. **Royalties**. On a Licensed Product-by-Licensed Product and country-by-country basis, ATSA will pay to Mersana royalties on worldwide annual aggregate Net Sales of each Licensed Product for each Calendar Year 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 Net Sales of the Licensed Product for each Calendar Year	**Royalty rate**
For Net Sales of the Licensed Product up to and including $[**]	[**]%
For that portion of Net Sales of the Licensed Product that is greater than $[**] up to and including $[**]	[**]%
For that portion of Net Sales of the Licensed that is greater than $[**] up to and including $[**]	[**]%
For that portion of Net Sales of the Licensed Product that is greater than $[**] up to and including $[**]	[**]%
For that portion of Net Sales of the Licensed Product that is greater than $[**]	[**]%

7.3.2. **Royalty Example**. For avoidance of doubt, the incremental royalty rates set forth in Section 7.3.1 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 a Licensed Product was equal to $[**], the royalty payable by ATSA would be calculated by [**]. For purposes of determining whether a royalty threshold has been attained, only Net Sales that are subject to a royalty payment shall be included in the total amount of Net Sales and any Net

Sales that are not subject to a royalty payment shall be excluded. In addition, in no event shall the manufacture of a Licensed Product, give rise to a royalty obligation. The obligation to pay royalties will be imposed only once with respect to the same unit of Licensed Product sold by ATSA, its Affiliates or Sublicensees.

7.3.3. **Royalty Term**. ATSA's obligation to pay royalties under Section 7.3.1 will commence on the First Commercial Sale of a Licensed Product constituting Net Sales and continue on a country-by-country and Licensed Product-by-Licensed Product basis until the latest to occur of (a) the expiration of the last-to-expire Valid Patent Claim of any ATSA ADC Patent covering or claiming the composition of matter of any Licensed ADC incorporated in such Licensed Product in such country, (b) the expiration of Regulatory Exclusivity for the Licensed Product in such country, and (c) ten (10) years following the date of First Commercial Sale of such Licensed Product in such country (the "**Royalty Term**").

7.3.4. **Compulsory License.** In the event that Mersana or ATSA receives a request for a Compulsory License anywhere in the world, it shall promptly notify the other Party. If any Third Party obtains a Compulsory License in any country, then Mersana or ATSA (whoever has first notice) shall promptly notify the other Party. [**].

7.3.5. **Royalty Adjustments for No Patent Right Coverage.** On a country-by-country and Licensed Product-by-Licensed Product basis during the Royalty Term, at such time that (a) there is no Valid Patent Claim of any ATSA ADC Patent covering or claiming the composition of matter of any Licensed ADC incorporated in such Licensed Product in such country, and (b) there is no Regulatory Exclusivity in such country, then the amount of payment owed pursuant to Section 7.3.1 with respect to Net Sales of such Licensed Product in such country will be reduced by [**] percent ([**]%) for purposes of determining the amount that would otherwise be due pursuant to Section 7.3.1.

Section 7.4. **Third Party Agreements**. With respect to Third Party royalties, milestones, reimbursement or other payment obligations or other liabilities or costs that become due under or arise in relation to existing or future in-license or other collaboration agreements with respect to Licensed ADCs or Licensed Products, the Parties agree as follows:

7.4.1. Mersana will be responsible for any payment obligations (including license fees, royalties, milestones or reimbursements), liabilities or costs that become due and payable or arise under any license agreement (but excluding, for clarity, liabilities or costs caused by breach of the agreement by ATSA or costs of ATSA's compliance with such agreement, which, in each case, shall be borne by ATSA) it has entered into or will enter into after the Effective Date with Third Parties to obtain rights to Platform Blocking IP (including any Future Mersana In-License). ATSA will provide any information requested by Mersana in the manner and on the schedule so requested by Mersana in order for Mersana to meet its payment obligations under any such license agreement (including any such Future Mersana In-License) pursuant to this Section 7.4.1. In the event that Mersana shall fail to make any undisputed payment when due under a Future Mersana In-License, then ATSA shall have the right to make such payment on behalf of Mersana. In such event, Mersana shall promptly reimburse ATSA any such amounts paid by ATSA or, at ATSA's election, ATSA may offset such amounts paid by ATSA against any amounts payable to Mersana hereunder.

7.4.2. ATSA will be responsible for obtaining any necessary rights to Third Party Know-How or Patent Rights that are necessary for use of the Designated Target or ATSA Antibody or for the Exploitation of any Licensed ADC or Licensed Product (except to the extent constituting Platform Blocking IP, for which Mersana would be responsible as set forth above),

and will be solely responsible for any payment obligations (including license fees, royalties, milestones or reimbursements), liabilities or costs that become due and payable or arise under any license agreements it has entered into or will enter into after the Effective Date with Third Parties to obtain rights to Product Blocking IP (including any Future ATSA In-License), but excluding, for clarity, liabilities or costs caused by breach of the agreement by Mersana or costs of Mersana's compliance with such agreement, which, in each case, shall be borne by Mersana, and except to the extent such become due and payable or arise in relation to Platform Blocking IP, for which Mersana would be responsible as set forth above.

7.4.3. **Royalty Payment Terms**. Royalties shown to have accrued by each Royalty Report provided for under Section 7.12. will be due on the date such Royalty Report is due pursuant to Section 7.12.

Section 7.5. **Development Milestone Payments**. ATSA shall promptly notify Mersana after the first occurrence of each event set forth in the table below with respect to each Designated Target under the Agreement, as applicable, to achieve such event and pay to Mersana the following milestone payments within [**] following the receipt of the corresponding invoice from Mersana:

No.	Development Milestone Event	Development Milestone Payment
[**]		
1.	[**]	[**]
2.	[**]	[**]
3.	[**]	[**]
[**]		
4.	[**]	[**]
5.	[**]	[**]
6.	[**]	[**]
7.	[**]	[**]
8.	[**]	[**]
9.	[**]	[**]
[**]		

10.	[**]	[**]
11.	[**]	[**]
12.	[**]	[**]
13.	[**]	[**]
14.	[**]	[**]
15.	[**]	[**]
16.	[**]	[**]
17.	[**]	[**]
18.	[**]	[**]

For clarity, with respect to each of Development Milestones 1-18, the milestone payments to be made under this Agreement shall be due and payable only once per Designated Target under the Agreement.

7.5.1. **Skipped Development Milestones**. On a Designated Target-by-Designated Target basis,

(a) if Development Milestone Event [**] or [**] has not occurred with respect to a Designated Target before Development Milestone Event [**] occurs with respect to such Designated Target, then Development Milestone Event [**] or [**], as applicable, will be deemed to have occurred with respect to such Designated Target on the same date as the occurrence of Development Milestone Event [**] with respect to such Designated Target.

(b) (i) if Development Milestone Event [**] has not occurred with respect to a Designated Target before Development Milestone Event [**] occurs with respect to such Designated Target, then Development Milestone Event [**] will be deemed to have occurred with respect to such Designated Target on the same date as the occurrence of Development Milestone Event [**] with respect to such Designated Target,

and (ii) if Development Milestone Event [**] has not occurred with respect to a Designated Target before Development Milestone Event [**] occurs with respect to such Designated Target, then Development Milestone Event [**] will be deemed to have occurred with respect to such Designated Target on the same date as the occurrence of Development Milestone Event [**] with respect to such Designated Target, and

(c) if any of Development Milestone Events [**] or [**] has not occurred with respect to a Designated Target before (i) [**] with respect to a Licensed Product Directed to such Designated Target, or (ii) the date Development Milestone Event [**] occurs with respect to such Designated Target, then such Development Milestone Event will be deemed to have occurred with respect to such Designated Target on the same date that is the earlier to occur of (c)(i) and (c)(ii) with respect to such Designated Target

(d) if any of Development Milestone Events [**] or [**] has not occurred with respect to a Designated Target before (i) [**] with respect to a Licensed Product Directed to such Designated Target, or (ii) the date Development Milestone Event [**] occurs with respect to such Designated Target, then such Development Milestone Event will be deemed to have occurred with respect to such Designated Target on the same date that is the earlier to occur of (d)(i) and (d)(ii) with respect to such Designated Target and

(e) if Development Milestone Events [**] has not occurred with respect to a Designated Target before (i) [**] with respect to a Licensed Product Directed to such Designated Target, or (ii) the date Development Milestone Event [**] occurs with respect to such Designated Target, then such Development Milestone Event will be deemed to have occurred with respect to such Designated Target on the same date that is the earlier to occur of (e)(i) and (e)(ii) with respect to such Designated Target

Section 7.6. **Sales Milestone Payments**.

7.6.1. **Sales Milestones**. On a Licensed Product-by-Licensed Product basis, with respect to each Licensed Product, ATSA shall notify Mersana within [**] 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 [**] after receipt of the corresponding invoice from Mersana:

First Calendar Year in which the worldwide annual Net Sales of Licensed Product are	**Payment**
Greater than $[**]	[**]
Greater than $[**]	[**]
Greater than $[**]	[**]
Greater than $[**]	[**]

Parties agree that for the purposes of this Section 7.6, Net Sales shall be calculated on the basis of total royalty bearing Net Sales in all Indications for such Licensed Product.

7.6.2. **Sales Milestones Payment Limitations**. 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 royalty bearing Net Sales threshold is reached in the same Calendar Year, all corresponding sales milestone payments will be payable during such Calendar Year provided they had not been previously triggered. For example, if annual worldwide royalty bearing Net Sales of a Licensed Product first reach $[**] in Calendar Year 1, [**].

Section 7.7. **Payment Method**. All payments by ATSA 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 ATSA at least [**] prior to any such payment becoming due hereunder.

Section 7.8. **Invoicing**. Invoices sent by Mersana to ATSA shall include the purchase order number provided by ATSA to Mersana,. If ATSA fails to provide such purchase order number to Mersana at the time of invoicing, ATSA shall upon written request from Mersana provide such purchase order number without undue delay. Invoices shall be sent via email to:

[**]

Section 7.9. **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 Laws and (b) [**] percent ([**]%) above the monthly SOFR (secured overnight financing rate) or any other successor US benchmark rate, if applicable, measured at 2 p.m. New York, USA time on the date payment is due. Interest will be calculated on a 365/360 basis.

Section 7.10. **Legal Restrictions.** If at any time legal restrictions prevent the remittance by ATSA of all or any part of royalties due on Net Sales in any country, ATSA shall have the right and option, solely during the period such legal restriction is in effect, to make such payment by depositing the amount thereof in local currency to an account in the name of Mersana in a bank or other depository selected by Mersana in such country; provided that ATSA will first use commercially reasonable efforts to cooperate with Mersana in finding an alternative method to make such payment to Mersana in accordance with Section 7.7, including by making the applicable payment to Mersana through another Affiliate of ATSA.

Section 7.11. **Taxes.**

7.11.1. **Withholding Taxes**. Except as otherwise provided below, all amounts due from ATSA to Mersana under this Agreement are net amounts. ATSA will be entitled to deduct the amount of any withholding Taxes payable or required by Applicable Laws to be withheld by ATSA, its Affiliates or Sublicensees, to the extent ATSA, its Affiliates or Sublicensees pay such withheld amounts to the appropriate Governmental Authority on behalf of Mersana. ATSA will use Commercially Reasonable Efforts to minimize any such Taxes, levies or charges required to be withheld on behalf of Mersana by ATSA, its Affiliates or Sublicensees. ATSA 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.

7.11.2. **Value Added Tax (VAT)**. For indirect tax (VAT, GST, sales tax and similar taxes, duties or levies, whether of Switzerland, the United States or elsewhere collectively referred to as "**VAT**") purposes, amounts payable under this Agreement shall be understood as net amounts, i.e. statutory VAT is to be added, if applicable, either additionally invoiced and paid or self-accounted by recipient of supply according to applicable VAT law. The invoicing party is obliged to issue an invoice for all payable amounts under this Agreement in accordance with applicable VAT law and irrespective of whether the sums may be netted for settlement purposes. The invoicing party shall comply with any additional reasonable requests of invoiced party in relation to such invoices. The parties shall cooperate in any way reasonably requested, to obtain available reductions, credits or refunds of any VAT amount attributable to the supply under this agreement, if applicable. The parties shall cooperate in any way reasonably requested to enable VAT compliant behavior including providing evidence for VAT purposes in accordance with applicable VAT law

Section 7.12. **Royalty Reports and Accounting**.

7.12.1. **Royalty Reports, Payments and Exchange Rates**.

(a) **Royalty Reports and Payments**. Within [**] after the end of each Calendar Quarter during which Licensed Products have been sold, ATSA 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 ATSA subject to the obligations of Article 8 and shall include on a Licensed Product-by-Licensed Product and a country-by-country basis in reasonable detail:

(i) [**];

(ii) [**]; and

(iii) [**].

(b) **Exchange Rates**. With respect to sales not denominated in United States Dollars, ATSA shall convert each applicable sales in foreign currency into United States Dollars by using the then-current and reasonable standard exchange rate methodology applied in MRKDG's 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 Laws at the place of payment or remittance. Any payment which falls due on a date which is not a Business Day may be made on the next succeeding Business Day.

7.12.2. **Audits**.

(a) Upon the written request of Mersana and with at least [**] prior written notice, but not more than [**], ATSA will permit an independent certified public accounting firm of internationally recognized standing, selected by Mersana and

reasonably acceptable to ATSA, at Mersana's sole cost and expense (except as set forth in this Section 7.12.2), to have access during normal business hours to such of the records of ATSA 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 [**] 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 ATSA. No other information obtained by such accountants will be shared with Mersana.

(b) If such accounting firm concludes that any royalties were owed but not paid to Mersana, ATSA will pay the additional royalties within [**] following the date Mersana delivers to ATSA such accounting firm's written report so concluding, together with the interest payment required by Section 7.10. The fees charged by such accounting firm will be paid by Mersana; provided, that if the audit discloses that the royalties payable by ATSA for the audited period are more than [**] percent ([**]%) of the royalties actually paid for such period, then ATSA 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 [**] following the date Mersana receives such accounting firm's written report so concluding.

(c) Upon the written request of ATSA and with at least [**] prior written notice, but not more than [**], Mersana will permit an independent certified public accounting firm of internationally recognized standing, selected by ATSA and reasonably acceptable to Mersana, at ATSA'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 total of the CMC Costs, Technology Transfer Costs and Regulatory Assistance Costs (collectively, the "**Reimbursed Costs**") due hereunder. Such accountants may audit such records made for any year ending not more than [**] prior to the date of such request. The accounting firm will disclose to ATSA only whether the total Reimbursed Costs 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 ATSA.

(d) If such accounting firm concludes that the total Reimbursed Costs were paid but not owed to Mersana, Mersana will refund or reimburse ATSA such overpaid amounts within [**] following the date ATSA delivers to Mersana such accounting firm's written report so concluding, together with the interest payment required by Section 7.10. The fees charged by such accounting firm will be paid by ATSA; provided, that if the audit discloses that the total Reimbursed Costs payable by ATSA 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 total Reimbursed Costs paid were less than what was owed during such period, ATSA will pay the amount of such underpayment within [**] following the date ATSA receives such accounting firm's written report so concluding.

7.12.3. **Confidential Financial Information**. Each Party will treat all financial information of the other Party subject to review under this Article 7 or under any sublicense agreement of the other Party as Confidential Information of such other Party as set forth in

Article 8, and will cause its accounting firm to retain all such financial information in confidence under terms substantially similar to those set forth in Article 8 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.

ARTICLE 8

CONFIDENTIALITY.

Section 8.1. **Non-Disclosure Obligations**. Except as otherwise provided in Article 8 or the ATSA Antibody Conditions during the Term and for a period of [**] 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 and ensure that its and its Affiliates' and Sublicensees' employees, agents, consultants and other contractors 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.

Section 8.2. **Permitted Disclosures**.

8.2.1. **Exceptions**. The provisions of Section 8.1 will not apply to information, documents or materials that the receiving Party can conclusively establish:

(a) 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;

(b) are permitted to be disclosed by prior written consent of the other Party;

(c) 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;

(d) prior to disclosure under this Agreement, were already in the possession of the receiving Party, its Affiliates or Sublicensees; or

(e) have been independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information;

8.2.2. **Limitations on Exceptions**. The exceptions described in Section 8.2.1(d) and Section 8.2.1(e) will not apply with respect to Confidential Information constituting (a) Mersana Know-How that was originally invented, conceived or developed by ATSA or (b) ATSA Know-How that was originally invented, conceived or developed by Mersana.

8.2.3. **Other Permitted Disclosures**. Except as otherwise set forth in the ATSA Antibody Conditions, each Party may also disclose Confidential Information as set forth below in this Section 8.2.3. Notwithstanding the disclosures permitted under this Section 8.2.3,

any Confidential Information so disclosed will remain subject to the confidentiality obligations of Section 8.1, unless and until any exceptions described in Section 8.2.1 will apply. Either Party may disclose Confidential Information to the extent such disclosure is made:

(a) 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 Laws, 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 Laws will be limited to that information which is legally required to be disclosed in response to such court or governmental order or Applicable Laws (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);

(b) solely to the extent reasonably necessary in a patent application claiming ATSA ADC Patents, ATSA Product Patents or Mersana Patents 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 [**] prior written notice of such disclosure to the other Party and take reasonable and lawful actions to avoid or minimize the degree of disclosure;

(c) by ATSA, to a Regulatory Authority, as reasonably required or useful in connection with any filing, submission or communication with respect to any Licensed 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;

(d) to an actual or potential Sublicensee as permitted hereunder; provided, that such Sublicensee or licensee is then subject to obligations of confidentiality and limitations on use of such Confidential Information substantially similar to those contained herein and ATSA otherwise complies with Section 4.6; and

(e) 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 [**]; 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, except that the term of any such obligation shall be customary for the nature of the other party.

(f) To a licensee of Joint Know-How as permitted hereunder, provided that disclosure of Confidential Information to a licensee of Joint Know-How is restricted to that portion of Confidential Information that comprises the Joint Know-How and is thus Confidential Information of both Parties; and further provided, that such licensee is then subject to obligations of confidentiality and limitations on use of such Confidential Information substantially similar to those contained herein.

Section 8.3. **Specific Restrictions with respect to Primary Target Information and Related ATSA Antibodies**. For clarity, any specific confidentiality restrictions set forth in Schedule 1.1.10 for ATSA Antibodies shall apply in addition to and as *lex specialis* to the confidentiality provisions set forth in this Article 8.

Section 8.4. **Press Releases and Other Disclosures to Third Parties**. Neither Mersana nor ATSA 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 Schedule 8.4, (b) disclosures made in compliance with Section 8.1, Section 8.2, Section 8.3 and Section 8.4, (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 ATSA, [**], regarding ATSA's activities under this Agreement with respect to a Licensed Product following ATSA 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.

Section 8.5. **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 8.5 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 Laws 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).

Section 8.6. **Publications Regarding Results of the Research Program**. Neither Party may publish, present or announce results of the Research Programs or Development of Licensed ADCs or Licensed Products hereunder either orally or in writing (a "**Publication**") without complying with the provisions of this Section 8.6. A Party wishing to make a Publication will provide the other Party with a copy of the proposed Publication. The other Party will have [**] from receipt of a proposed Publication to provide comments or proposed changes to the publishing Party. The publishing Party will take into good faith 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 would entail the public disclosure of such Party's Confidential Information or of a patentable invention upon which a patent application 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 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 [**] 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 8.6 only to the extent that ATSA has the right to review such Publications, and ATSA will use Commercially Reasonable Efforts to obtain such right. For clarity, Mersana may make publications, presentations and announcements with respect to the Mersana Technology and Mersana IP without the prior written consent of ATSA and without complying with the process outlined in this Section 8.6; provided that, such publication, presentation or announcement does not include the results of the Research Programs or Development of Licensed ADCs or Licensed Products or other Confidential Information of ATSA hereunder.

Section 8.7. **Return of Confidential Information**. Upon the effective date of the termination or expiration of this Agreement for any reason with respect to a Designated Target (with termination or expiration of the entire Agreement being deemed termination or expiration of all Designated Targets), 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 of the requesting Party related to such Designated Target 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 of the requesting Party related to such Designated Target 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) in any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, 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 8.1.

ARTICLE 9

INVENTIONS AND PATENTS.

Section 9.1. **Notifications, Assignments**. Each Party shall fully disclose in writing to the other Party any inventions within the Foreground IP that are discovered, developed, or invented by or on behalf of such Party, independent of whether or not such Foreground IP is protectable under any Applicable Laws, within [**] from such Party's awareness of such invention. Such disclosure will (A) be made promptly and in any event reasonably prior to the filing of any patent application with respect to such Foreground IP, and (B) include all invention disclosures or other similar documents submitted to such Party by its or its Affiliates' employees, independent contractors, or other agents relating thereto.

Section 9.2. **Ownership of Intellectual Property**.

9.2.1. **Mersana Rights**. 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 IP.

9.2.2. **ATSA Rights**. The Parties acknowledge and agree that ATSA is and will be the sole and exclusive owner of all right, title and interest in and to any ATSA IP.

9.2.3. **Joint IP**. The Parties acknowledge and agree that the Parties will each own an equal, undivided interest in Joint IP. Each Party will have the right to Exploit the Joint IP and to grant a license under its interest in the Joint IP without a duty of seeking consent of or accounting to the other Party, which consent, to the extent required, is hereby deemed provided.

9.2.4. **Assignment of Rights**. ATSA will and hereby does assign to Mersana, and will cause each of its officers, directors, employees, Affiliates, sublicensees (including any Sublicensees), subcontractors and agents to assign to Mersana, without additional compensation, (a) all of its right, title and interest in and to Mersana IP, and (b) a joint undivided right, title and interest under its right, title and interest under the Joint IP. Mersana will and hereby does assign to ATSA, and will cause each of its officers, directors, employees, Affiliates, sublicensees, subcontractors and agents to assign to ATSA, without additional compensation, (a) all of its right, title and interest in and to the ATSA IP, and (b) a joint undivided right, title and interest under its right, title and interest under the Joint IP.

Section 9.3. **Patent Prosecution and Maintenance**.

9.3.1. **Mersana Patents**. Mersana will have the sole right and authority, but not the obligation, to prepare, file, prosecute and maintain the Mersana Patents 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.

9.3.2. **ATSA Patents**. Subject to Section 9.3.3, ATSA will have the sole right and authority, but not the obligation, to prepare, file, prosecute and maintain the ATSA Patents on a worldwide basis, and to be responsible for any related interference, re-issuance, re-examination and opposition proceedings, in each case, at ATSA's sole expense.

9.3.3. **ATSA ADC Patents and ATSA Product Patents**. Subject to Section 9.3.6, ATSA will have the sole right and authority, but not the obligation, to prepare, file, prosecute and maintain the ATSA ADC Patents and the ATSA Product Patent covering or claiming such Licensed ADC or 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 ATSA's sole expense. With regard to each ATSA ADC Patent and ATSA Product Patent, ATSA will have the exclusive right to decide whether to opt-in or opt-out of the EU Unitary Patent System, and Mersana will make any required statements and filings accordingly. For clarity, "to opt-in or opt-out" refers to both the right to have or have not a European patent application or an issued European patent registered to have unitary effect within the meaning of Regulation (EU) No 1257/2012 of December 17, 2012 as well as the Agreement on the Unified Patent Court as of February 19, 2013; and to the right to opt-in or opt-out from the exclusive competence of the Unified Patent Court in accordance with Article 83 (3) of that Agreement on the Unified Patent Court.

9.3.4. **Joint Patents**. [**] will have the first right and authority, but not the obligation, to prepare, file, prosecute and maintain the Joint Patents on a worldwide basis and to be responsible for any related interference, re-issuance, re-examination and opposition proceedings. [**] will keep [**] reasonably informed and provide reasonable opportunity for [**] to comment with respect to all material steps with regard to the filing, prosecution and maintenance of Joint Patents and will reasonably consider such comments in good faith. The Parties will share equally all the costs associated with filing, prosecution, and maintenance of such Joint Patents; provided, that [**] will have the right, on written notice to [**] to elect not to bear such costs with respect to a Joint Patent, in which case [**] will, and does hereby, assign its right, title and interest in and to such Joint Patent to [**]. If [**] decides not to continue

prosecuting any Joint Patents, then [**] will promptly so notify [**] in writing (which written notice will be at least [**] before any relevant deadline prior to taking any extension for such Joint Patent), in which case, [**] will, and does hereby, assign its right, title and interest in and to such Joint Patent to [**]. Thereafter, [**] will have the right, but not the obligation, to prosecute or maintain such Joint Patent, and to be responsible for any related interference, re-issuance, re-examination and opposition proceedings, at [**] sole expense.

9.3.5. **Cooperation**. The Parties will at all times fully cooperate with each other in order to reasonably implement the foregoing provisions of this Section 9.3. 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 via the JIPC to avoid creating potential issues in prosecution of the patent applications covering or claiming Mersana Patents, ATSA Patents, ATSA ADC Patents, ATSA Product Patents or Joint Patents arising from the performance of activities under this Agreement. With respect to the preparation, filing, prosecution and maintenance of the Patent Rights in the ATSA Foreground IP, ATSA will (a) keep Mersana reasonably informed with respect to any filing, prosecution and maintenance actions, consult with Mersana in good faith, and provide Mersana with drafts of any material documents to be filed (reasonably in advance (but in any event, at least [**] in advance if reasonably practicable) as to give Mersana a meaningful opportunity to review and comment) or that are received, and (b) consider in good faith any comments provided by Mersana with respect thereto.

9.3.6. **Patent Term Extension and Supplementary Protection Certificate**. As between the Parties, ATSA 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 ATSA ADC Patents and ATSA Product Patents, in each case including whether or not to do so. Mersana will provide prompt and reasonable assistance with respect thereto, as requested by ATSA, including by taking such action as is required under any Applicable Laws to obtain such extension or supplementary protection certificate. As between the Parties, Mersana will have the sole right to make decisions regarding, and to apply for, Extensions for the Mersana Patents.

9.3.7. **Common Ownership Under Joint Research Agreements**. Notwithstanding anything to the contrary in this Article 9, neither Party will have the right to make an election under 35 U.S.C. 103(c) when exercising its rights under this Article 9 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).

Section 9.4. **Enforcement of Patent Rights**.

9.4.1. **Notification of Infringement**. In the event either Party becomes aware of an infringement by a Third Party of a Mersana Patent, ATSA Patent or Joint Patent, 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 or, in the case of ATSA, a Mersana Patent, or, in the

case of Mersana, an ATSA Patent to be invalid or unenforceable without the other Party's prior written consent.

9.4.2. **Mersana Patents**. 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 Patents or otherwise to abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce the Mersana Patents, 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 Patents. ATSA shall cooperate with and assist Mersana in all reasonable respects with any such litigation, enforcement action, or settlement. Upon the reasonable request of Mersana, ATSA shall join such litigation, enforcement action, or settlement and shall be represented using counsel of its own choice, at Mersana's expense.

9.4.3. **ATSA Patents**. Subject to Section 9.4.4, ATSA will have the sole right, at its sole expense, but not the obligation, to determine the appropriate course of action to enforce ATSA Patents, or otherwise to abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce the ATSA Patents, 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 ATSA Patents. Mersana shall cooperate with and assist ATSA in all reasonable respects with any such litigation, enforcement action, or settlement. Upon the reasonable request of ATSA, Mersana shall join such litigation, enforcement action, or settlement and shall be represented using counsel of its own choice, at ATSA's expense.

9.4.4. **ATSA ADC Patents and ATSA Product Patents**. ATSA will have the sole right, at its sole expense, to determine the appropriate course of action to enforce ATSA ADC Patents or ATSA Product Patents, or otherwise to abate the infringement thereof, to take (or refrain from taking) appropriate action to enforce the ATSA ADC Patents or ATSA Product Patents, 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 ATSA ADC Patents or ATSA Product Patents. Mersana will cooperate with ATSA, at ATSA's request and expense, in any action to enforce the ATSA ADC Patents or ATSA Product Patents. With respect to actions related to the ATSA ADC Patents or ATSA Product Patents, ATSA will (a) keep Mersana reasonably informed with respect to any litigation or enforcement actions, consult with Mersana in good faith, and provide Mersana with drafts of any material documents to be filed (reasonably in advance (but in any event, at least [**] in advance if reasonably practicable) as to give Mersana a meaningful opportunity to review and comment) or that are received, and (b) consider in good faith any comments provided by Mersana with respect thereto and with respect to the strategy of such action. To the extent the action relates to events arising during the Royalty Term, all monies recovered upon the final judgment or settlement of any such suit to enforce any such ATSA ADC Patents or ATSA Product Patents will be allocated first to ATSA to the extent necessary to compensate it for its expenses in its enforcement, second to Mersana to the extent necessary to compensate it for its expenses in cooperating with ATSA in its enforcement, and finally any remaining amounts will be split between the Parties so that Mersana retains [**] percent ([**]%) and ATSA retains [**] percent ([**]%) of such amounts.

9.4.5. **Joint Patents**. 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.

Section 9.5. **In-Licensed Patent Rights**. Notwithstanding anything to the contrary in this Agreement, with respect to any Mersana Patents that are subject to any Future Mersana In-Licenses, the rights and obligations of the Parties under Section 9.3 and 9.4 will be subject to

Mersana's licensors' rights to participate in and control prosecution, maintenance and enforcement of such Mersana Patents, and to receive a share of damages recovered in such action, in accordance with the terms and conditions of the applicable Future Mersana In-License.

Section 9.6. **Trademarks**.

9.6.1. ATSA 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 ATSA's own cost and expense, and ATSA will own such Product Trademarks.

9.6.2. 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 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.

9.6.3. ATSA 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 ("**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. ATSA 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 Mersana Trademark and (b) do any act that endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to any Mersana Trademark.

ARTICLE 10

INFRINGEMENT OR OTHER ACTIONS BROUGHT BY THIRD PARTIES.

Section 10.1. **Third Party Actions**.

10.1.1. **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**").

10.1.2. **Consultation**; **Settlement**. 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.

10.1.3. **Practice or Exploitation of a Licensed ADC or Licensed Product**.

(a) ATSA, at its own expense, 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 or the practice of any Licensed ADC or Licensed Product infringes or misappropriates a Third Party's intellectual property rights. ATSA will have the sole and exclusive right to select counsel for such Third Party Action.

(b) In the event that any Third Party Action in the Territory involves an allegation that the Exploitation of any Licensed ADC or Licensed Product infringes or misappropriates a Third Party's intellectual property rights, and if ATSA declines to defend or fails to assert its intention to defend or to settle such a Third Party Action under Section 10.1.3(a) within [**] following the receipt or provision of notice under Section 10.1.1, then Mersana, 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. Mersana will have the sole and exclusive right to select counsel for such Third Party Action.

10.1.4. **Practice of Mersana Technology**.

(a) Except as provided in Section 10.1.3(a) and Section 10.1.3(b), Mersana, at its own expense, 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 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.

10.1.5. **Practice of ATSA Technology**. Except as provided in Section 10.1.3 and Section 10.1.4, ATSA, at its own expense, 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 ATSA Technology infringes or misappropriates a Third Party's intellectual property rights. ATSA will have the sole and exclusive right to select counsel for such Third Party Action.

ARTICLE 11

REPRESENTATIONS, WARRANTIES AND COVENANTS.

Section 11.1. **Mutual Representations and Warranties**. Each Party hereby represents and warrants, as of the Effective Date, and covenants (as applicable) to the other Party as follows:

11.1.1. **Corporate Existence and Power**. 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.

11.1.2. **Authority and Binding Agreement**. 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.

11.1.3. **No Conflict**. 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.

11.1.4. **No Debarment**. It will not knowingly 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.

11.1.5. **Government Authorizations**. 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.

Section 11.2. **Additional Representations and Warranties of Mersana**. Mersana hereby represents and warrants, as of the Effective Date, to ATSA as follows:

11.2.1. **Non-Infringement of Mersana Patents by Third Parties**. To Mersana's knowledge, there are no activities by Third Parties that would constitute infringement of the Patent Rights in the Mersana Background IP within the Territory.

11.2.2. **Ownership**. Mersana Controls the Mersana Background IP free and clear of all liens (excluding licenses that do not conflict with the rights granted to ATSA hereunder).

11.2.3. **Validity and Enforceability**. Mersana has complied in all material respects with all Applicable Laws with respect to the filing, prosecution and maintenance of those Patent Rights in the Mersana Background IP 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 Patent Rights in the Mersana Background IP has been in compliance in all material respects with all Applicable Laws with respect thereto. Mersana has paid all maintenance and annuity fees due with respect to the Mersana Prosecution Patent Rights due and, to Mersana's knowledge, all maintenance and annuity fees with respect to all other Patent Rights in the Mersana Background IP have been paid when due. No dispute regarding inventorship has been alleged or threatened with respect to the Mersana Prosecution Patent Rights or, to Mersana's knowledge, with respect to any other Mersana Patents.

11.2.4. **No Action or Claim**. 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 Patent Rights in the Mersana Background IP 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 Patent Rights in the Mersana Background IP, 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 Patent Rights in the Mersana Background IP in connection with the activities to be conducted hereunder, or to fulfill its obligations pursuant to the terms of this Agreement.

11.2.5. **Completeness**. Schedule 1.1.103 includes a complete and correct list, in all material respects, of all Patent Rights in the Mersana Background IP as of the Effective Date.

11.2.6. **Manufacturing Agreements**. There are no exclusivity provisions or any other restrictive covenants imposed on Mersana or its Affiliates in any agreement between Mersana or its Affiliates, on the one hand, and any anticipated Third Party manufacturer of the ADCs (including any intermediate or component thereof), on the other hand, that would prevent ATSA's ability to have the Licensed ADCs or Licensed Products (including any intermediate or component thereof) Manufactured by itself or by its designated Third Party manufacturers.

11.2.7. **Compliance with Applicable Laws**. The development of the Mersana Technology has been conducted by Mersana and its Affiliates and its and their subcontractors, in compliance with all Applicable Laws 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.

Section 11.3. **Additional Covenants of Mersana**.

11.3.1. **Derogation of Rights**. Mersana will maintain and perform its obligations under the Future Mersana In-Licenses as applicable and maintain such 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 ATSA's rights hereunder, without having first obtained ATSA's express prior written consent, such consent not to be unreasonably withheld, delayed or conditioned.

11.3.2. **Conformance of Materials**. All ADCs provided by or on behalf of Mersana hereunder will be Manufactured in conformance with Applicable Laws and this Agreement.

11.3.3. **[**]**.

Section 11.4. **Additional Representations and Warranties of ATSA**. ATSA hereby represents and warrants, as of the date ATSA provides an ATSA Antibody to Mersana under a Research Program, to Mersana as follows (except as disclosed in writing to Mersana prior to the date ATSA provides a ATSA Antibody to Mersana under a Research Program, and where Mersana has agreed to receive the ATSA Antibody despite such disclosure).

11.4.1. **Ownership**. ATSA Controls the ATSA Background IP covering the ATSA Antibody or the Designated Targets to be used in the Research Programs within the Territory as of the Effective Date, free and clear of all liens (excluding licenses that do not conflict with the rights granted to ATSA hereunder) [**].

11.4.2. **Sufficiency.** As of the date of entering into a Research Plan and CMC Plan for a Designated Target (or except as otherwise disclosed transparently to Mersana in accordance with Section 3.4.2(f)), to ATSA's knowledge, the license granted by ATSA to Mersana pursuant to Section 4.1 provides Mersana with sufficient rights with respect to any ATSA Antibody provided by ATSA to Mersana, for Mersana to conduct its activities under this

Agreement, including under the Research Plan and CMC Plan, with respect to such ATSA Antibody.

11.4.3. **Relationship of ATSA to MRKDG**. ATSA is a wholly-owned subsidiary of MRKDG.

Section 11.5. **Additional Covenants of ATSA**.

11.5.1. **Conformance of Materials**. All ATSA Antibodies provided by or on behalf of ATSA hereunder will be Manufactured in conformance with Applicable Laws and this Agreement.

Section 11.6. **DISCLAIMER OF WARRANTIES**. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY 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.

ARTICLE 12

TERM AND TERMINATION.

Section 12.1. **Term**. Unless earlier terminated pursuant to this Article 12, the term of this Agreement (the "**Term**") will commence on the Effective Date and will remain in full force and effect on a Designated Target-by-Designated Target basis until expiry of the last applicable Royalty Term for a Licensed Product Directed to such Designated Target.

Section 12.2. **Termination by ATSA**. At any time during the Term, ATSA may, at its convenience, terminate this Agreement in its entirety, or on a Designated Target-by-Designated Target basis by providing not less than [**] prior written notice to Mersana of such termination. Any such termination of a Designated Target will not affect the continuation of the Agreement with respect to any remaining Designated Target that has not been terminated.

Section 12.3. **Termination for Cause**. Either Party may (but is not required to and without limitation of any other right or remedy such Party may have) terminate this Agreement, in its entirety (with respect to a material breach of the entire Agreement), or with respect to a Designated Target (for a material breach of the Agreement only with respect to such Designated Target), for material breach by the other Party (the "**Breaching Party**") of this Agreement if the Breaching Party has not cured such breach within [**] after written 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 [**], 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, for up to an additional [**]); provided, that if either Party initiates a dispute resolution procedure under Section 14.6 as permitted under this Agreement to resolve the dispute for which termination is being sought within [**] 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 [**] after the final resolution of the dispute through such dispute resolution procedure (or, if the breach cannot be cured within such [**] period, if the Breaching Party commences actions to cure such breach within such period and thereafter diligently continues such actions, for up to an additional [**]).

Section 12.4. **Termination for Patent Challenge**. Mersana may terminate this Agreement upon [**] notice to ATSA, in the event ATSA, or any of its Affiliates or Sublicensees, with regard to the licenses granted here under this Agreement challenges in a legal or administrative proceeding the validity or enforceability of a Valid Patent Claim of a Mersana Patent, except as (a) required under a court order or subpoena or (b) a defense against a claim, action or proceeding asserted by Mersana or an Affiliate or licensee of Mersana against ATSA or any of its Affiliates or Sublicensees; provided that any such termination shall not become effective if (i) such action has been withdrawn before the end of the aforementioned notice period or (ii) in the event that the challenging party is a Sublicensee of ATSA, ATSA terminates any and all sublicense agreements with such Sublicensee that includes a sublicense of any Mersana Patent to such Sublicensee, before the end of the aforementioned notice period.

Section 12.5. **Termination for Failure to Progress Programs**. Mersana may terminate this Agreement with respect to a Designated Target upon [**] written notice to ATSA, if (a) [**] following the approval by the JRC of a Research Plan for such Designated Target (with the Research Plan for the Primary Target being deemed to be approved by the JRC upon the Effective Date), there has not been a Pre-Clinical Development Candidate Designation with respect to an ADC Directed to such Designated Target by the end of such [**] period, or (b) upon the expiration of the Research Program Term for such Designated Target, if ATSA has not filed an IND with the applicable Regulatory Authorities with respect to an ADC Directed to such Designated Target during such Research Program Term. In each instance (a) and (b), prior to expiry of the time periods outlined in (a) or (b) respectively, the Parties will, at the request of either Party, in good faith discuss through the JRC whether such time period should be prolonged to account for any reasonable aspects of delay, but Mersana shall have no obligation to prolong such periods, and such discussions shall not limit Mersana's right to terminate this Agreement in accordance with this Section 12.5.

Section 12.6. **License Survival Upon Insolvency**. 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 Laws. 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 Licensed 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 bankruptcy proceeding, upon the other Party's written request therefor (which request must identify the specific intellectual property), unless the bankrupt Party (or trustee on behalf of the bankrupt Party) elects within [**] 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.

Section 12.7. **Effect of Expiration and Termination**.

12.7.1. **General Effects**. 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 CMC Costs, Technology Transfer Costs, costs owed to Mersana under Clinical Supply Agreement and other non-cancelable, non-refundable costs, royalties or other sums which have accrued in line with Mersana's Accounting Standards up until the date of termination or expiration. Notwithstanding the foregoing, but subject to Section 12.7.4, 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 a Designated Target only, only the licenses granted by either Party to the other Party hereunder with respect to such Designated Target will terminate.

12.7.2. **Effect of Termination by ATSA for Convenience or by Mersana for Cause or Failure to Progress Programs**.

(a) If ATSA terminates this Agreement in its entirety pursuant to Section 12.2 or Mersana terminates this Agreement in its entirety pursuant to Section 12.3 or Section 12.5, all Exclusive Licenses granted by Mersana to ATSA (and then in effect) will automatically be terminated, all Designated Targets will cease to be a Designated Targets under this Agreement, and ATSA will immediately cease Exploitation, directly or indirectly, of any Licensed Product in the Territory for which, and for so long as, there remains any Valid Patent Claim of any Mersana Patent or ATSA ADC Patent covering or claiming the Exploitation of such Licensed Product.

(b) If ATSA terminates this Agreement with respect to a Designated Target pursuant to Section 12.2 or Mersana terminates the Agreement with respect to a Designated Target pursuant to Section 12.3 or Section 12.5, the Exclusive License granted by Mersana to ATSA (and then in effect) with respect to such Designated Target will automatically be terminated, the terminated Designated Target will cease to be a Designated Target under this Agreement, and ATSA will immediately cease Exploitation, directly or indirectly, of Licensed Products Directed to such Designated Target in the Territory if, and for so long as, there remains any Valid Patent Claim of any Mersana Patent or ATSA ADC Patent covering or claiming the Exploitation of such Licensed Product.

12.7.3. **Effect of Termination Right by ATSA for Cause**. In the event that ATSA is entitled to terminate this Agreement in its entirety pursuant to Section 12.3, ATSA may elect by providing written notice to Mersana, to instead maintain this Agreement except that ATSA's obligations to make payments to Mersana pursuant to Section 7.3, Section 7.5 and Section 7.6 will be reduced to [**] percent ([**]%) of the amount otherwise payable thereunder, provided that ATSA acknowledges and agrees that such reduction to ATSA's payment obligations, if elected, shall be ATSA's sole and exclusive remedy with respect the applicable material breach of the Agreement by Mersana leading to ATSA's right to terminate pursuant to Section 12.3. For clarity, if ATSA elects the remedy in this Section 12.7.3, then ATSA shall no longer have the right to terminate this Agreement pursuant to Section 12.3 related to or arising from the same events as such material breach.

12.7.4. **License to ATSA Upon Royalty Term Expiration**. Upon the date of expiration of each Royalty Term with respect to a Licensed Product Directed to a Designated

Target 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 IP to Exploit such Licensed ADC or Licensed Product, with no further obligation to Mersana; provided that the Agreement has not earlier expired or has not terminated with respect to such Designated Target prior to the expiration of the Royalty Term for such Licensed ADC or Licensed Product.

12.7.5. **Survival**. The following provisions will survive expiration or termination of this Agreement: Article 1(Definitions and Interpretation), Section 2.5 (Restrictions on use of Materials), Section 4.4 (Unblocking License Upon Termination of Exclusivity or Termination of Agreement), Article 7 (Fees, Milestones, and Royalties) (solely with respect to payment obligations arising during the Term), Article 8 (Confidentiality), Section 9.2 (Ownership of Intellectual Property), Section 9.3 (Patent Prosecution and Maintenance) (solely with respect to Joint Patents), Section 9.4 (Enforcement of Patent Rights) (solely with respect to Joint Patents), Section 11.6 (Disclaimer of Warranties), Section 12.6 (License Survival Upon Insolvency), Section 12.7 (Effect of Expiration and Termination), Article 13 (Indemnity; Limitation of Liability; Insurance), and Article 14 (Miscellaneous) (except for Section 14.10 (Data Privacy Laws) and Section 14.11 (Business Conduct)).

ARTICLE 13

INDEMNITY; LIMITATION OF LIABILITY; INSURANCE.

Section 13.1. **Indemnity**.

13.1.1. **Mersana Indemnity**. Mersana will defend, indemnify and hold harmless ATSA, its Affiliates, Sublicensees 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 ATSA must indemnify Mersana under Section 13.1.2.

13.1.2. **ATSA Indemnity**. ATSA 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, relate to or arise out of (a) the breach or non-fulfillment of this Agreement by ATSA, (b) the negligence, recklessness or willful misconduct of ATSA in connection with the performance of its obligations hereunder, or (c) the Exploitation of Licensed Products by or on behalf of ATSA, its Affiliates or Sublicensees, except, in each case, to the extent such Liabilities resulted from any action for which Mersana must indemnify ATSA under Section 13.1.1.

Section 13.2. **Procedure**. A Party (the "**Indemnitee**") that intends to claim indemnification under Section 13.1 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 has failed to assume the defense of the applicable Claim, in which case ((a) or (b)), such fees and expenses will be paid by 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 and employees and agents of the Indemnitor, in each case as may be reasonably requested in connection therewith; provided, that the Indemnitor will reimburse the Indemnitee for its reasonable and verifiable out-of-pocket expenses in connection therewith. The Indemnitor may not settle any Claim, and the Indemnitee will not be responsible for or be bound by any settlement of a Claim that imposes an obligation on it, without the prior written consent of the Indemnitee, which consent will not be unreasonably withheld, conditioned or delayed.

Section 13.3. **Limitation of Liability**. EXCEPT [**], 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.

Section 13.4. **Insurance**. 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 13.4.

ARTICLE 14

MISCELLANEOUS.

Section 14.1. **Force Majeure**. No Party (or any of its Affiliates or Sublicensees) 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 or Sublicensees), including fire, floods, embargoes, quarantines, pandemic, epidemic, 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 [**], the affected Party will promptly notify in writing the other Party of such Event of Force Majeure and within [**] of the other Party's receipt of such notice, the Parties will negotiate in good faith a resolution of the Event of Force

Majeure, if possible, which resolution may include (a) an extension by mutual agreement of the time period to resolve, eliminate, cure or overcome such Event of Force Majeure, (b) an amendment of this Agreement to the extent reasonably possible, or (c) an early termination of this Agreement.

Section 14.2. **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 14.2, assign this Agreement and its rights and obligations hereunder (a) to any of its Affiliates, (b) in connection with a Change in Control of such Party or (c) 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 14.2 will be void and of no effect.

Section 14.3. **Severability**. 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.

Section 14.4. **Notices**. 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 first class air mail or courier, postage prepaid (where applicable), in each case 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 14.4 and (except as otherwise provided in this Agreement) will be effective upon receipt by the addressee. This Section 14.4 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: Chief Executive Officer
Telephone: (617) 498-0020

With a copy to: Chief Legal Officer.

If to ATSA:

Ares Trading S.A.
Attention: Legal Department
Rue de l'Ouriette 151

Zone industrielle de l'Ouriettaz,
CH-1170 Aubonne,
Switzerland

In case of legal notifications with a copy to

Merck KGaA, Darmstadt, Germany
Frankfurter Straße 250
64293 Darmstadt
Germany
Attention: Alliance Management

and
Merck KGaA, Darmstadt, Germany
Attention: Legal Department / LE-H
Frankfurter Strasse 250
64293 Darmstadt, Germany

Section 14.5. **Applicable Laws; Jurisdiction**.

14.5.1. **Applicable Laws**. Subject to Section 9.2.4, this Agreement will be governed by and construed in accordance with the laws of the State of New York, without regard to the conflict of law principles thereof that may dictate application of the laws of any other jurisdiction.

14.5.2. **Jurisdiction**. The Parties irrevocably agree that the courts of [**] 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 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.

Section 14.6. **Dispute Resolution**. The Parties agree that if any dispute or disagreement arises between ATSA on the one hand and Mersana on the other in respect of this Agreement, subject to Section 3.2.4, Section 3.3.4 and Section 14.15, they will follow the following procedure in an attempt to resolve the dispute or disagreement.

14.6.1. 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.

14.6.2. Within [**] following receipt of a Notice of Dispute, a nominee or nominees of ATSA and a nominee or nominees of Mersana will meet in person or by virtual means 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.

14.6.3. If, within a further period of [**], the dispute has not been resolved, the Executive Officers will meet in person or by virtual means at a mutually agreed upon time and location for the purpose of resolving such dispute.

14.6.4. In the event of an unresolved dispute between the Parties, such dispute will, at either Party's election and subject to Section 14.5.1, be submitted for resolution by a court of competent jurisdiction.

14.6.5. 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.

Section 14.7. **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. For clarity, the collaboration and commercial license agreement between MRKDG and Mersana, Inc., dated June 23, 2014 including any amendments or related agreements thereto remains completely separate and unaffected by this Agreement.

Section 14.8. **Independent Contractors**. Mersana and ATSA 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 ATSA 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.

Section 14.9. **Performance and Exercise by Affiliates**. Each Party shall have the right to have any of its obligations hereunder performed, or its rights hereunder exercised, by, any of its Affiliates and the performance of such obligations by any such Affiliate shall be deemed to be performance by such Party; provided, however, that each Party shall be responsible for ensuring the performance of its obligations under this Agreement and that any failure of any Affiliate performing obligations of such Party hereunder shall be deemed to be a failure by such Party to perform such obligations.

Section 14.10. **Data Privacy Laws**.

14.10.1. Each Party acknowledges that it may have access to certain Personal Data for the performance of this Agreement. Each Party will materially comply with all Applicable Laws and regulations relating to any information relating to an identified or identifiable natural person ("Personal Data") which is shared between the Parties for the purpose of this Agreement. The Parties will endeavor to use commercially reasonable efforts to protect Personal Data and will not use, disclose, transfer or otherwise process such Personal Data except as necessary to perform its obligations or exercise its rights under this Agreement, or as authorized by the relevant data subject or in accordance with Applicable Laws.

14.10.2. **Party outside EEA**. If a Party has its registered office outside the EU/EEA in a country not providing an adequate data protection level recognized by the European Commission, the Parties shall take the necessary steps to ensure that Personal Data is transferred according to applicable Data Protection Laws; to this end the Parties shall ensure that the Personal Data will be sufficiently protected in accordance with applicable Data Protection Laws, in particular with the Regulation (EU) 2016/679 (General Data Protection Regulation).

14.10.3. **Data Privacy Agreement**. To the extent that Personal Data is processed or transferred under this Agreement following the Effective Date, the Parties agree to (i) discuss and determine their respective roles, if any, with respect to such processing of Personal Data and (ii) discuss and, if required by Applicable Laws, negotiate and enter into an appropriate data privacy agreement (substantially in the form set forth in Schedule 14.10.3). For clarity, upon any execution of a data privacy agreement, such data privacy agreement shall be deemed integrated into and part of this Agreement.

Section 14.11. **Business Conduct**. ATSA intends to conduct its business in accordance with environmental, labor and social standards and to abide by the standards set forth in the Our Code of Conduct Document (available at https://www.emdgroup.com/company/responsibility/us/regulations-and-guidelines/code-of-conduct.pdf). Each Party shall comply, and shall ensure that its Affiliates, Sublicensees or subcontractors comply, with commercially reasonable environmental, labor and social standards. Each Party shall ensure its and its Affiliates' and Sublicensees' compliance with the provisions of the OECD Anti Bribery Convention, the US Foreign Corrupt Practices Act, the UK Bribery Act 2010, and any other applicable local anti-bribery or anti-corruption laws, as are in force from time to time (jointly "**Anti-Bribery Laws**").

Section 14.12. **Waiver and Non-Exclusion of Remedies**. 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 Laws or otherwise available, except as expressly set forth herein.

Section 14.13. **Further Assurances**. Each Party will execute such additional documents as are necessary to effect the purposes of this Agreement.

Section 14.14. **No Third Party Rights**. Except as provided in Article 13, 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.

Section 14.15. **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.

Section 14.16. **Counterparts**. 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.

ARES TRADING S.A.

By: _/s/ Cedric Hyde_____

Name:__Cedric Hyde_____

Title:___Authorized Representative_

By: __/s/ Willem De Weerd_____

Name:___Willem De Weerd ____

Title:___Authorized Representative__

MERSANA THERAPEUTICS, INC.

By: __/s/ Anna Protopapas_____

Name:__Anna Protopapas _____

Title:___CEO_____

Exhibit 10.21

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.

SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT (this "**Amendment**") is entered into as of October 17, 2022, 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 Schedule 1.1 to the Loan Agreement (as defined below) or otherwise a party thereto from time to time including Oxford in its capacity as a Lender and SILICON VALLEY BANK, a California corporation 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, 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. Amendment to Loan Agreement.

2.1 Section 13 (Definitions). The following defined term in Section 13 of the Loan Agreement is amended and restated as follows:

"**Permitted Indebtedness**" is:

(a) Borrower's Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s);

(c) Subordinated Debt;

(d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed [**] Dollars ($[**]) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);

(f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower's business;

(g) other unsecured Indebtedness in an aggregate amount outstanding at any time not to exceed [**] Dollars ($[**]);

(h) Indebtedness between or among co-Borrowers or secured Guarantors hereunder;

(i) Indebtedness consisting of Investments under clause (f) of the definition of "Permitted Investments";

(j) Indebtedness relating to insurance premium financing arrangements, not to exceed [**] Dollars ($[**]) outstanding at any time;

(k) any obligations owing with respect to corporate credit cards or merchant services in an aggregate amount not to exceed [**] Dollars ($[**]) outstanding at any time;

(l) Indebtedness in respect of letters of credit, bank guarantees, bonds and similar instruments issued for the account of the Borrower or any Subsidiary in the ordinary course of business supporting obligations under (A) workers' compensation, unemployment insurance and other social security laws and (B) bids, trade contracts, leases, statutory obligations, surety and appeal bonds, performance bonds and obligations of a like nature; in an aggregate amount for (A) and (B) not to exceed [**] Dollars ($[**]) at any time;

(m) Indebtedness of either Borrower and its respective Subsidiaries arising from the honoring by a bank or other financial institution of a check, draft or similar instrument in the ordinary course of business;

(n) Indebtedness representing deferred compensation, severance, pension and health and welfare retirement benefits or the equivalent thereof to current and former employees of either Borrower or its Subsidiaries incurred in the ordinary course of business or in connection with Permitted Investments, not to exceed [**] Dollars ($[**]) in the aggregate in any fiscal year

(o) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (n) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be; and

(p) Indebtedness relating to credits, exemptions and other tax benefits awarded by the Massachusetts Life Sciences Center pursuant to that certain Life Sciences Tax Incentive Agreement dated June 14, 2022, as amended by that certain Amendment No. 1 dated as of October 5, 2022 between the Massachusetts Life Scienses Center and Borrower, not to exceed [**] Dollars ($[**]) outstanding at any time.

3. Limitation of Amendment.

3.1 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.

3.2 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.

4. 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:

4.1 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;

4.2 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;

4.3 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;

4.4 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;

4.5 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;

4.6 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.

5. 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.

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

7. 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.

8. 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.

[*Balance of Page Intentionally Left Blank*]

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

BORROWER:

MERSANA THERAPEUTICS, INC.

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

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

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

LENDER:

SILICON VALLEY BANK

By /s/ Nate Meaux
Name: Nate Meaux
Title: Senior Vice President

THIRD AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS THIRD AMENDMENT TO LOAN AND SECURITY AGREEMENT (this "**Amendment**") is entered into as of December 27, 2022, 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 Schedule 1.1 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 2020-1, LLC, a Delaware limited liability company, each with offices located at 115 South Union Street, Suite 300, Alexandria, Virginia 22314, and SILICON VALLEY BANK, a California corporation 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 and that certain Second Amendment to Loan and Security Agreement dated as of October 17, 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. Amendment to Loan Agreement.

2.1 Section 2.2(a) (Term Loans). Sections 2.2(a)(i) and (ii) of the Loan Agreement are amended and restated as follows:

"(a) Availability.

(i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Term A Draw Period, to make term loans to Borrower in an aggregate amount of up to Forty Million Dollars ($40,000,000.00) to be disbursed in an amount equal to Twenty-Five Million Dollars ($25,000,000.00) on the Effective Date according to each Lender's Term A Loan Commitment as set forth on Schedule 1.1 hereto, with the remaining Fifteen Million Dollars ($15,000,000.00) available to be disbursed, upon Borrower's request, in up to three (3) additional single advances according to each Lender's Term A Loan Commitment as set forth on Schedule 1.1 hereto (such term loans on the Effective Date and thereafter are hereinafter referred to singly as a "**Term A Loan**", and collectively as the "**Term A Loans**"). Each disbursement of Term A Loans after the Effective Date shall be in an aggregate amount of at least Five Million Dollars ($5,000,000.00) and, unless the entire remaining amount of the Term A Loan Commitment will be disbursed at such disbursement, in a denomination that is a whole number multiple of Five Million Dollars ($5,000,000.00). After repayment, no Term A Loan may be re-borrowed.

(ii) Subject to the terms and conditions of this Agreement and upon Borrower's request, the Lenders agree, severally and not jointly, during the Term B Draw Period, to make term loans to Borrower in an aggregate amount equal to Forty Million Dollars ($40,000,000.00) and disbursed in a single advance according to each Lender's Term B Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term B Loan**", and collectively as the "**Term B Loans**"). After repayment, no Term B Loan may be re-borrowed."

2.2 Section 2.5(f) (Third Amendment Fee). Section 2.5(f) of the Loan Agreement is hereby added as follows:

"(f) Third Amendment Fee. A fully earned, non-refundable amendment fee in an aggregate amount of One Hundred and Fifty Thousand Dollars ($150,000.00) to be shared between the Lenders in accordance with their respective Pro Rata Shares and due and payable on the Third Amendment Effective Date."

2.3 Section 3.4 (Procedures for Borrowing). Section 3.4 of the Loan Agreement is amended and restated as follows:

"**3.4 Procedures for Borrowing.** Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan, Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 2:00 p.m. Eastern time ten (10) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to the Lenders by electronic mail or facsimile a completed Disbursement Letter (and the Loan Payment/Advance Request Form, with respect to SVB) executed by a Responsible Officer or his or her designee. The Lenders may rely on any telephone notice given by a person whom a Lender reasonably believes is a Responsible Officer or designee. On the Funding Date, each Lender shall credit and/or transfer (as applicable) to the Designated Deposit Account, an amount equal to its Term Loan Commitment."

2.4 Section 13 (Definitions). The following defined terms in Section 13 of the Loan Agreement are amended and restated as follows:

"**Term A Draw Period**" is the period commencing on the Effective Date and ending on the earlier of (i) June 30, 2023 and (ii) the occurrence of an Event of Default.

"**Term B Draw Period**" is the period commencing on the date of the occurrence of the Term B Milestone and ending on the earliest of (i) the date that is ninety (90) days after the occurrence of the Term B Milestone, (ii) September 30, 2023 and (iii) the occurrence of an Event of Default; provided, however, that the Term B Draw Period shall not commence if on the date of the occurrence of the Term B Milestone an Event of Default has occurred and is continuing.

2.5 Section 13 (Definitions). The following term and such definition is hereby added to Section 13.1 of the Loan Agreement in proper alphabetical order as follows:

"**Third Amendment Effective Date**" is December 27, 2022.

2.6 Schedule 1.1 (Lenders and Commitments). Schedule 1.1 of the Loan Agreement is amended and restated with Schedule 1.1 attached to this Amendment.

3. Limitation of Amendment.

3.1 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.

3.2 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.

4. 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:

4.1 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;

4.2 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;

4.3 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;

4.4 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;

4.5 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;

4.6 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.

5. 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.

6. Release by Borrower.

6.1 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, administration, servicing and/or enforcement of any of the foregoing (collectively "**Released Claims**").

6.2 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."

6.3 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.

6.4 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.

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

8. 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.

9. 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.

[*Balance of Page Intentionally Left Blank*]

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

BORROWER:

MERSANA THERAPEUTICS, INC.

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

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

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

LENDER:

OXFORD FINANCE FUNDING IX, LLC

By /s/ Colette H. Featherly
Name: Colette H. Featherly
Title: Secretary

OXFORD FINANCE FUNDING XIII, LLC

By /s/ Colette H. Featherly
Name: Colette H. Featherly
Title: Secretary

OXFORD FINANCE FUNDING 2020-1, LLC

By /s/ Colette H. Featherly
Name: Colette H. Featherly
Title: Secretary

SILICON VALLEY BANK

By /s/ Nate Meaux
Name: Nate Meaux
Title: Senior Vice President

SCHEDULE 1.1

Lenders and Commitments

Term A Loans

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	$20,000,000.00	50%
SILICON VALLEY BANK	$20,000,000.00	50%
TOTAL	**$40,000,000.00**	**100.00%**

Term B Loans

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	$20,000,000.00	50%
SILICON VALLEY BANK	$20,000,000.00	50%
TOTAL	**$40,000,000.00**	**100.00%**

Aggregate (all Term Loans)

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	$40,000,000.00	50%
SILICON VALLEY BANK	$40,000,000.00	50%
TOTAL	**$80,000,000.00**	**100.00%**

MERSANA THERAPEUTICS, INC.
2017 EMPLOYEE STOCK PURCHASE PLAN
(AS AMENDED THROUGH JANUARY 23, 2019)

1. DEFINED TERMS

The following terms, when used in the Plan (as defined below), have the meanings and are subject to the provisions set forth below:

(a) "401(k) Plan": A savings plan qualifying under Section 401(k) of the Code that is sponsored by the Company for the benefit of its employees.

(b) "Account": A notional payroll deduction account maintained in the Participant's name on the books of the Company.

(c) "Administrator": The Compensation Committee, except that the Compensation Committee may delegate (i) to one or more of its members (or one or more other members of the Board, including the full Board) such of its duties, powers and responsibilities as it may determine; (ii) to one or more officers of the Company the power to grant Awards to the extent permitted by Section 152 or 157(c) of the Delaware General Corporation Law; and (iii) to such Employees or other persons as it determines such ministerial tasks as it deems appropriate. In the event of any delegation described in the preceding sentence, the term "Administrator" will include the person or persons so delegated to the extent of such delegation.

(d) "**Affiliate**"**:** Any corporation or other entity that stands in a relationship to the Company that would result in the Company and such corporation or other entity being treated as a single employer under Sections 414(b) or 414(c) of the Code, except that such sections shall be applied by substituting "at least 50%" for "at least 80%" wherever applicable. The Company may at any time by amendment provide that different ownership thresholds apply.

(e) "Board": The Board of Directors of the Company.

(f) "Business Day": Any day on which the national stock exchange on which the Stock is traded is available and open for trading.

(g) "Code": The U.S. Internal Revenue Code of 1986, as from time to time amended and in effect, or any successor statute as from time to time in effect.

(h) "Company": Mersana Therapeutics, Inc.

(i) "Compensation Committee": The Compensation Committee of the Board.

(j) "Corporate Transaction": A (i) consolidation, merger or similar transaction or series of related transactions, including a sale or other disposition of stock, in which the Company (or any Affiliate) is not the surviving corporation or which results in the acquisition of all or substantially all of the then-outstanding shares of Stock by a single person or entity or by a group of persons and/or entities acting in concert; (ii) sale or transfer of all or substantially all of

the Company's assets; (iii) dissolution or liquidation of the Company; or (iv) a "change in control event" as that term is defined in the regulations under Section 409A. For the avoidance of doubt, an initial public offering shall not constitute a Change in Control. Where a Corporate Transaction involves a tender offer that is reasonably expected to be followed by a merger described in clause (i) as determined by the Compensation Committee of the Board, the Corporate Transaction shall be deemed to have occurred upon consummation of the tender offer.

(k) "Designated Subsidiary": A Subsidiary of the Company that has been designated by the Board or the Compensation Committee from time to time as eligible to participate in the Plan as set forth on Exhibit A.

(l) "Effective Date": The date set forth in Section 23.

(m) "Eligible Employee": Any Employee who meets the eligibility requirements set forth in Section 4.

(n) "Employee": Any person who is employed by the Company or a Designated Subsidiary. For the avoidance of doubt, independent contractors and consultants are not "Employees" for purposes of the Plan.

(o) "**Eligible Compensation**"**:** Regular base salary, overtime payments, annual bonuses, commissions and other sales incentives (excluding, for the avoidance of doubt, any long-term incentive payments). Eligible Compensation will not be reduced by any income or employment tax withholdings or any contributions by the Employee to a 401(k) Plan or a plan intended to qualify under Section 125 of the Code, but will be reduced by any contributions made on the Employee's behalf by the Company or any Subsidiary to any deferred compensation plan or welfare benefit program now or hereafter established.

(p) "Exercise Date": The date set forth in Section 5 or otherwise designated by the Administrator with respect to a particular Option Period on which a Participant will be deemed to have exercised the Option granted to him or her for such Option Period.

(q) "Fair Market Value": As of a particular date, (i) the closing price for a share of Stock reported on the Nasdaq Stock Market (or any other national securities exchange on which the Stock is then listed) for that date or, if no closing price is reported for that date, the closing price on the immediately preceding date on which a closing price was reported or (ii) in the event that the Stock is not traded on a national securities exchange, the fair market value of a share of Stock determined by the Administrator consistent with the rules of Section 409A and Section 422 of the Code, to the extent applicable.

(r) "Maximum Share Limit": The meaning set forth in Section 10.

(s) "Option": An option granted pursuant to the Plan entitling the holder thereof to acquire shares of Stock upon payment of the Purchase Price with respect to such shares of Stock.

(t) "Option Period": An offering period established in accordance with Section 5.

(u) "Parent": A "parent corporation" as defined in Section 424(e) of the Code.

(v) "Participant": An Eligible Employee who elects to enroll in the Plan.

(w) "Plan": The Mersana Therapeutics, Inc. 2017 Employee Stock Purchase Plan, as from time to time amended and in effect.

(x) "Purchase Price": The price per share of Stock with respect to an Option Period determined in accordance with Section 9.

(y) "Section 409A": Section 409A of the Code and the regulations thereunder.

(z) "Section 423": Section 423 of the Code and the regulations thereunder.

(aa) "Stock": Common stock of the Company, par value $0.0001 per share.

(bb) "Subsidiary": A "subsidiary corporation" as defined in Section 424(f) of the Code.

2. PURPOSE

The Plan is intended to enable Eligible Employees to use payroll deductions to purchase shares of Stock in offerings under the Plan, and thereby acquire an interest in the future of the Company. The purposes of the Plan are to attract, retain and reward Eligible Employees, to incentivize them to generate stockholder value, to enable them to participate in the growth of the Company and to align their interests with the interests of the Company's stockholders. The Plan is intended to qualify as an "employee stock purchase plan" under Section 423 and to be exempt from the application and requirements of Section 409A, and is to be construed accordingly.

3. OPTIONS TO PURCHASE STOCK

Subject to adjustment pursuant to Section 16, the aggregate number of shares of Stock available for purchase pursuant to the exercise of Options granted under the Plan to Eligible Employees will be 225,000 shares of Stock, plus an annual increase, to be added as of January 1st of each year from January 1, 2018 to January 1, 2027, equal to least of (i) 450,000 shares of Stock; (ii) one percent of the number of shares of Stock outstanding as of the close of business on the immediately preceding December 31st; and (iii) the number of shares of Stock determined by the Board on or prior to such date for such year, up to maximum of 4,725,000 shares of Stock in the aggregate. The shares of Stock to be delivered upon exercise of Options under the Plan may be either shares of authorized but unissued Stock, treasury Stock, or Stock acquired in an open-market transaction. If any Option granted under the Plan expires or terminates for any reason without having been exercised in full or ceases for any reason to be exercisable in whole or in part, the unpurchased shares of Stock subject to such Option will again be available for purchase pursuant to the exercise of Options under the Plan. If, on an Exercise Date, the total number of shares of Stock that would otherwise be subject to Options granted under the Plan exceeds the number of shares then available under the Plan (after deduction of all shares for which Options have been exercised or are then-outstanding), the Administrator shall make a pro rata allocation of the shares remaining available for the Option grants in as uniform a manner as shall be practicable and as it shall determine to be equitable. In such event, the Administrator

shall give written notice to each Participant of such reduction of the number of Options affected thereby and shall similarly reduce the rate of the Participant's payroll deductions, if necessary.

4. ELIGIBILITY

(a) Eligibility Requirements. Subject to Section 13, and the exceptions and limitations set forth in Sections 4(b) and (c) and 6, or as may be provided elsewhere in the Plan, each Employee (i) who has been continuously employed by the Company or a Designated Subsidiary, as applicable, for a period of at least ten (10) Business Days as of the first day of an Option Period; (ii) whose customary Employment with the Company or a Designated Subsidiary, as applicable, is for more than five (5) months per calendar year; (iii) who customarily works twenty (20) hours or more per week; and (iv) who satisfies the requirements set forth in the Plan, will be an Eligible Employee.

(b) Five Percent Shareholders. No Employee may be granted an Option under the Plan if, immediately after the Option is granted, the Employee would own (or pursuant to Section 424(d) of the Code, would be deemed to own) stock possessing five percent (5%) or more of the total combined voting power or value of all classes of stock of the Company or of its Parent or Subsidiaries, if any.

(c) Additional Requirements. The Administrator may, for Option Periods that have not yet commenced, establish additional or other eligibility requirements, or amend the eligibility requirements set forth in subsection (a) above, in each case, not inconsistent with Section 423.

5. OPTION PERIODS

The Plan will generally be implemented by a series of separate offerings referred to as "**Option Periods**". Unless otherwise determined by the Administrator, the Option Periods will be successive periods of approximately six (6) months commencing on the first Business Day in January and July of each year, anticipated to be on or around January 1 and July 1, and ending approximately six (6) months later on the last Business Day in June or December, as applicable, of each year, anticipated to be on or around June 30 and December 31, as applicable, of each year. The last Business Day of each Option Period will be an "**Exercise Date**". The Administrator may change the Exercise Date and the commencement date, ending date and duration of the Option Periods to the extent permitted by Section 423, *provided, however,* that no Option may be exercised after 27 months from its grant date.

6. OPTION GRANT

Subject to the limitations set forth in Sections 4 and 10, on the first day of an Option Period, each Participant automatically will be granted an Option to purchase shares of Stock on the Exercise Date; *provided*, *however*, that no Participant will be granted an Option under the Plan that permits the Participant's right to purchase shares of Stock under the Plan and under all other employee stock purchase plans of the Company and its Parent and Subsidiaries, if any, to accrue at a rate that exceeds $25,000 in Fair Market Value (or such other maximum as may be prescribed from time to time by the Code) for each calendar year during which any Option granted to such Participant is outstanding at any time, as determined in accordance with Section 423(b)(8) of the Code.

7. METHOD OF PARTICIPATION

(a) **Payroll Deduction Authorization**. To participate in an Option Period, an Eligible Employee must execute and deliver to the Administrator a payroll deduction authorization, in accordance with the procedures prescribed by, and in a form acceptable to, the Administrator and, in so doing, the Eligible Employee will thereby become a Participant as of the first day of such Option Period. Such an Eligible Employee will remain a Participant with respect to subsequent Option Periods until his or her participation in the Plan is terminated as provided herein. Such payroll deduction authorization must be delivered not later than ten (10) Business Days prior to the first day of an Option Period, or such other time as specified by the Administrator.

(b) **Changes to Payroll Deduction Authorization for Subsequent Option Periods**. A Participant's payroll deduction authorization will remain in effect for subsequent Option Periods unless the Participant files a new payroll deduction authorization not later than ten (10) Business Days prior to the first day of the subsequent Option Period, or such other time as specified by the Administrator, or the Participant's Option is cancelled pursuant to Section 13 or 14 or such payroll deduction authorization is changed in accordance with Section 7(c).

(c) **Changes to Payroll Deduction Authorization for Current Option Period**. During an Option Period, a Participant's payroll deduction rate may not be increased by the Participant and may be decreased only to the extent provided in this Section 7(c). A Participant may, at any time up to fifteen (15) Business Days prior to the applicable Exercise Date (or such other time specified by the Administrator) for an Option Period, but not more than one time during such Option Period, reduce his or her payroll deduction rate for future payroll periods during an Option Period by filing a new payroll deduction authorization with the Administrator, which payroll deduction authorization will become effective as soon as administratively practicable following the Administrator's receipt. In addition, a Participant may terminate his or her payroll deduction authorization during an Option Period by canceling his or her Option in accordance with Section 13. The Administrator may at any time reduce a Participant's payroll deduction rate to zero percent (0%) of the Participant's Eligible Compensation at any time during an Option Period if the Administrator determines that the accumulated payroll deductions credited to the Participant's Account for the Option Period prior to such reduction would permit the Participant to purchase shares in excess of the Maximum Share Limit or the limits set forth in Section 6 or otherwise to the extent necessary to comply with Section 4(b). If the Participant's payroll deduction rate is so reduced by the Administrator, payroll deductions at the rate elected by the Participant shall recommence as of the subsequent Option Period unless the Participant files a new payroll deduction authorization in accordance with Section 7(b) or the Participant's Option is cancelled pursuant to Section 13 or 14.

(d) **Payroll Deduction Percentage**. Each payroll deduction authorization will request payroll deductions as a whole percentage from one percent (1%) to ten percent (10%) of an employee's Eligible Compensation each payroll period.

(e) **Payroll Deduction Account**. All payroll deductions made pursuant to this Section 7 will be credited to the Participant's Account. Amounts credited to a Participant's Account will not be required to be set aside in trust or otherwise segregated from the Company's general assets.

8. METHOD OF PAYMENT

A Participant must pay for shares of Stock purchased upon the exercise of an Option with accumulated payroll deductions credited to the Participant's Account.

9. PURCHASE PRICE

The Purchase Price of shares of Stock issued pursuant to the exercise of an Option on each Exercise Date will be eighty-five percent (85%) (or such greater percentage specified by the Administrator to the extent permitted under Section 423) of the lesser of (i) the Fair Market Value of a share of Stock on the date on which the Option was granted pursuant to Section 6(*i.e.*, the first day of the Option Period) and (ii) the Fair Market Value of a share of Stock on the date on which the Option is deemed exercised pursuant to Section 10 (*i.e.*, the Exercise Date).

10. EXERCISE OF OPTIONS

(a) **Purchase of Shares**. Subject to the limitations set forth in Section 6 and this Section 10, with respect to each Option Period, on the applicable Exercise Date, each Participant will be deemed to have exercised his or her Option and the accumulated payroll deductions in the Participant's Account will be applied to purchase the greatest number of shares of Stock (rounded down to the nearest whole share) that can be purchased with such Account balance at the applicable Purchase Price; *provided, however,* that no more than 4,000 shares of Stock may be purchased by a Participant on any Exercise Date, or such lesser number as the Administrator may prescribe in accordance with Section 423 (the "**Maximum Share Limit**"). As soon as practicable thereafter, shares of Stock so purchased will be placed, in book-entry form, into a recordkeeping account in the name of the Participant. No fractional shares of Stock will be purchased pursuant to the exercise of an Option under the Plan; any accumulated payroll deductions in a Participant's Account that are not sufficient to purchase a whole share of Stock will be retained in the Participant's Account for the subsequent Option Period, subject to earlier withdrawal by the Participant as provided in Section 13.

(b) **Return of Account Balance**. Except as provided in Section 10(a) with respect to fractional shares, any amount of payroll deductions in a Participant's Account that is not used for the purchase of shares of Stock, whether because of the Participant's withdrawal from participation in an Option Period or for any other reason, will be returned to the Participant (or his or her designated beneficiary or legal representative, as applicable), without interest, as soon as administratively practicable after such withdrawal or other event, as applicable. To the extent the Administrator has not previously acted under Section 7(c), if the Participant's accumulated payroll deductions on the Exercise Date of an Option Period would otherwise enable the Participant to purchase shares of Stock in excess of the Maximum Share Limit or the limits set forth in Section 6, the excess of the amount of the accumulated payroll deductions over the aggregate Purchase Price of the shares of Stock actually purchased will be returned to the Participant, without interest, as soon as administratively practicable after such Exercise Date.

11. INTEREST

No interest will be payable on any amount held in the Account of any Participant.

12. TAXES

Payroll deductions will be made on an after-tax basis. The Administrator will have the right, as a condition to exercising an Option, to make such provision as it deems necessary to satisfy the Company's obligations to withhold federal, state, local or other taxes incurred by reason of the purchase or disposition of shares of Stock under the Plan. In the Administrator's discretion and subject to applicable law, such tax obligations may be satisfied in whole or in part by delivery of shares of Stock to the Company, including shares of Stock purchased under the Plan, valued at Fair Market Value, but not in excess of the maximum withholding amount consistent with the award being subject to equity accounting treatment under Financial Accounting Standards Board Accounting Standards Codification Topic 718, or any successor provision.

13. CANCELLATION AND WITHDRAWAL

(a) **Cancellation of Payroll Deduction Authorization**. A Participant who holds an Option under the Plan may cancel all (but not less than all) of his or her Option and terminate his or her payroll deduction authorization by notice delivered to the Administrator in accordance with the procedures prescribed by, and in a form acceptable to, the Administrator. To be effective with respect to an upcoming Exercise Date, such cancellation notice must be delivered not later than ten (10) Business Days prior to such Exercise Date (or such other time as specified by the Administrator). Upon such termination and cancellation, the balance in the Participant's Account will be returned to the Participant, without interest, as soon as administratively practicable thereafter. For the avoidance of doubt, a Participant who reduces his or her withholding rate for future payroll periods to zero percent (0%) pursuant to Section 7 will be deemed to have terminated his or her payroll deduction authorization and cancelled his or her Option as to future Option Periods, unless the Participant has delivered a new payroll deduction authorization for a subsequent Option Period in accordance with the rules of Section 7(b). The prior sentence shall not apply to the Administrator's actions under the last two sentences of Section 7(c).

(b) **401(k) Hardship Withdrawal**. A Participant who makes a hardship withdrawal from a 401(k) Plan will be deemed to have terminated his or her payroll deduction authorization for subsequent payroll dates relating to the then-current Option Period as of the date of such hardship withdrawal and amounts accumulated in the Participant's Account as of such date will be returned to the Participant, without interest, as soon as administratively practicable thereafter. An Employee who has made a hardship withdrawal from a 401(k) Plan will not be permitted to participate in Option Periods commencing after the date of his or her hardship withdrawal until the first Option Period that begins at least six months after the date of his or her hardship withdrawal.

14. TERMINATION OF EMPLOYMENT OR DEATH OF PARTICIPANT

Upon the termination of a Participant's employment with the Company or a Designated Subsidiary, as applicable, for any reason or the death of a Participant during an Option Period prior to an Exercise Date or in the event the Participant ceases to qualify as an Eligible Employee, the Participant will cease to be a Participant, any Option held by him or her under the Plan will be deemed canceled, the balance in the Participant's Account will be returned to the

Participant (or his or her estate or designated beneficiary, in the event of the Participant's death), without interest, as soon as administratively practicable thereafter, and the Participant will have no further rights under the Plan.

15. EQUAL RIGHTS; PARTICIPANT'S RIGHTS NOT TRANSFERABLE

All Participants granted Options in an offering under the Plan will have the same rights and privileges, consistent with the requirements set forth in Section 423. Any Option granted under the Plan will be exercisable during the Participant's lifetime only by him or her and may not be sold, pledged, assigned, or transferred in any manner. In the event any Participant violates or attempts to violate the terms of this Section 15, as determined by the Administrator in its sole discretion, any Options held by him or her may be terminated by the Company and, upon the return to the Participant of the balance of his or her Account, without interest, all of the Participant's rights under the Plan will terminate.

16. CHANGE IN CAPITALIZATION; CORPORATE TRANSACTION

(a) **Change in Capitalization**. In the event of any change in the outstanding Stock by reason of a stock dividend, stock split, reverse stock split, split-up, recapitalization, merger, consolidation, reorganization, or other capital change, the aggregate number and type of shares of Stock available under the Plan, the number and type of shares of Stock granted under any outstanding Options, the maximum number and type of shares of Stock purchasable under any outstanding Option, and the Purchase Price under any outstanding Option will be appropriately adjusted; *provided*, that any such adjustment shall be made in a manner that complies with Section 423.

(b) **Corporate Transaction**. In the event of a Corporate Transaction, the Administrator may, in its discretion, (i) if the Company is merged with or acquired by another corporation, provide that each outstanding Option will be assumed or exchanged for a substitute Option granted by the acquirer or successor corporation or by a parent or subsidiary of the acquirer or successor corporation; (ii) cancel each outstanding Option and return the balances in Participants' Accounts to the Participants; and/or (iii) pursuant to Section 18, terminate the Option Period on or before the date of the proposed Corporate Transaction.

17. ADMINISTRATION OF PLAN

The Plan will be administered by the Administrator, which will have the authority to interpret the Plan, determine eligibility under the Plan, prescribe forms, rules and procedures relating to the Plan and otherwise do all things necessary or appropriate to carry out the purposes of the Plan. All determinations and decisions by the Administrator regarding the interpretation or application of the Plan will be final and binding on all Participants and all other persons.

The Administrator may specify the manner in which the Company and/or Employees are to provide notices and forms under the Plan, and may require that such notices and forms be submitted electronically.

18. AMENDMENT AND TERMINATION OF PLAN

(a) **Amendment**. The Board reserves the right at any time or times to amend the Plan to any extent and in any manner it may deem advisable; *provided*, *however*, that any amendment that would be treated as the adoption of a new plan for purposes of Section 423 will have no force or effect unless approved by the shareholders of the Company within 12 months before or after its adoption.

(b) **Termination**. The Board reserves the right at any time or times to suspend or terminate the Plan. In connection therewith, the Board may provide, in its sole discretion, either that outstanding Options will be exercisable either at the Exercise Date for the applicable Option Period or on such earlier date as the Board may specify (in which case such earlier date will be treated as the Exercise Date for the applicable Option Period), or that the balance of each Participant's Account will be returned to the Participant, without interest.

19. APPROVALS

Shareholder approval of the Plan will be obtained prior to the date that is 12 months after the date of Board approval. In the event that the Plan has not been approved by the shareholders of the Company prior to June 13, 2018, all Options to purchase shares of Stock under the Plan will be cancelled and become null and void.

Notwithstanding anything herein to the contrary, the obligation of the Company to issue and deliver shares of Stock under the Plan will be subject to the approval required of any governmental authority in connection with the authorization, issuance, sale or transfer of such shares of Stock and to any requirements of any national securities exchange applicable thereto, and to compliance by the Company with other applicable legal requirements in effect from time to time.

20. PARTICIPANTS' RIGHTS AS SHAREHOLDERS AND EMPLOYEES

A Participant will have no rights or privileges as a shareholder of the Company and will not receive any dividends in respect of any shares of Stock covered by an Option granted hereunder until such Option has been exercised, full payment has been made for such shares of Stock, and the shares of Stock have been issued to the Participant.

Nothing contained in the provisions of the Plan will be construed as giving to any Employee the right to be retained in the employ of the Company or any Designated Subsidiary or as interfering with the right of the Company or any Designated Subsidiary to discharge, promote, demote or otherwise re-assign any Employee from one position to another within the Company or any Designated Subsidiary at any time.

21. RESTRICTIONS ON TRANSFER; INFORMATION REGARDING DISQUALIFYING DISPOSITIONS

Shares of Stock purchased under the Plan may, in the discretion of the Administrator, be subject to a restriction prohibiting the transfer, sale, pledge or alienation of such shares of Stock

by a Participant, other than by will or by the laws of descent and distribution, for such period following such purchase as may be determined by the Administrator.

By electing to participate in the Plan, each Participant agrees to provide such information about any transfer of Stock acquired under the Plan that occurs within two years after the first day of the Option Period in which such Stock was acquired and within one year after the acquisition of such Stock as may be requested by the Company or any Designated Subsidiary in order to assist it in complying with applicable tax laws.

22. GOVERNING LAW

The Plan will be governed by and interpreted consistently with the laws of the State of Delaware, except as may be necessary to comply with applicable requirements of federal law.

23. EFFECTIVE DATE AND TERM

The Plan will become effective upon adoption of the Plan by the Board and no rights will be granted hereunder after the earliest to occur of (i) the Plan's termination by the Company; (ii) the issuance of all shares of Stock available for issuance under the Plan; and (iii) the day before the 10-year anniversary of the date the Board approves the Plan.

EXHIBIT A

Designated Subsidiaries

Designated Subsidiaries as of the date of adoption of the Plan by the Board are listed below:

None.

Mersana Therapeutics, Inc.

AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Board of Directors (the "***Board***") of Mersana Therapeutics, Inc. (the "***Company***") who is not also serving as an employee of the Company or any of its subsidiaries (each such member, an "***Non-Employee Director***") will be eligible to receive the compensation described in this Amended and Restated Non-Employee Director Compensation Policy (this "***Policy***") for his or her Board service. Unless otherwise defined herein, capitalized terms used in this Policy will have the meaning given to such terms in the Company's 2017 Stock Incentive Plan, as from time to time amended and in effect, or any successor equity incentive plan (the "***Plan***").

This Policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

I. Annual Cash Compensation

Each Non-Employee Director will be entitled to receive the following annual cash retainers for service on the Board:

Annual Board Service Retainer:

- All Non-Employee Directors: $40,000
- Non-Executive Chairperson *(additional retainer)*: $30,000

Annual Committee Member Service Retainer:

- Member of the Audit Committee: $7,500
- Member of the Compensation Committee: $5,000
- Member of the Nominating and Corporate Governance Committee: $4,000

Annual Committee Chair Service Retainer *(in lieu of Committee Member Service Retainer)*:

- Chairperson of the Audit Committee: $15,000
- Chairperson of the Compensation Committee: $10,000
- Chairperson of the Nominating and Corporate Governance Committee: $8,000

The annual cash retainers set forth above will be payable in equal quarterly installments, payable in arrears on the last day of each fiscal quarter (each such date, a "***Retainer Accrual Date***") in which the service occurred, prorated for any partial quarter of service (based on the number of days served in the applicable position divided by the total number of days in the quarter). All annual cash fees are vested upon payment.

II. Election to Receive Shares of Common Stock in Lieu of Cash Retainer

A. **Retainer Grant**. Each Non-Employee Director may elect (such election, a "***Retainer Grant Election***") to convert all of his or her cash compensation under Section I for each calendar quarter in a calendar year into either Unrestricted Stock (a "***Stock Retainer Grant***") or a Stock Option (an "***Option Retainer Grant***" and, any Stock Retainer Grant or Option Retainer Grant, a "***Retainer Grant***") in accordance with this Section II(A). If a Non-Employee Director timely makes a Retainer Grant Election pursuant to Section II(B) below, then on the first business day following each applicable Retainer Accrual Date to which the Retainer Grant Election applies, and without any further action by the Board or designated committee of the Board, any such Non-Employee Director electing a Stock Retainer Grant automatically will be granted a number of shares of Unrestricted Stock equal to (a) the aggregate amount of cash compensation otherwise payable to such Non-Employee Director on the Retainer Accrual Date to which the Retainer Grant Election applies divided by (b) the closing sales price per share of the Stock on the applicable Retainer Accrual Date (or, if such date is not a market trading day, on the first market trading day thereafter), rounded down to the nearest whole share, and any such Non-Employee Director electing an Option Retainer Grant automatically will be granted a Stock Option to acquire a number of shares of Stock having a grant date fair value equal to the aggregate amount of cash compensation otherwise payable to such Non-Employee Director on the Retainer Accrual Date to which the Retainer Grant Election applies, with the number of shares of Stock determined in accordance with Accounting Rules, rounded down to the nearest whole share. Each Retainer Grant will be fully vested on the applicable grant date.

B. **Election Mechanics**. Each Retainer Grant Election must be submitted to the Company's Chief Financial Officer (or such other individual as the Company designates) in writing by no later than December 31 preceding each calendar year to which such Retainer Grant Election shall apply (e.g., a Retainer Grant Election for the calendar year 2023 must be submitted by no later than December 31, 2022), and each Retainer Grant Election shall subject to any other conditions specified by the Board or designated committee of the Board. A Non-Employee Director may only make a Retainer Grant Election during a period in which the Company is not in a quarterly or special blackout period and the Non-Employee Director is not aware of any material non-public information. Once a Retainer Grant Election is properly submitted, it will be in effect for the next Retainer Accrual Date and will remain in effect for each successive Retainer Accrual Date in the calendar year covered by the Retainer Grant Election. A Non-Employee Director who fails to make a timely Retainer Grant Election will not receive Retainer Grants on the Retainer Accrual Dates occurring in such calendar year and instead will receive the cash compensation set forth under Section I.

III. Equity Compensation

Equity compensation awards to Non-Employee Directors will be automatic and nondiscretionary (without the need for any additional corporate action by the Board or designated committee of the Board) and will be made in accordance with the following provisions:

A. **Initial Grant**. For each Non-Employee Director who is first elected or appointed to the Board, on the date of such Non-Employee Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Non-Employee Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted both (a) a Stock Option to purchase the lesser of (i) 45,000 shares of Stock or (ii) a number of shares of Stock having a grant date fair value equal to $250,000, with the number of shares of Stock determined in accordance with Accounting Rules, rounded down to the nearest whole share and (b) a Restricted Stock Unit covering the lesser of (i) 45,000 shares of Stock or (ii) a number of shares of Stock equal to (a) $250,000 divided by (b) the closing sales price per share of the Stock on the date of the Non-Employee Director's initial election or appointment to the Board (or, if such date is not a market trading day, on the first market trading day thereafter), rounded down to the nearest whole share (the "***Initial Grant***"). The shares subject to each Initial Grant that is a Stock Option will vest annually in equal quarterly installments over a three-year period, subject to the Non-Employee Director's continuous service as a Director on each vesting date. The shares subject to each Initial Grant that is a Restricted Stock Unit will vest annually over a three-year period, subject to the Non-Employee Director's continuous service as a Director on each vesting date.

B. **Annual Grant**. On the date of each annual stockholder meeting of the Company (or, if such date is not a market trading day, the first market trading day thereafter), each Non-Employee Director who continues to serve as a non-employee member of the Board following such stockholder meeting will be automatically, and without further action by the Board or Compensation Committee of the Board, granted both (a) a Stock Option to purchase the lesser of (i) 22,500 shares of Stock or (ii) a number of shares of Stock having a grant date fair value equal to $125,000, with the number of shares of Stock determined in accordance with Accounting Rules, rounded down to the nearest whole share and (b) a Restricted Stock Unit covering the lesser of (i) 22,500 shares of Stock or (ii) a number of shares of Stock equal to (a) $125,000 divided by (b) the closing sales price per share of the Stock on the grant date, rounded down to the nearest whole share (the "***Annual Grant***"). The shares subject to each Annual Grant will vest in full upon the earlier of the first anniversary of the date of grant or the date of the following annual meeting of stockholders of the Company, subject to the Non-Employee Director's continuous service as a Director on each vesting date.

C. **Stock Options.** All Stock Options granted under this Policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock on the date of grant, and a term of 10 years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

D. **Additional Provisions**: All provisions of the Plan not inconsistent with this policy will apply to awards granted to a Non-Employee Director. Non-Employee Directors will be required to execute an award agreement in a form satisfactory to the Company prior to receipt of an Initial Grant or Annual Grant. All shares subject to any Initial Grant and/or Annual Grant that is then-outstanding will vest in full upon the Non-Employee Director's death or termination of service due to disability or upon a change in control event (within the meaning of Section 1.409A-3(i)(5)(i)).

IV. Non-Employee Director Compensation Limit

Notwithstanding anything herein to the contrary, the cash compensation and equity compensation that each Non-Employee Director is entitled to receive under this Policy shall be subject to the limits set forth in Section 4(d) of the Plan.

V. Ability to Decline Compensation

A Non-Employee Director may decline all or any portion of his or her compensation under this Policy by giving notice to the Company prior to the date such cash is earned or such equity awards are to be granted, as the case may be.

VI. Expenses

The Company will reimburse each Non-Employee Director for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and committee meetings; provided, that the Non-Employee Director timely submits to the Company appropriate documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.

Amended and Restated by the Board of Directors: December 1, 2022

Exhibit 21.1

Subsidiaries of the Registrant

Entity	State of Incorporation or Organization
Mersana Securities Corp.	Massachusetts

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-260895) of Mersana Therapeutics, Inc. and in the related Prospectus,
(2) Registration Statement (Form S-3 No. 333-238140) of Mersana Therapeutics, Inc. and in the related Prospectus,
(3) Registration Statement (Form S-8 No. 333-263085) pertaining to the Mersana Therapeutics, Inc. 2017 Stock Incentive Plan, the Mersana Therapeutics, Inc. 2022 Inducement Stock Incentive Plan, and certain inducement stock option awards,
(4) Registration Statement (Form S-8 No. 333-255975) pertaining to the Mersana Therapeutics, Inc. 2017 Stock Incentive Plan, and certain inducement stock option awards,
(5) Registration Statement (Form S-8 No. 333-236775) pertaining to the Mersana Therapeutics, Inc. 2017 Stock Incentive Plan and the Mersana Therapeutics, Inc. 2017 Employee Stock Purchase Plan,
(6) Registration Statement (Form S-8 No. 333-230159) pertaining to the Mersana Therapeutics, Inc. 2017 Stock Incentive Plan and the Mersana Therapeutics, Inc. 2017 Employee Stock Purchase Plan,
(7) Registration Statement (Form S-8 No. 333-222845) pertaining to the Mersana Therapeutics, Inc. 2017 Stock Incentive Plan, and
(8) Registration Statement (Form S-8 No. 333-219388) pertaining to the Mersana Therapeutics, Inc. 2007 Stock Incentive Plan, as amended, the Mersana Therapeutics, Inc. 2017 Stock Incentive Plan and the Mersana Therapeutics, Inc. 2017 Employee Stock Purchase Plan;

of our report dated February 28, 2023, with respect to the consolidated financial statements of Mersana Therapeutics, Inc. included in this Annual Report (Form 10-K) of Mersana Therapeutics, Inc. for the year ended December 31, 2022.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 28, 2023

Exhibit 31.1

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 Annual Report on Form 10-K 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report), that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2023

By: /s/ Anna Protopapas

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

Exhibit 31.2

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 Annual Report on Form 10-K 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report), that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2023

By: /s/ Brian DeSchuytner

Brian DeSchuytner
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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 this Annual Report on Form 10-K of Mersana Therapeutics, Inc. (the "Company") for the year ended December 31, 2022 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.

Date: February 28, 2023

By: /s/ Anna Protopapas

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

Date: February 28, 2023

By: /s/ Brian DeSchuytner

Brian DeSchuytner
Chief Financial Officer
(Principal Financial Officer)

MERSANA THERAPEUTICS, INC.

Clawback Policy

1. Persons Subject to this Policy. This policy is applicable to all officers (as defined in Rule 16(a)-f under the Securities Exchange Act of 1934, as amended) of Mersana Therapeutics, Inc. (the "Company"). This policy will also apply to such other employees, or classes of employees, of the Company as may be determined from time to time by the Company's Board of Directors or a duly established committee thereof (the "Board"). Each person to whom this policy applies is referred to herein as a "Covered Person."

2. Definitions.

(a) "Accounting Restatement" means an accounting restatement for periods that end on or after the effective date of this policy due to material noncompliance of the Company with any financial reporting requirement under the U.S. federal securities laws.

(b) "Incentive-Based Compensation" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of any financial reporting measure, including stock options and other equity awards under the Company's long-term incentive plans that is awarded to a Covered Person as compensation.

3. Recovery of Excess Compensation Following an Accounting Restatement. In the event the Company is required to prepare an Accounting Restatement, the Board shall determine, in its sole discretion, the amount, if any, to seek to recover from any current or former Covered Person who received Incentive-Based Compensation from the Company, based on erroneous data, during the 3-year period preceding the date on which the Company is required to prepare the Accounting Restatement, which amount shall in no event be greater than the excess of what would have been paid to the Covered Person based on the restated data.

4. Potential Recovery of Additional Amounts Upon an Accounting Restatement. In addition to (and without limiting) the provisions of Section 3 above, in the event that the Board, in its sole discretion, determines that a current or former Covered Person's acts or omissions that contributed to the circumstances requiring an Accounting Restatement involved either: (i) intentional misconduct or an intentional violation of any of the Company's policies or any applicable legal or regulatory requirements in the course of the Covered Person's employment by the Company or (ii) fraud in the course of the Covered Person's employment by the Company, then in each such case, the Company will use reasonable efforts to recover from such Covered Person up to 100% (as determined by the Board in its sole discretion to be appropriate based on the conduct involved) of the Incentive-Based Compensation, and not just the excess of what would have been paid to the Covered Person as provided under Section 3.

5. Interpretation of Policy. This policy will apply to Incentive-Based Compensation that is granted to a Covered Person after the adoption of this policy (or, if later, the date on which such person becomes a Covered Person). This policy will be interpreted in a manner that is consistent with any applicable rules or regulations adopted by the Securities and Exchange Commission or Nasdaq pursuant to Section 10D of the Securities Exchange Act of 1934 (the "Applicable Rules") and any other applicable law and will otherwise be interpreted (including in the determination of amounts recoverable) in the business judgment of the Board. To the extent the Applicable Rules require recovery of incentive-based compensation in additional circumstances besides those specified above, nothing in this policy will be deemed to limit or restrict the right or obligation of the Company to recover incentive-based compensation to the fullest extent required by the Applicable Rules. Moreover, nothing in this policy shall be deemed to limit the

Company's right to terminate employment of any Covered Person, to seek recovery of other compensation paid to a Covered Person, or to pursue other rights or remedies available to the Company under applicable law.

Adopted by the Board of Directors: September 8, 2022