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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, 2020.

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. ☒

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, 2020, 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 $1,147,647,431, based on the last reported sale price of such stock on the Nasdaq Global Select Market as of such date.

As of February 23, 2021, the registrant had 69,042,942 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 2021 Annual Meeting of Stockholders are incorporated by reference in Part III.

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PART I

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 and preclinical and clinical studies;
- the adequacy of our inventory of upifitamab rilsodotin (UpRi, XMT-1536) and XMT-1592 to support our ongoing clinical studies, 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 need of ovarian cancer and non-small cell lung cancer;
- our ability to quickly and efficiently identify and develop additional product candidates;
- our ability to advance any product candidate into, and successfully complete, clinical studies;
- our intellectual property position, including with respect to our trade secrets;
- the potential benefits of strategic partnership agreements and our ability to enter into selective strategic partnerships;
- 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.

In addition, while we expect that the COVID-19 pandemic might adversely affect our preclinical and clinical development efforts, business operations and financial results, the extent of the impact and the value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, physical distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat the disease.

The forward-looking statements contained herein represent our views as of the date of this Annual Report on Form 10-K. 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 FACTORS SUMMARY

Our business is subject to varying degrees of risk and uncertainty. Investors should consider the risks and uncertainties summarized below, as well as the risks and uncertainties discussed in Part 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 operating covenants and place 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 two product candidates, upifitamab rilsodotin (UpRi, XMT-1536) and XMT-1592, in clinical studies. 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 product candidates based on the same technology.
- We can provide no assurance that our clinical product candidates will obtain regulatory approval or that the results of clinical studies 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 ADC products.
- If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our ADC product candidates, conduct our clinical studies and commercialize our ADC product candidates.
- We may encounter difficulties in managing our growth and expanding our operations successfully.
- As a pharmaceutical manufacturer, 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.
- Our business is subject to risks arising from the outbreaks of disease, such as epidemics or pandemics, including the ongoing COVID-19 pandemic.

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 proprietary and differentiated technology platforms that enable us to design ADCs that have improved efficacy, safety and tolerability relative to existing ADC therapies.

Our innovative platforms, which include Dolaflexin and Dolasynthen, delivering our DolaLock payload, as well as Immunosynthen, delivering a novel stimulator of interferon genes, or STING, agonist, compose a highly efficient product engine that has enabled a robust discovery pipeline for us and our partners. Our ADCs in preclinical and clinical studies include

first-in-class molecules that target multiple tumor types with high unmet medical need and have exhibited improved safety and efficacy compared to ADCs developed using first-generation technology.

We have assembled a management team with extensive and relevant experience, including specific ADC experience, from prior work at leading pharmaceutical companies such as Millennium Pharmaceuticals, Inc., Takeda Pharmaceuticals, Biogen, Inc., Bayer AG, Tesaro, Inc., Vertex Pharmaceuticals Inc., Cubist Pharmaceuticals Inc. and Bristol Myers Squibb. We are supported by our board of directors and scientific advisory board, who offer complementary experience in drug discovery and development, as well as expertise in building public companies, management and business development. We believe that our highly differentiated platforms, together with the team we have assembled, position us well to discover and develop life-changing antibody-drug conjugates for patients fighting cancer.

Strategy

Our goal is to become a leading oncology company by leveraging the potential of our innovative and differentiated ADC technologies 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. Key components of our strategy to achieve this goal are as follows:

- **Rapidly advance upifitamab rilsodotin (UpRi, XMT-1536).** Our lead product candidate, UpRi, is a first-in-class Dolaflexin ADC currently in a Phase 1 proof-of-concept clinical trial in patients with tumors likely to express NaPi2b, an antigen broadly expressed in ovarian cancer and non-small cell lung cancer, or NSCLC, adenocarcinoma. We expect to initiate a single-arm registration strategy in platinum-resistant ovarian cancer, UPLIFT, and a combination dose escalation study, UPGRADE, in earlier lines of platinum-resistant ovarian cancer in 2021.

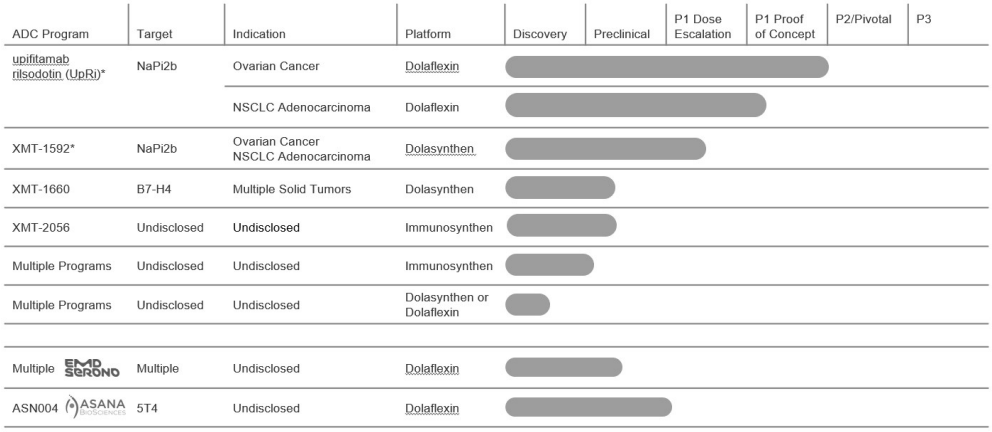
- **Rapidly advance XMT-1592 through dose escalation.** Mersana's second product candidate targeting NaPi2b-expressing tumors, XMT-1592, is an ADC created using our Dolasynthen platform. In the first half of 2020, we initiated a Phase 1 dose escalation study of XMT-1592 in ovarian cancer and NSCLC adenocarcinoma. We believe that we have a path to advance XMT-1592 through rapid dose escalation and clinical validation.

- **Expand our ADC pipeline.** We intend to establish a leading position in the field of ADCs by continuing to advance platform innovations that further broaden the potential of our ADCs to deliver clinically meaningful benefit for cancer patients, by focusing on first-in-class targets and payloads, and by pursuing fast-to-market opportunities. We are advancing a new, potentially first-in-class ADC targeting B7-H4, XMT-1660, which leverages our Dolasynthen platform in IND-enabling studies. We have taken ADCs beyond cytotoxics by developing the Immunosynthen platform, an approach that may allow tumor-targeted activation of the innate immune system. Our first Immunosynthen STING-agonist ADC development candidate, XMT-2056, is in IND-enabling studies.

- **Attract and retain talented and experienced people.** In addition to our team's deep experience with ADC science, drug development and operational management, we believe that our accomplishments are a testament to the talent and commitment of our people. Our team is driven by a shared passion to advance therapies that make a significant difference in the lives of cancer patients. We will continue to cultivate the collaborative and passionate workplace culture that has allowed us to advance this mission.

- **Build strategic partnerships to maximize the value of our programs and platforms.** Our platform technologies, and product discovery and development capabilities, drive the potential for multiple clinically meaningful opportunities for cancer patients. In order to preserve a disciplined drug development and commercialization focus, we may choose to enter into strategic partnerships that facilitate our ability to bring differentiated product candidates to more patients. Our current partnerships with Merck KGaA and Asana Biosciences exemplify different aspects of this strategy.

Our current pipeline is summarized in the chart below:



*NaPi2b antibody used in UpRi (formerly XMT-1536) and XMT-1592 is in-licensed from Recepta Biopharma. Recepta has rights to commercialize UpRi and XMT-1592 in Brazil.

ADC Background

Traditional ADCs are a class of cancer biotherapeutics that combine the targeting capabilities of monoclonal antibodies with the cancer-killing ability of cytotoxic drug payloads. Antibodies and payloads are chemically linked, allowing specific drug delivery to cancer cells targeted by the antibody. After ADCs enter a cell, the conjugated payload is released and kills the cell. Despite the promise of ADCs, companies in the field have faced certain challenges in developing product candidates that achieve the optimal therapeutic index, or the balance between efficacy and tolerability. These challenges are characterized as follows:

- **Linker stability**: Linkers must be stable in the bloodstream to ensure that free payload is not released into circulation prior to delivery into the tumor. Free payload in circulation causes toxicity. Efforts to design better linkers to increase stability have, in turn, reduced the efficiency of payload release once the ADC is internalized in the tumor cell, resulting in decreased efficacy.

- **Drug-to-antibody ratio**: Increasing the number of payload molecules delivered per antibody internalization event increases potency. However, the drug-to-antibody ratio, or DAR, has typically been limited to three to four payload molecules per antibody due to aggregation, poor pharmacokinetics and loss of drug-like properties of the ADC at levels above this threshold. Other attempts to increase efficacy have involved the introduction of ultra-potent payloads, however these efforts appear to face safety and tolerability challenges, necessitating even further reduced DAR to maintain acceptable pharmacokinetics and drug-like properties.

- **Target antigen expression level**: Tumor cells typically require a threshold number of payload molecules to be internalized in order to kill the cell. Antigens with lower levels of expression have proven less desirable as targets for ADCs, as a result of fewer binding, internalization and payload delivery events to drive cell-killing activity. In turn, this has limited the number of cancers amenable to treatment with low-DAR ADC approaches, as the use of ADCs requires antigen targets to be highly expressed on tumor cells.

- **Bystander effect**: Once ADCs release their cytotoxic payload into targeted cells, the drug is often able to cross cell membranes, entering and potentially killing neighboring cells whether those cells are cancerous or not. This is known as the ‘bystander effect,’ which is advantageous when bystander cells are cancerous, but toxic if the cytotoxic drug is able to enter adjacent healthy cells, leading to dose-limiting toxicities such as neutropenia, peripheral neuropathy, or ocular toxicity.

Our Technologies and Platforms

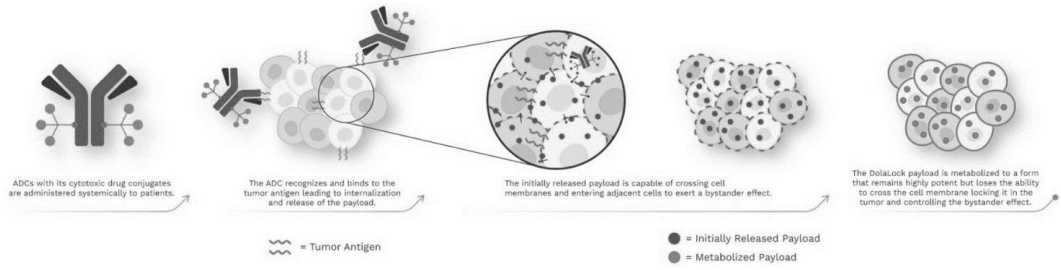
The development of ADCs is not a one-size-fits-all approach. In fact, a number of diverse factors impact the properties of an ADC, including payload, drug-to-antibody ratio, site of conjugation and homogeneity. For each target antigen, there is an optimal combination of these factors. Our novel and highly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

DolaLock Payload

Our DolaLock payload is a proprietary auristatin cytotoxic drug and is a highly potent anti-tubulin agent selectively toxic to rapidly dividing cells. The DolaLock payload has been shown in preclinical studies to control the bystander effect by locking the cytotoxic drug inside cells after allowing a short period of diffusion throughout the tumor. As the drug diffuses through neighboring tissue, the DolaLock payload is metabolized to a form that is still highly potent but is no longer able to cross the cell membrane, effectively locking the drug inside cells and controlling the bystander effect for a safer and more effective cancer therapy.

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 actively pump drugs out of cancer cells to help them survive. Once metabolized, our DolaLock payload cannot be pumped out by PgPs, thereby avoiding this resistance mechanism. 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, synergy with immuno-oncology agents such as PD-1 inhibitors has been observed in preclinical models. Our DolaLock payload with controlled bystander effect is designed to allow us to create ADCs that produce a highly potent, well-tolerated and specifically-targeted cancer therapy.

Figure 1. DolaLock Payload with Controlled Bystander Effect



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 able to carry multiple drug molecules. Instead of direct conjugation to an antibody, drug molecules are attached through an optimized, cleavable linker to the Fleximer scaffold, which is then conjugated to the antibody through a non-cleavable linker. Fleximer has demonstrated dramatically improved drug solubility, pharmacokinetics and immunogenicity, and an increased number of drug molecules carried by each ADC compared with traditional ADC therapies.

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

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

- **Higher Drug-to-Antibody Ratio:** Historically, ADCs have been limited to a DAR of 3-4. The Dolaflexin platform can deliver ADCs with DAR of about 10, allowing for greater efficacy while also maintaining pharmacokinetics and drug-like properties.

- **Expanded Range of Addressable Tumor Targets:** The higher DAR enabled by Dolaflexin results in more chemotherapeutic drug released into the tumor cell for every ADC internalized. As a result, Dolaflexin ADCs can have efficacy against tumor targets with lower levels of antigen expression where traditional ADCs have not been effective.

We believe these advantageous characteristics of our Dolaflexin platform provide a substantial opportunity to develop clinically meaningful ADC therapies with potential to address a broader range of cancers than traditional ADC-based approaches. Our lead clinical candidate, UpRi, is a Dolaflexin ADC that targets NaPi2b. UpRi is currently in a proof-of-concept study in patients with ovarian cancer and NSCLC adenocarcinoma.

Dolasynthen Platform

The Dolasynthen platform enables an iterative approach to develop the right ADC for a given indication through customization and optimization. Dolasynthen utilizes a synthetic scaffold for precise control of DAR, from 2-24, and site-specific antibody bioconjugation. The platform is also able to homogeneously generate ADCs with precisely defined DARs for consistent drug delivery to cancer cells. The Dolasynthen scaffold has been precisely designed to provide optimal water solubility, charge balance, linker stability and DAR. We believe that Dolasynthen retains the favorable properties of Dolaflexin, including our proprietary DolaLock technology for a controlled bystander effect, with superior physicochemical and pharmacokinetic properties.

Illustrated by our preclinical data, optimized Dolasynthen ADCs exhibit a broad therapeutic index as a cancer therapy. These 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, and has the potential to offer the following benefits relative to traditional ADCs:

- **Precise Control of DAR:** The optimal DAR may vary between different targets and antigens. Dolasynthen allows for precise DARs between 2-24, 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 throughout ADCs developed with the Dolasynthen platform allowing for consistent and precise drug delivery to targeted cancer cells.

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

Our second clinical candidate, XMT-1592, is a Dolasynthen ADC targeting NaPi2b-expressing tumors. In the first half of 2020 we initiated a Phase 1 dose escalation trial of XMT-1592 in ovarian cancer and NSCLC adenocarcinoma. XMT-1660, our B7-H4 targeted ADC, was selected as our next Dolasynthen ADC and is currently in IND-enabling studies.

Immunosynthen STING-Agonist ADC Platform and Pipeline

Immunosynthen is our novel immunostimulatory ADC platform designed to take ADCs beyond traditional cytotoxic payloads and into targeted stimulation of the innate immune system. Stimulator of Interferon Genes (STING) is a well-studied innate immune pathway capable of inducing anti-tumor immune activity. 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 the intratumoral or intravenous injection of free STING agonist. Our preclinical data show that the anti-tumor activity of Immunosynthen STING-agonist ADCs 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 that activate only the immune cells. Further, 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 micro environment, as well as the induction of immunological memory. We have demonstrated excellent tolerability and 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:

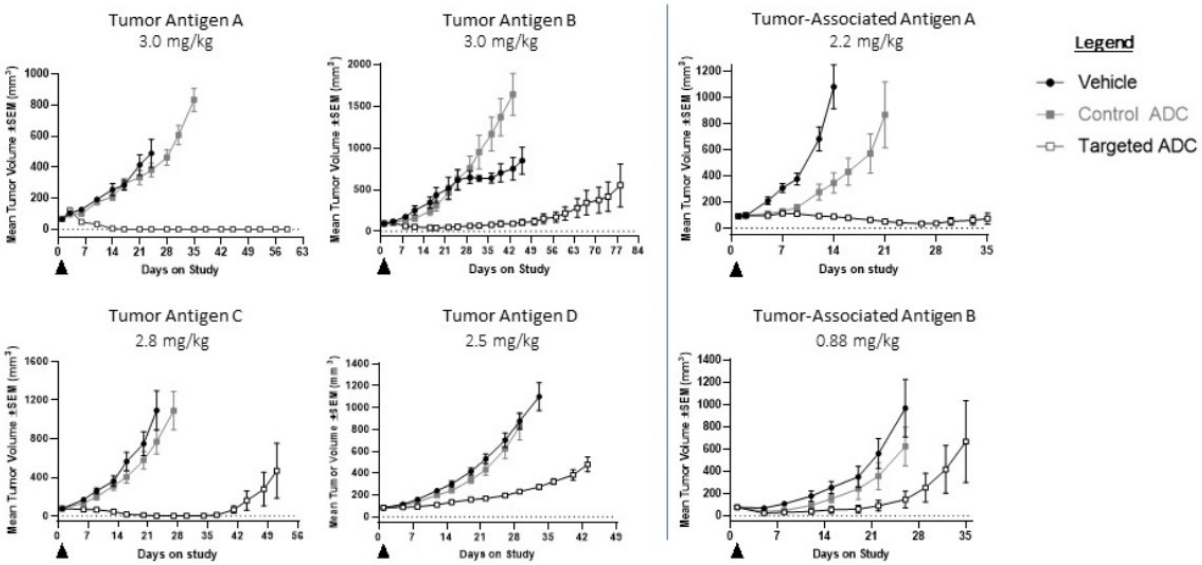
- **Systemic Administration with Targeted Delivery:** ADCs have the convenience of systemic administration with potential to provide targeted delivery specifically to all tumor lesions, including metastatic sites.

- **Improved Therapeutic Index:** Conjugation of the STING agonist provides protection in the systemic circulation to minimize off-target effects.

- **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.

- **Immunosynthen STING ADCs Provide 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.

Figure 2. Immunosynthen ADCs Active Against Diverse Tumor Antigens and Tumor-Associated Antigens in Multiple Models After Single, Low IV Dose



We are building a pipeline of Immunosynthen ADC candidates applicable to a broad range of clinical indications. Our first Immunosynthen ADC development candidate, XMT-2056, is in IND-enabling studies.

Our product candidates

We are leveraging our platforms to develop a robust pipeline of clinically meaningful cancer therapies. Our pipeline strategy focuses on targets that have been biologically validated (either as ADCs or through another modality), where the advantages of our platforms may lead to clinically superior therapeutic benefits, where we have the potential to achieve first-in-class status, and where fast-to-market opportunities are available. Our lead product candidate, UpRi, is in a Phase 1 proof-of-concept study with expansion cohorts in ovarian cancer and NSCLC adenocarcinoma. We expect to initiate a single-arm registration strategy in platinum-resistant ovarian cancer, UPLIFT, and a combination dose escalation study, UPGRADE, in ovarian cancer in 2021. Our next product candidate, XMT-1592, is in a Phase 1 dose escalation study. We are also advancing a potentially first-in-class B7-H4-targeted Dolasynthen ADC, XMT-1660, currently in IND-enabling studies and have nominated our first Immunosynthen development candidate, XMT-2056, currently in IND-enabling studies. In addition, our partners have multiple ADC product candidates leveraging our Dolaflexin technology in development.

Upifitamab rilsodotin (UpRi, XMT-1536): 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. The NaPi2b antigen is broadly expressed in NSCLC adenocarcinoma and ovarian cancer 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. There are currently no tests approved by the U.S. Food and Drug Administration, or FDA, to measure NaPi2b expression on tumor cells. Given the prevalence of its expression on epithelial ovarian and NSCLC adenocarcinoma tumors, our initial clinical studies of UpRi are being conducted without prospective identification of patients with NaPi2b-expressing tumors. Nonetheless, we have developed

an immunohistochemistry assay to measure NaPi2b expression which we intend to use retrospectively to confirm the broad prevalence of NaPi2b expression in our target patient populations while correlating 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.

In March 2020, we presented data from the UpRi Phase 1 dose escalation study establishing the maximum tolerated dose and showing encouraging clinical activity with confirmed responses and prolonged stable disease in heavily pretreated patients, without pre-selection for NaPi2b expression. Interim data from the expansion portion of the ongoing UpRi Phase 1 study were presented at the American Society of Clinical Oncology (ASCO) virtual meeting in May 2020. Updated interim data from the ovarian cancer cohort of the UpRi Phase 1 Expansion Study were presented at the European Society for Medical Oncology (ESMO) virtual meeting in September 2020, as well as at a virtual analyst and investor day in January 2021. These data showed clinically meaningful activity in heavily-pretreated patients with an objective response rate >30% and complete responses in patients with ovarian cancer with higher NaPi2b expression. While serious adverse events have been experienced in this heavily-pretreated population, the data showed that UpRi was generally well tolerated without the severe toxicities commonly seen with other ADCs such as neutropenia, ocular toxicities, or peripheral neuropathy. We continue to enroll ovarian cancer and NSCLC adenocarcinoma patients in the expansion portion of the Phase 1 study.

In the fourth quarter of 2020, data from the expansion portion of the Phase 1 study of UpRi in ovarian cancer were discussed with the FDA in order to inform the design and initiation of a single-arm registration strategy in platinum-resistant ovarian cancer, to be named UPLIFT. We plan to initiate UPLIFT to evaluate the safety and efficacy of UpRi in heavily-pretreated platinum-resistant ovarian cancer patients. Patients with one to four prior lines of therapy may enroll without regard to NaPi2b expression; however, the role of the biomarker will be evaluated retrospectively. Patients with three to four prior lines of therapy may enroll without prior bevacizumab treatment, accommodating differences in bevacizumab use in early disease. The primary endpoint will be the objective response rate, or ORR, in the higher NaPi2b patient population and the secondary endpoints will be the ORR regardless of NaPi2b expression, as well as duration of response and safety. The single-arm registration strategy will be initiated as an amendment to the ongoing multinational, multi-center, open label study protocol leveraging expansion enrollment momentum. We expect to enroll approximately 100 patients with higher NaPi2b expression and up to 180 patients overall. The single-arm registration strategy is intended to support a potential regulatory submission under the FDA's accelerated approval pathway.

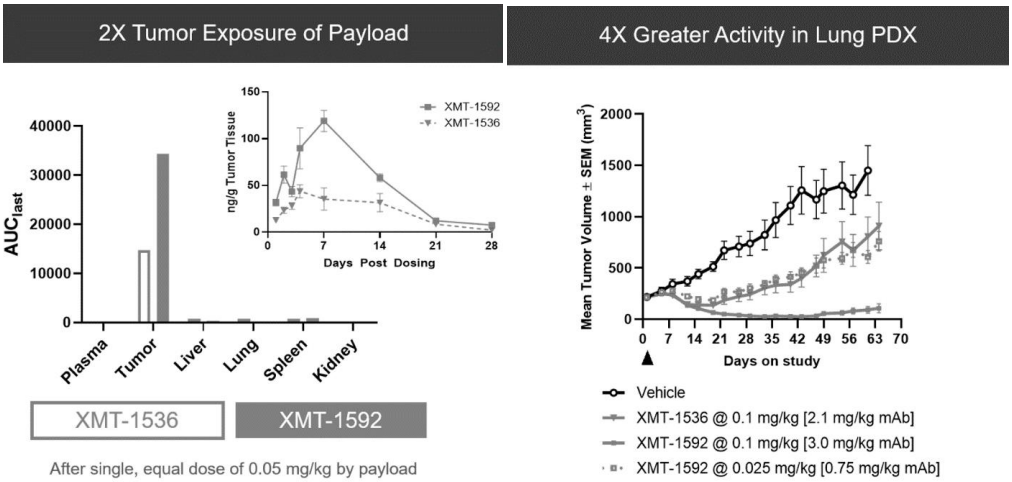
We also expect to initiate a combination dose escalation study, to be named UPGRADE, in earlier lines of ovarian cancer in 2021. UPGRADE is expected to evaluate the combination of UpRi with a variety of other agents, starting with a platinum chemotherapy. This study is designed to inform the lifecycle management strategy for UpRi in earlier lines of ovarian cancer, including platinum-sensitive disease.

In August 2020, the FDA granted Fast Track Designation for UpRi.

XMT-1592: our NaPi2b targeted Dolasynthen ADC

XMT-1592 was created using our Dolasynthen platform and also targets NaPi2b. XMT-1592 comprises the same proprietary NaPi2b antibody and potent auristatin DolaLock payload with controlled bystander effect as UpRi, with the additional features of homogeneous, site-specific bioconjugation and precise DAR. Preclinically, XMT-1592 has shown a differentiated profile particularly in NSCLC adenocarcinoma, where it was four times more efficacious than UpRi, consistent with higher tumor penetration, as described in below in Figure 2. Based on these preclinical data, we believe that XMT-1592 has the potential to provide us with a second opportunity to treat NSCLC adenocarcinoma patients. XMT-1592 is in a Phase 1 dose escalation study in patients with ovarian cancer and NSCLC adenocarcinoma. We plan to evaluate the clinical differentiation of Dolasynthen by leveraging our experience in NaPi2b to rapidly progress XMT-1592 through dose escalation.

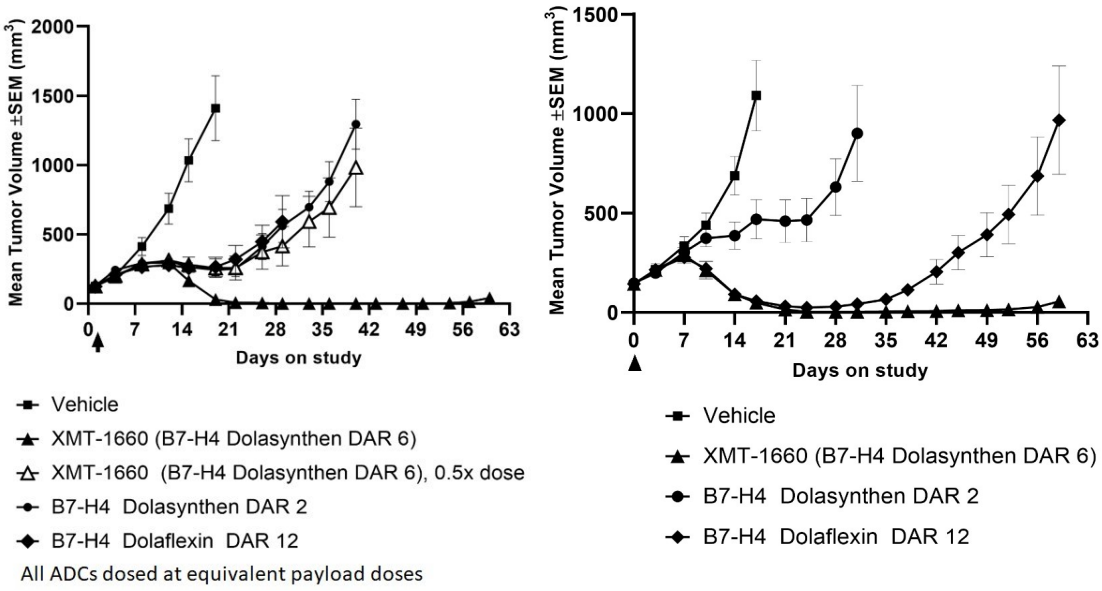
Figure 3. XMT-1592 Shows Four-Fold Greater Efficacy in Lung Tumor Model



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

Our early stage programs include XMT-1660, a potentially first-in-class B7-H4-targeted ADC development candidate, created with our Dolasynthen platform, addressing areas of high unmet medical need. The expression profile of B7-H4 is well suited for our unique DolaLock payload. B7-H4 can be expressed in two places: 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. DolaLock's dual mechanisms of action with a direct cytotoxic effect as well as an immunostimulatory effect through dendritic cell activation and immunogenic cell death are well suited to the biology of the B7-H4 target. We have generated favorable efficacy and non-human primate tolerability data with both Dolaflexin and Dolasynthen ADCs targeting B7-H4. Our objective in 2021 is to rapidly progress XMT-1660 through IND-enabling studies and scale up manufacturing activities with third parties. B7-H4 provides significant opportunities for development in areas of high unmet need such as breast cancer, endometrial and ovarian cancer.

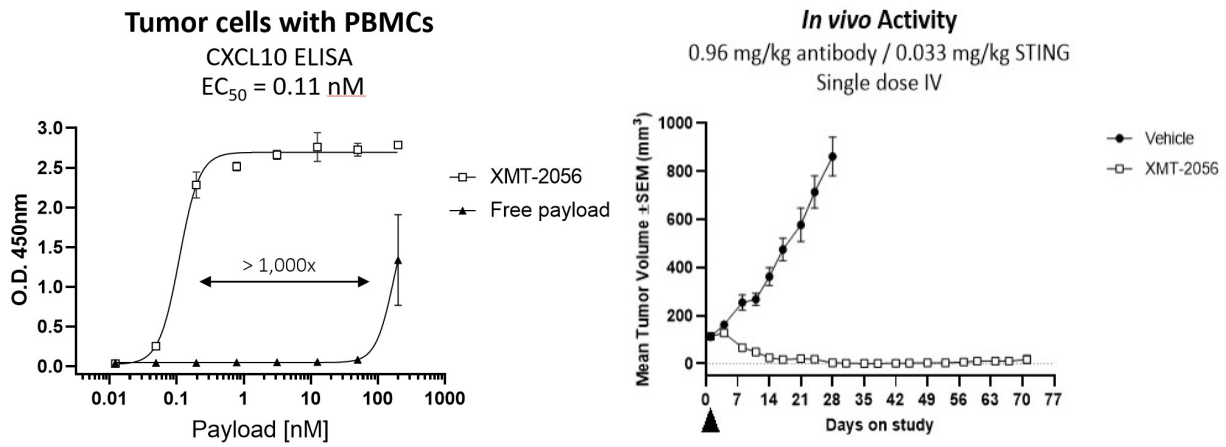
Figure 4. XMT-1660 Selected Based on Direct Comparison of Candidates in Multiple In Vivo Models



XMT-2056: our First Immunosynthen ADC candidate

Our early stage programs also include XMT-2056, our first STING-agonist ADC development candidate, created using our Immunosynthen platform. 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. Our preclinical studies have demonstrated that XMT-2056 has robust activity, resulting in complete tumor regressions in mouse models after a single intravenous low dose. In addition, preclinical studies have also shown excellent tolerability in multi-dose non-human primate, or NHP, studies after intravenous dosing, at exposure levels far exceeding those needed for complete responses in mouse models, which indicates a high preclinical therapeutic index. XMT-2056 is in IND-enabling studies.

Figure 5. XMT-2056 Shows Robust Activity in In Vitro and In Vivo Models



Ovarian cancer unmet need and epidemiology

Worldwide, ovarian cancer had incidence of approximately 295,000 and caused an estimated 185,000 deaths in 2018. With a U.S. incidence of approximately 25,000 new cases (including fallopian tube and primary peritoneal cancers) and mortality of 14,000 in 2020, ovarian cancer was the second most common gynecologic malignancy and the most common cause of gynecologic cancer death in the United States. The majority of ovarian malignancies (approximately 90%) are derived from epithelial cells. 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 periods of either observation or maintenance. Nearly 85% of ovarian cancer patients typically relapse following initial treatment. Subsequent treatment depends on the depth and 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 and paclitaxel. Multiple Phase 3 studies 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.

With targeted agents approved in platinum-resistant disease increasingly being prescribed in earlier lines of therapy, the unmet need is expected to remain severe. Bevacizumab in combination with chemotherapy is indicated 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 shown no overall survival benefit. Use of bevacizumab in combination with platinum-containing chemotherapy in the frontline and platinum-sensitive recurrent settings mean an increasing number of platinum-resistant patients are pre-treated with bevacizumab and are not candidates for additional bevacizumab combination treatment. More recently, PARP inhibitors have been approved for heavily-pretreated ovarian cancer including platinum-resistant disease. However, they are predominantly used in a subset of patients with cancers harboring BRCA1 and BRCA2 mutations. Similarly, use of PARP inhibitors in earlier lines of recurrent platinum-sensitive maintenance and more recently frontline maintenance therapy following platinum-based chemotherapy means an increasing number of platinum-resistant patients are pre-treated with PARP inhibitors and are not candidates for additional PARP inhibitor therapy.

NSCLC unmet need and epidemiology

Worldwide, lung cancer had an incidence of approximately 2.1 million and caused an estimated 1.7 million deaths in 2018. With a U.S. incidence of approximately 230,000 new cases and over 130,000 deaths in 2020, lung cancer was the most deadly form of cancer in the United States. The five year survival rate is less than 20% on average. Approximately 95% of all lung cancers are classified as either small cell lung cancer or NSCLC. NSCLC can be further divided into squamous or non-squamous. The majority of non-squamous NSCLC is classified as adenocarcinoma. These histological distinctions are important for proper staging, treatment and prognosis. For patients with NSCLC, initial treatment is largely determined by the stage of disease. Surgical resection offers the best opportunity for long-term survival and cure in patients with resectable early-stage NSCLC. Locally-advanced NSCLC is treated by combinations of radiotherapy, immunotherapy, chemotherapy and surgery. The majority of patients present with inoperable disease. Metastatic NSCLC is managed with systemic chemotherapy and immunotherapy.

The standard of care is evolving for NSCLC with the introduction of immunotherapies for patients without oncogenic driver mutations and new targeted therapies for patients with EGFR, ALK, ROS-1, NTRK or BRAF mutations. For patients with metastatic disease without oncogenic driver mutations, frontline platinum-based chemotherapy is combined with or, depending on PD-L1 expression status, replaced by, immunotherapy using anti-PD-1 or anti-PD-L1 monoclonal antibodies. For patients with metastatic disease harboring oncogenic driver mutations, several generations of targeted agents are available with different resistance profiles. Frontline therapy is often followed by relapse and recurrence and treatment options for these patients are substantially more limited. The standard of care of docetaxel alone or in combination with targeted agents has an overall response rate of 14-23%, median progression-free survival of 3-4 months and median overall survival of 9-12 months.

With PD-1 and PD-L1 inhibitors and next generation targeted therapies moving into frontline, the unmet need in recurrent lung cancer is expected to remain severe.

Strategic partnerships

Strategic partnerships with leading biopharmaceutical companies to advance Fleximer ADC product candidates

We believe that our ADC platforms have broad applicability across a number of targets. We have used strategic partnering to accelerate bringing Fleximer ADCs to patients. Fleximer is our proprietary, biodegradable, highly biocompatible and water-soluble polymer that is able to carry multiple drug molecules, and it is a key component of our Dolaflexin platform. Since 2012, we have entered into strategic research and development partnerships with Merck KGaA and Asana BioSciences, LLC (by assignment from Endo Pharmaceuticals Inc.) to enable development of certain ADC product candidates utilizing Fleximer. In establishing each of these partnerships, our primary objectives were to collaborate with leading biopharmaceutical companies to validate the potential of ADC product candidates utilizing Fleximer, gain meaningful near-term funding and drive significant long-term value. Under each of our partnerships, we own the rights to any improvements to our ADC platform. The details of our material existing strategic partnerships are as follows:

Merck KGaA strategic research and development partnership

In June 2014, we entered into a collaboration agreement with Merck KGaA for the development and commercialization of ADC product candidates utilizing Fleximer for up to six target antigens. We formed a strategic partnership with Merck KGaA because of their expertise in oncology drug development. Under this 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 Fleximer and our proprietary payloads 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 GLP toxicology studies and Phase 1 clinical studies 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. The most advanced product candidates in this partnership are in the lead optimization stage.

Through December 31, 2020, we have received an upfront payment of $12 million and milestone payments of $3 million under this 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 this agreement.

Unless earlier terminated, this 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 this agreement in its entirety or with respect to any target antigen for convenience upon 60 days' prior written notice. Each party may terminate this agreement in its entirety upon an uncured material breach of the agreement by the other party.

Asana Biosciences collaboration agreement

In March 2012, we entered to a collaboration agreement with Asana Biosciences, or Asana, formerly part of Endo Pharmaceuticals, to develop next-generation ADCs. Under this agreement, Asana paid us an upfront fee for the right to utilize our Fleximer technology to develop novel ADC candidates against a single cancer target. We are responsible for conducting research and creating ADCs that are conjugates of our diverse, highly potent cytotoxic payloads, our Fleximer polymer and custom linkers, and Asana's novel antibodies. In addition to providing novel antibodies, Asana is responsible for product development, manufacturing and commercialization of any Fleximer ADC products. Through December 31, 2020, we have received an upfront payment of $0.8 million and milestone payments of $3.3 million under this agreement.

Strategic partnerships 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 partnered 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 partnerships have facilitated the acceleration 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 XMT-1592 and granting Recepta the exclusive right to commercialize UpRi and XMT-1592 in Brazil. Under this agreement, 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 the worldwide development and commercialization of products under this agreement at our own expense in certain major markets, including at least one study site in our Phase 3 clinical studies in Brazil. 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 this agreement, 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. Through December 31, 2020, we have paid $1.9 million in milestone payments. 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. This agreement will remain in effect until otherwise terminated as set forth below. We may terminate this agreement 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 this agreement 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 agreement 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, to develop, manufacture and commercialize ADC targets using Synaffix's proprietary site-specific conjugation technology for a total of six targets, including XMT-1592. At contract inception we designated the first target and paid an upfront, non-refundable license fee of $0.8 million. We are required to make milestone payments to Synaffix of up to an aggregate of $24.8 million in development and regulatory milestones and up to $20.0 million in one-time sales milestones based on the achievement of annual sales objectives for the first target. In addition, upon designation of additional targets, we will be obligated to pay in the range of $44.8 million to $62.0 million for issuance, development, regulatory and one time sales milestones. Through December 31, 2020, we have paid $0.8 million in milestone payments. Pursuant to the terms this license agreement, upon commencement of commercial sales of a product, 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 agreement 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 agreement covering such product in such country. Upon the expiration of the agreement 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 agreement in its entirety or on a licensed product-by-licensed product basis at any time. Either party may terminate the agreement, 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 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 and Dolasynthen 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 XMT-1592 supply chain utilizes the same vendors that we could use for commercialization with the exception of components necessary for the Synaffix bioconjugation technology, where the identification of a commercially capable vendor is ongoing.

Government regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, clinical and preclinical studies, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including imposition of a clinical hold, refusal to approve marketing applications, withdrawal of an approval, import/export delays, issuance of warning letters and other types of

enforcement letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal investigations and penalties.

Review and approval in the United States

In the United States, our ADC product candidates are subject to regulation by the FDA as biologics. The FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHS Act, and associated implementing regulations. The failure to comply with the FDCA, the PHS Act and other applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of enforcement-related letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal investigations and penalties brought by the FDA and the Department of Justice, or DOJ, or other governmental entities.

A biologic may not be marketed in the United States until it has been approved by the FDA. The steps before a biological product may be approved for marketing in the United States generally include:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- the submission to the FDA of an Investigational New Drug, or IND application which must take effect before human clinical studies may begin in the United States;
- approval by an independent Institutional Review Board, or IRB representing each clinical site before each clinical study may be initiated;
- performance of adequate and well-controlled clinical studies to establish the safety and efficacy of the proposed product for each indication, conducted in accordance with good clinical practice, or GCP, requirements;
- preparation and submission to the FDA of a Biologics License Application, or BLA;
- FDA acceptance and review of the BLA, which might include an Advisory Committee review;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP requirements and 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 inspections or audits of the sponsor, clinical research organizations and clinical study sites to assure compliance with GCP requirements and the integrity of the clinical data;
- payment of user fees, if any, for FDA review of the BLA;
- FDA approval of the BLA; and
- compliance with any post-approval requirements, including a Risk Evaluation and Mitigation Strategy, or REMS, where applicable, and post-approval studies required by the FDA as a condition of approval.

The testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval is uncertain.

Preclinical studies

Preclinical studies include laboratory evaluation of the product candidate, as well as *in vitro* and animal studies to assess the potential safety and efficacy of the product candidate for use in humans. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND. Additional preclinical testing, such as toxicity studies, may continue after the IND is submitted.

Clinical studies

Clinical studies involve the administration of the product candidate to human subjects under the supervision of qualified investigators in accordance with GCP requirements. GCP requirements include, among other things, conducting the study in accordance with a written protocol, maintaining the integrity of study data, obtaining informed consent from study subjects and approval and ongoing review of the study by an IRB.

A protocol for each clinical study 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 a proposed clinical study or places the study on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin.

Clinical studies are typically conducted in three sequential phases prior to approval, which may overlap or be combined:

Phase 1: The product candidate is initially introduced into healthy human subjects or, in some cases, patients with the target disease (e.g., cancer) or condition. In Phase 1, the product candidate is typically tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

Phase 2: The product candidate is administered to a limited patient population to preliminarily evaluate the efficacy of the product for specific targeted diseases, to identify possible adverse effects and safety risks and to determine dosage tolerance and optimal dosage.

Phase 3: The product candidate is administered to an expanded patient population, generally at geographically dispersed clinical study sites, in well-controlled clinical studies to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Phase 4 clinical studies may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of products approved under accelerated approval regulations or when otherwise requested by the FDA in the form of post-market requirements or commitments.

Clinical studies at each phase of development may not be completed successfully within any specified period, or at all. Furthermore, the FDA, an IRB, the sponsor or the data monitoring committee, if applicable, may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Submission of a marketing application to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications.

BLA pathway

Our ADC product candidates must be licensed via FDA approval of a BLA under Section 351 of the PHS Act on the basis of a demonstration that the product is safe, pure and potent. Once a BLA has been accepted for filing, the FDA's goal is to review BLAs within ten months of the filing date for standard review or six months of the filing date for priority review. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving the BLA, the FDA will inspect the facilities at which the biological product is manufactured and will not approve the product unless the facility is compliant with cGMPs. Additionally, the FDA will typically inspect one or more clinical study sites for compliance with GCP and integrity of the data supporting safety and efficacy.

During the approval process, the FDA also will determine whether to require post-approval testing, including Phase 4 clinical studies and surveillance programs to monitor the effect of approved biologics after they are commercialized. In addition, the FDA will determine whether the biologic will require a REMS to ensure that the benefits of the product outweigh its risks, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

On the basis of the FDA's evaluation of the BLA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA will issue either an approval of the BLA or a Complete Response Letter, detailing the deficiencies in the submission and the additional testing or information required for reconsideration of the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical studies, be conducted to further assess the product's safety after approval, require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including 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-market studies or surveillance programs. After approval, many 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.

Fast track, breakthrough therapy and priority review designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

First, the FDA may designate a product for "fast track" review if it is intended for the treatment of a serious or life-threatening disease or condition and it demonstrates the potential to address unmet medical needs for such 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 BLA before the application is complete. This "rolling review" is available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees.

Second, the FDA may designate a product as a breakthrough therapy if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross-disciplinary project lead for the review team and taking other steps to design the clinical studies in an efficient manner.

Third, the FDA may designate a product for priority review if it treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. A priority designation is intended to direct overall attention and resources to the evaluation of such applications and shortens the FDA's goal for taking action on a marketing application from ten months to six months from the filing date.

Accelerated approval pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of

products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large studies to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical studies to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Post-approval requirements

Products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for certain supplemental applications.

In addition, manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, 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 revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks or imposition of distribution or other restrictions under a REMS program. Other potential consequences of regulatory non-compliance or post-market problems with a product include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning or other enforcement-related letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Such products may be promoted only for the approved indications and consistent with the provisions of the approved label. 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.

Biosimilars and exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, signed into law on March 23, 2010, or the Health Care Reform Act, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products shown to be

biosimilar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity requires a showing that the product is "highly similar" to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

A reference biologic is entitled to 12 years of exclusivity from the time of first licensure of the product. In addition, the first biological product submitted under the abbreviated approval pathway that is determined to be interchangeable with, not just biosimilar to, the reference product has exclusivity against other biologics submitting under the abbreviated approval pathway for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

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.

Pediatric studies and exclusivity

Under the Pediatric Research Equity Act of 2003, all applications for new active ingredients, new indications, new dosage forms, new dosing regimens or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred or inapplicable.

Under the Best Pharmaceuticals for Children Act, a product may be eligible for pediatric exclusivity, which, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued written request for such a study.

Orphan drug designation and exclusivity

Under the Orphan Drug Act, the FDA may designate a product, including a biological product, as an "orphan drug" if it is intended to treat a rare disease that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, a disease for which there is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales in the United States.

A product that receives the first FDA approval for a product for the indication for which it has orphan designation is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same product for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity.

Patent term restoration

A patent claiming a new product may be eligible for a limited patent term extension under the Hatch-Waxman Amendments, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of a BLA, plus the time between the submission date of a BLA 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. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. The United States Patent and Trademark Office, or USPTO, reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

FDA Approval or Clearance of Companion Diagnostics

As described above, we may seek approval or partner with a third-party to seek approval of a companion diagnostic for one or more of our ADC product candidates. 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 drugs and 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 products and in vitro companion diagnostic devices on issues related to co-development of the products.

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 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 a 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 applicant 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.

A clinical trial is typically required for a PMA application and, in a small percentage of cases, the FDA may require a clinical study in support of a 510(k) submission. A manufacturer that wishes to conduct a clinical study involving the device is subject to the FDA's investigational device exemption, or IDE, regulation. The IDE regulations distinguish between significant and non-significant risk device studies and the procedures for obtaining approval to begin the study differ accordingly. Also, some types of studies are exempt from the IDE regulations. A significant risk device presents a potential for serious risk to the health, safety, or welfare of a subject. Significant risk devices are devices that are substantially important in diagnosing, curing, mitigating, or treating disease or in preventing impairment to human health. Studies of devices that pose a significant risk require both FDA and an IRB approval prior to initiation of a clinical study. Many companion diagnostics are considered significant risk devices due to their role in diagnosing a disease or condition. Non-significant risk devices are devices that do not pose a significant risk to the human subjects. A non-significant risk device study requires only IRB approval prior to initiation of a clinical study.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA.

In the United States, device manufacturers are also subject to FDA's medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, and FDA's correction and removal reporting regulations, which require that manufacturers report to the FDA corrections or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the Quality System Regulation, which covers the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

Review and approval outside the United States

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions governing, among other things, clinical studies, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical studies or

marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union and other geographies, the approval process varies between countries and jurisdictions and can involve additional product 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.

Certain countries outside of the United States have a process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical studies. In the European Union, for example, a CTA must be submitted for each clinical trial to the national health authority and an independent ethics committee in each country in which the company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, the clinical trial may proceed. In all cases, the clinical trials must be conducted in accordance with GCPs and other applicable regulatory requirements and ethical principles.

To obtain regulatory approval of an investigational product under European Union regulatory systems, we must submit a marketing authorization application under either a centralized or decentralized procedure. The centralized procedure is compulsory for medicinal products produced by biotechnology. The application used to file the BLA in the United States is similar to that required in the European Union, with the exception of, among other things, region-specific document requirements.

The European Union also provides opportunities for market exclusivity. For example, upon receiving marketing authorization, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic or biosimilar application. There is no guarantee that a product will be considered by the European Union's regulatory authorities to be an innovative medicinal product, and products may not qualify for data exclusivity. Products receiving orphan designation in the European Union can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the European Union for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The collection, use, disclosure, transfer or other processing of personal data regarding individuals in the European Economic Area, including personal health data, is subject to the Regulation (EU) 2016/679 (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, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches and taking certain measures when engaging third-party data processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Economic Area, 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 will be 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.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Pharmaceutical coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of pharmaceutical products depend in significant part on the availability and adequacy of third-party payor reimbursement. Third-party payors include government health administrative authorities, including authorities at the U.S. federal and state level, managed care providers, private health insurers and other organizations. Third-party payors are increasingly challenging the prices charged for, examining the medical necessity of and assessing the cost-effectiveness of medical products and services.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the

product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs and biologics have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies, or so called health technology assessments, to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company.

The downward pressure on healthcare costs in general, particularly prescription drugs and biologics, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for products may not allow favorable reimbursement and pricing arrangements.

Healthcare law and regulation

Within the United States, the activities of pharmaceutical companies are subject to extensive regulation and our activities could possibly be subject to challenge as a result. Laws and regulations that may affect our ability to operate (including certain laws that will apply if and when we have a product approved for marketing) include:

- 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 soliciting, offering, 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 anti-kickback prohibition known as Eliminating Kickbacks in Recovery Act or EKRA, 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 HIPAA, which, in addition to privacy protections applicable to healthcare providers and other entities (see "*Government regulation – Data privacy and security*"), 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 FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;

- the 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 ; and

- state law analogues 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, and state and local 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.

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and reputational harm. Additionally, we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

Healthcare reform

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

In the United States, there have been and continue to be a number of significant legislative initiatives to contain healthcare costs. Federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, which include initiatives to reduce the cost of healthcare. For example, the Health Care Reform Act expanded health care coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and included changes to the coverage and reimbursement of drug products under government healthcare programs. Under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the Health Care Reform Act. For example, tax reform legislation was enacted at the end of 2017 that eliminated the tax penalty established under Health Care Reform Act for individuals who do not maintain mandated health insurance coverage beginning in 2019. The Health Care Reform Act has also been subject to judicial challenge. The case *Texas v. Azar*, which challenges the constitutionality of the Health Care Reform Act, including provisions that are unrelated to healthcare reform but were enacted as part of the Health Care Reform Act, was argued before the Supreme Court in November 2020. Pending resolution of the litigation, all of the Health Care Reform Act but the individual mandate to buy health insurance remains in effect.

Beyond the Health Care Reform Act, there have been ongoing health care reform efforts, including a number of recent actions. Some recent healthcare reform efforts have sought to address certain issues related to the COVID-19 pandemic, including an expansion of telehealth coverage under Medicare and accelerated or advanced Medicare payments to healthcare providers. Other reform efforts affect pricing or payment for drug products. For example, the Medicaid Drug Rebate Program has been subject to statutory and regulatory changes and the discount that manufacturers of Medicare Part D brand name drugs must provide to Medicare Part D beneficiaries during the coverage gap from 50% to 70%. A number of regulations were issued in late 2020 and early 2021. For example, effective January, 2022, revisions to the federal antikickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to PBMs and health plans. Some of these changes have been and may continue to be subject to legal challenge. For example, courts temporarily enjoined a new "most favored nation" payment model for select drugs covered under Medicare Part B that was to take effect on January 1, 2021 and would limit payment based on international drug price. The nature and scope of health care reform in the wake of the transition from the Trump administration to the Biden administration remains uncertain. President Biden has temporarily halted implementation of new rules issued immediately prior to the transition that had not yet taken effect (which include a number of health care reforms) to allow for review by the new administration. More generally, President Biden supported reforms to lower drug prices during his campaign for the presidency.

There have also been efforts by federal and state government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There

have also been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices.

Adoption of new healthcare reform legislation at the federal or state level could affect demand for, or pricing of, our product candidates if approved for sale. We cannot predict, however, the ultimate content, timing or effect of any healthcare reform legislation or action, or its impact on us, and healthcare reform could increase compliance costs and may adversely affect our future business and financial results.

Data privacy and security

We may be subject to privacy and security laws in the various jurisdictions in which we operate, obtain or store personally identifiable information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business.

Within the United States, our operations may be affected by the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, collectively, 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. Although we believe that we currently are neither a "covered entity" nor a "business associate" under the legislation, HIPAA may affect our interactions with customers who are covered entities or their business associates because HIPAA affects the ability of these entities to disclose patient health information to us. Various states also have laws that regulate the privacy and security of patient information and so may affect our business operations. For example, we are subject to the California Consumer Privacy Act, or CCPA, that became effective on January 1, 2020. The CCPA gives California consumers (defined to include all California residents) certain rights, including the right to ask companies to disclose the types of personal information collected, specific pieces of information collected by a company, the categories of sources from which such information was collected, the business purpose for collecting or selling the consumer's personal information, and the categories of third parties with whom a company shares personal information. The CCPA also imposes several obligations on companies to provide notice to California consumers regarding a company's data processing activities. Additionally, the CCPA gives California consumers the right to ask companies to delete a consumer's personal information and it places limitations on a company's ability to sell personal information, including providing consumers a right to opt out of sales of their personal information.

Outside the United States, other data privacy and security regulations may apply. For example, the processing of personal data in the European Economic Area, or the EEA, is subject to the General Data Protection Regulation, or the GDPR, which took effect in May 2018. The GDPR increases obligations with respect to clinical trials conducted in the EEA, such as in relation to the provision of fair processing notices, exercising data subject rights and reporting certain data breaches to regulators and affected individuals, as well as how we document our relationships with third parties that process GDPR-covered personal data on our behalf. The GDPR also increases the scrutiny applied to transfers of personal data from the EEA (including from clinical trial sites in the EEA) to countries that are considered by the European Commission to lack an adequate level of data protection, such as the United States. Adoption of new healthcare reform legislation at the federal or state level could affect demand for, or pricing of, our product candidates if approved for sale. We cannot predict, however, the ultimate content, timing or effect of any healthcare reform legislation or action, or its impact on us, and healthcare reform could increase compliance costs and may adversely affect our future business and financial results.

Compliance with data privacy and security regulation can require allocation of resources as well as changes in operations. Any failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages by data subjects, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

Additional regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservation and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biologic, chemical and radioactive substances used in, and wastes generated by, operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. Equivalent laws have been adopted in foreign countries that impose similar obligations.

Intellectual property

We actively seek to protect the proprietary technology that we consider important to our business, including pursuing patents that cover our ADC platform, proprietary composition 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.

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 studies 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 January 31, 2021, we owned, in all of our patent portfolios, 21 issued U.S. patents, 12 pending non-provisional U.S. patent applications (including one allowed U.S. patent application), seven pending provisional U.S. patent applications, 95 issued foreign patents, five pending PCT patent applications and 102 pending foreign patent applications (including two allowed foreign patent applications) in a number of foreign jurisdictions, including, but being not limited to, Argentina, Australia, Brazil, Canada, China, Europe, Eurasia, Gulf Cooperation Council, Hong Kong, Israel, India, Indonesia, Iran, Japan, Mexico, Macau, Pakistan, New Zealand, Russia, South Korea, South Africa, and Taiwan. 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 additional nine issued U.S. patents are projected to expire between 2030 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 is projected to expire between 2037 and 2042, 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. These in licensed issued U.S. and foreign patents are projected to expire in 2029, 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 platform, our ADC product candidates and components thereof and companion diagnostics are summarized below. Some of these portfolios are in very early stages and prosecution has yet to commence on most 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 compounds (and by extension our proprietary DolaLock feature) and conjugates thereof (e.g., to Fleximer and/or an antibody or antibody fragment). As of January 31, 2021, we owned 10 issued U.S. patents, one pending non-provisional U.S. patent application, 48 issued foreign patents, and three 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 January 31, 2021, we owned two issued U.S. patents, and one pending non-provisional U.S. patent application, 33 issued foreign patent, and 12 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, Russia, 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, 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 our NaPi2b ADC product candidate, UpRi, 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, making these novel conjugates, methods of administration and companion diagnostics. As of January 31, 2021, we owned four pending non-provisional U.S. patent applications (including one allowed U.S. patent application), 37 pending foreign patent applications, and one pending PCT application directed to the composition of matter for UpRi, methods of using and making same, companion diagnostics for UpRi ADC and UpRi dosing regimens. We also intend to enter the national/regional phase of the pending PCT patent application in foreign jurisdictions, including, but not limited to, Australia, Brazil, Canada, China, Eurasia, Europe, Hong Kong, Israel, India, Japan, South Korea, Macau, Mexico and South Africa. Any U.S. or foreign patent issuing from the pending applications covering UpRi is projected to expire in 2037, and any U.S. or foreign patent issuing from the pending applications covering UpRi companion 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.

In addition, 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 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.

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 January 31, 2021, we owned one pending non-provisional U.S. patent application, 16 pending foreign patent applications, and one pending PCT patent application. We intend to enter the national/regional phase of the PCT 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 novel Dolasynthen platform is projected to expire between 2037 and 2039, excluding any additional term for patent term adjustments or patent term extensions.

XMT-1592 ADC

The intellectual property portfolio for our site-specific NaPi2b ADC product candidate, XMT-1592, is directed to compositions of matter for our novel ADC based on exclusively in licensed NaPi2b antibody and our Dolasynthen platform, as well as methods of using, making these novel conjugates and administration of these novel conjugates. As of January 31, 2021, we owned one pending non-provisional U.S. patent application, one pending provisional application, three pending foreign patent applications and one pending PCT patent application. We intend to enter the national/regional phase of the PCT patent applications in a number of foreign jurisdictions, including, but mot 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 XMT-1592 is projected to expire in 2041, excluding any additional term for patent term adjustments or patent term extensions.

XMT-1660 ADC

The intellectual property portfolio for our site-specific B7-H4 ADC product candidate, XMT-1660, 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 January 31, 2021, we owned one pending provisional application, Any U.S. or foreign patent issuing from the pending applications covering XMT-1660 is projected to expire in 2042, 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, as well as methods of using and methods of making these novel payloads. As of January 31, 2021, we owned one pending non-provisional U.S. patent application, five pending provisional U.S. patent applications, two pending foreign patent applications and two pending PCT patent applications related to the Immunosynthen platform. We intend to enter the national/regional phase of the PCT patent applications in a number of foreign jurisdictions, including, but mot 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 is projected to expire between 2040 and 2041, 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 agreements with our collaborators and scientific advisors and non-competition, non-solicitation, confidentiality and invention assignment agreements with our employees and consultants. 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. With respect to the building of our proprietary compound library, we consider trade secrets and know-how to be our primary intellectual property. Trade secrets and know-how can be difficult to protect. In particular, we anticipate that with respect to this technology platform, these 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 and the new platform 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, ImmunoGen, Gilead (Immunomedics), Pfizer and SeaGen. These companies or their partners, including Astellas, AstraZeneca, AbbVie, Genentech/Roche and Takeda, may develop product candidates which compete in the same indications as our current and future product candidates. We expect to compete on improved efficacy, safety and tolerability compared to other product candidates and if our products are not demonstrably superior in these respects compared to other approved therapeutics, we may not be able to compete effectively.

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 study sites and patient registration for clinical studies 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 January 31, 2021, we had 110 full time employees, including 76 with M.D., Ph.D. or other advanced degrees. Of these full time employees, 87 are engaged in research and development and 23 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. 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.

Facilities

Our corporate headquarters are located in Cambridge, Massachusetts. We occupy approximately 35,000 square feet of office and laboratory space that we lease in the multi-tenant building in which our corporate headquarters are located. 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

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. 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. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

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 partner's discovery programs and our product candidates are in early stages of preclinical or clinical development, there is a relatively higher risk of failure and we or our partners may never succeed in generating revenue from such discovery programs or product candidates.

Our early encouraging clinical results for UpRi, our lead product candidate, our early encouraging preclinical results for XMT-1592 and the early results of any other current or future product candidates, are not necessarily predictive of the results of our ongoing or future discovery programs or clinical studies. 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 studies. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical studies after achieving positive results in early-stage development, including early-stage clinical studies, 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 studies were underway or safety or efficacy observations made in preclinical studies and clinical studies, including previously unreported adverse events.

Any clinical studies 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 products in our pipeline. If the results of our ongoing or future clinical studies are inconclusive with respect to the efficacy of our product candidates or 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 or delayed in obtaining marketing approval for our product candidates. There can be significant variability in safety or efficacy results between different clinical studies of the same product candidate due to numerous factors, including changes in study procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical study protocols and the rate of dropout among clinical study 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 studies nonetheless failed to obtain FDA approval.

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 studies 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 (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.

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

From time to time, we may publish interim, "top-line" or preliminary data from our clinical studies. Positive preliminary data may not be predictive of such trial's subsequent or overall results. Interim data from clinical trials that we may complete 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. 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 data we previously published. As a result, interim and preliminary 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 currently have only two ADC product candidates, UpRi and XMT-1592 in clinical studies. 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 and XMT-1592 are currently our only clinical-stage development product candidates. While we have certain other preclinical programs in development and we intend to develop other product candidates, including XMT-1660 and XMT-2056, it will take additional investment and time 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 and XMT-1592. If either 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 or XMT-1592, or if UpRi or XMT-1592 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 studies 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 studies, including our ongoing Phase 1b clinical study and anticipated additional clinical studies for UpRi, our lead product candidate, and our ongoing Phase 1 does escalation study of XMT-1592, will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing, and other events may cause us to temporarily or permanently cease a clinical study. Events that may prevent successful or timely commencement, enrollment or completion of clinical development include, among others:

- delays by us in reaching a consensus with regulatory agencies on study design;
- delays in reaching, or failing to reach, agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical study sites;
- difficulties in obtaining required Institutional Review Board, or IRB, or Ethics Committee, or EC, approval at each clinical study site;
- challenges in recruiting and enrolling suitable patients to participate in clinical studies that meet the criteria of the protocol for the clinical study;
- imposition of a clinical hold by regulatory agencies or IRBs or ECs for any reason, including safety concerns or after an inspection of clinical operations or study sites;
- failure by CROs, other third parties or us to adhere to clinical study 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 studies, 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 study or not returning for post-treatment follow-up, including as a result of the ongoing COVID-19 pandemic;
- clinical study sites or patients dropping out of a study;
- safety issues, including occurrence of serious adverse events, or SAEs, in clinical studies that are associated with the product candidates that are viewed to outweigh their potential benefits or unforeseen safety issues in our ongoing preclinical studies;
- changes in regulatory requirements or guidance that require amending or submitting new clinical protocols; or
- lack of adequate funding to continue the clinical study.

Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to complete a clinical study. If we or our partners are not able to successfully complete clinical studies, we or they will not be able to obtain regulatory approval and will not be able to commercialize our product candidates or our partners' product candidates based on our technology.

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

Clinical studies 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 study protocol, including eligibility criteria for the study;
- the number of clinical study sites and the proximity of patients to those sites;
- standard of care in the diseases under investigation;
- the commitment of clinical investigators to identify eligible patients;
- competing studies or trials; and
- clinicians' and patients' perceptions as to 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.

Challenges in recruiting and enrolling suitable patients to participate in clinical studies that meet the criteria of the protocol for clinical studies could increase costs and result in delays to our current development plan for UpRi, our lead product candidate, XMT-1592 or any other current or future product candidate.

We may seek a Breakthrough Therapy Designation or Fast Track Designation by the FDA for any of our ADC product candidates, and we may be unsuccessful. If we are successful, the designation may not actually lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that any ADC product candidate would receive marketing approval.

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. We may seek a Breakthrough Therapy Designation for UpRi, or we may seek Breakthrough Therapy Designation or Fast Track Designation for XMT-1592 or any of our product candidates. Fast Track Designation may be available if a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment

effects observed early in clinical development. Drugs that receive Breakthrough Therapy Designation or Fast Track Designation by the FDA may also be eligible for accelerated approval and/or priority review if they satisfy the criteria for those programs.

The FDA has broad discretion whether or not to grant Breakthrough Therapy Designation or Fast Track Designation. Even if we receive Breakthrough Therapy Designation or Fast Track Designation for a product candidate, such designation may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if any of our product candidates receives Breakthrough Therapy Designation or Fast Track Designation, the FDA may later decide that the drugs no longer meet the conditions for qualification and rescind the designation.

We may not be able to obtain orphan drug designation for our ADC product candidates, and even if we do, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

We may seek orphan drug designation status for one of our current or future product candidates, and we may be unsuccessful. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the European Medicines Agency or the FDA from approving another marketing application for the same drug and indication for a set time period, except in limited circumstances. Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the drug from competition because different drugs can be approved for the same condition, or the drug may be used off-label. Even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the other drug is clinically superior. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our current or future product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

Clinical development, regulatory review and approval by the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If we or our partners are ultimately unable to obtain regulatory approval for our ADC product candidates, our business will be substantially harmed.

The preclinical studies and clinical studies of our product candidates are subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any such product candidate.

These government regulations relate to, among other things, development, clinical studies, manufacturing and commercialization. In order to obtain regulatory approval for the commercial sale of any product candidates, we or our partners must demonstrate through extensive preclinical studies and clinical studies that the product candidate is safe and effective for use in each target indication.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical studies and depends upon numerous factors. Of the large number of drugs in development in the United States, only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and preclinical studies and clinical studies, we cannot be assured that any of our product candidates will be successfully developed or commercialized.

In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary among jurisdictions, which may cause delays in the approval of or the decision not to approve an application. Regulatory approval has not been obtained for any product candidate based on our technologies, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. In addition, we may gain regulatory approval for UpRi, our lead product candidate, or XMT-1592, or any other current or future product candidates in some but not all of the territories in

which we seek approval or some but not all of the target indications, resulting in limited commercial opportunity for the approved product candidates.

Applications for our or our partners' product candidates could be delayed or could fail to receive regulatory approval for many reasons, including, but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the number, design or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical studies;
- the data collected from clinical studies of our product candidates may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for marketing approval or may otherwise not be sufficient to support the submission of a new drug application or biologics license application, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA may not accept data generated at our preclinical studies and clinical study sites;
- the FDA may require us to conduct additional preclinical studies and clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- we or any third-party service providers may be unable to demonstrate compliance with current Good Manufacturing Practices, or cGMPs, to the satisfaction of the FDA or comparable foreign regulatory authorities, which could result in delays in or prevent regulatory approval or require us to withdraw or recall products and interrupt commercial supply of our products; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Any of these factors, many of which are beyond our control, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

We may conduct clinical trials for ADC product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.

We plan to conduct clinical trials outside 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 ethical principles. 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 trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly, time-consuming and could delay or permanently halt our development of the applicable product candidates.

Accelerated approval by the FDA, even if granted for UpRi, XMT-1592- or any other future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek approval of UpRi, XMT-1592 and 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. As a condition of approval, the FDA requires that a sponsor of a product receiving accelerated approval perform a post-marketing confirmatory clinical trial or trials. These confirmatory trials must be completed with due diligence. 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. 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. Accelerated approval may also be withdrawn if, among other things, a confirmatory trial required to verify the predicted clinical benefit of the product fails to verify such benefit or if such trial is not conducted with due diligence.

If we fail to obtain regulatory approval in jurisdictions outside the United States, we will not be able to market our products in those jurisdictions.

We intend to market our product candidates, including UpRi, our lead product candidate, and XMT-1592, each, if approved, in international markets either directly or through partnerships. Such marketing will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary from country to country and may require additional testing that we are not required to perform to obtain regulatory approval in the United States. Moreover, the time required to obtain approval in countries outside the United States may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, a drug must be approved for reimbursement before it can be approved for sale in that country. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We or our partners may not obtain foreign regulatory approvals on a timely basis, if at all. We or our partners may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we or any existing or future partner are unable to obtain regulatory approval for UpRi, XMT-1592, or any of our other current or future product candidates in one or more significant foreign jurisdictions, then the commercial opportunity for such product candidate and our financial condition will be adversely affected.

Even if we receive regulatory approval for our ADC product candidates, such products will be subject to ongoing regulatory review, which may result in significant additional expense. Additionally, our ADC product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor safety and efficacy. In addition, if the FDA or any other governing regulatory body approves any of our product candidates, the manufacturing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP, for any clinical studies that we conduct post-approval.

Later discovery of previously unknown problems with an approved drug, including adverse events of unanticipated severity or frequency, or with manufacturing operations or processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical studies;
- refusal by the FDA or any other governing regulatory body to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;

- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The policies of the FDA or any other governing regulatory body may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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

Undesirable side effects caused by our product candidates or ADCs being developed or commercialized by our partners or competitors could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label or the denial of regulatory approval by the FDA or other regulatory authorities and potential product liability claims. Further, clinical studies 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 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.

If we or others identify undesirable side effects caused by our product candidates or those of our competitors either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including:

- our clinical studies may be put on hold;
- 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.

If we or our third-party collaborators are unable to successfully develop and commercialize any required companion diagnostics for our product candidates or 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 ADC product candidates.

If a companion diagnostic is required for the label for UpRi, our lead product candidate, XMT-1592, or any of our other current or future product candidates, therefore conditioning our ability to market such product candidates on the commercial availability of an approved companion diagnostic, we may seek approval for our validated assay as a companion diagnostic or we may contract with third parties to create and obtain approval for a companion diagnostic. To be successful in developing and commercializing such a companion diagnostic, we need to address a number of scientific, technical and logistical challenges.

We have little experience in the development and commercialization of diagnostics and may not be successful in developing and commercializing appropriate diagnostics to pair with UpRi, XMT-1592, or any of our other current or future product candidates. Companion 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 and commercializing diagnostics, we may 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 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 diagnostics could delay or prevent approval 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 diagnostics for our product candidates, or experience delays in doing so:

- the development of UpRi, XMT-1592, and our other current or future product candidates, may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;
- our product candidates may not receive marketing approval if safe and effective use of a therapeutic product candidate depends on the availability of an *in vitro* diagnostic; 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.

As a result, our business would be harmed, possibly materially.

In addition, third-party collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion 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 that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of 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.

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

Our and our partners' research programs to identify new product candidates will require substantial technical, financial and human resources, and we or our partners may be unsuccessful in our or their efforts to identify new product candidates. If we or our partners 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 partners' 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 the foreseeable future. We may never achieve or sustain profitability.

We have incurred net losses since our inception. Our net loss was $88.0 million for the year ended December 31, 2020. As of December 31, 2020, we had an accumulated deficit of $280.4 million. We do not know when or whether we will become profitable. To date, we have not commercialized any products and therefore have never generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. 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.

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 through the sale of equity securities, the receipt of funds through strategic partnerships with third parties and our credit facility. The amount of our future net losses will depend, in

part, on the rate of our future expenditures. We have not completed pivotal clinical studies for any product candidate and only have one product candidate in a clinical study. 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 increasing net losses for at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- conduct clinical development of upifitamab rilsodotin (UpRi, XMT-1536), our lead product candidate, XMT-1592, and any other current or future product candidates;
- seek regulatory approval for UpRi, XMT-1592, and any other current or future product candidates, if our development efforts are successful;
- add personnel to support our product development efforts;
- continue our research and development efforts for new product opportunities; and
- continue to operate as a public company.

If we are required by the United States Food and Drug Administration, or FDA, or any equivalent foreign regulatory authority to perform clinical studies or preclinical studies in addition to those we currently expect to conduct, or if there are any delays in completing the clinical studies of UpRi, XMT-1592, 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 partnerships 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 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 and cash equivalents were $255.1 million as of December 31, 2020. 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, our lead product candidate, XMT-1592, and any other current or future product candidates. These expenditures may include costs associated with research and development, conducting preclinical studies and clinical studies, 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 studies 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 studies for UpRi, XMT-1592 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-1592 and any other current or future product candidates and conducting preclinical studies and clinical studies;
- the timing of, and the costs involved in, obtaining regulatory approvals for UpRi, XMT-1592 and any other current or future product candidates if preclinical studies and clinical studies are successful;
- the cost of manufacturing UpRi, XMT-1592 and any other current or future product candidates for clinical studies in preparation for regulatory approval and in preparation for commercialization;

- the cost of commercialization activities for UpRi, XMT-1592 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 partnerships, 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 such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any, or products developed by our partners.

Based on our current operating plan, we believe that our currently available funds will be sufficient to fund our operations through at least the next twelve months following the filing of our Annual Report on Form 10-K. Our operating plan, however, 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. 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 studies 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. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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 on unfavorable terms to us.

We may seek additional capital through a variety of means, including through private and public 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 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 partnerships 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, our lead product candidate, XMT-1592, 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 have a credit facility that requires us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility.

On August 28, 2020, we entered into a second amendment to our existing loan and security agreement, or the Credit Facility, with Silicon Valley Bank, or SVB, pursuant to which we may borrow, at our option, up to $25.0 million through April 30, 2022. We also may be able to borrow, at our option, an additional $5.0 million, if we reach certain development milestone events. The Credit Facility is secured by substantially all of our assets, except for our intellectual property, which is subject to a negative pledge, and certain other customary exclusions, which ensures that SVB's rights to repayment would be senior to the rights of the holders of our common stock in the event of liquidation.

The Credit Facility includes customary covenants including covenants requiring us to maintain our corporate existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. Additionally, we are restricted in our 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. Upon the occurrence of an event of default, which includes our failure to satisfy our payment obligations under the Credit Facility, the breach of certain of the covenants under the Credit Facility, or the occurrence of a material adverse change in our business, SVB is entitled to increase the applicable interest rate, accelerate amounts due under the Credit Facility and dispose the collateral as permitted under applicable law. Any declaration by SVB of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

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 partnering, 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 manufacturing and supply partners, 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 study 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 cGMP. 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 studies 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 partner;
- 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 studies of our product candidates and commercialize any approved product candidates, we, or our manufacturing partners, will need to manufacture them in large quantities. We, or our manufacturing partners, 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 manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical studies of that product candidates 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 manufactures to engage for scale-up to commercial supply of our product candidates, including UpRi, our lead product candidate and XMT-1592, and we have begun transfer and scale-up of 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 studies for UpRi and XMT-1592 and if such third parties do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for UpRi, XMT-1592, or any other current or future ADC product candidates.

We designed the Phase 1 clinical studies for UpRi, our lead product candidate, and XMT-1592, and we intend to design any future clinical studies for any future unpartnered product candidates that we may develop if preclinical studies are successful. However, we rely on CROs and other third parties to assist in managing, monitoring and otherwise carrying out many of these studies. As a result, we have less direct control over the conduct, timing and completion of these clinical studies and the management of data developed through clinical studies than would be the case if we were relying entirely upon our own staff. These CROs 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 studies, resulting in the preclinical studies or clinical studies 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 studies to assure that the data and

results are credible and accurate and that the rights, integrity and confidentiality of study participants are protected. Although we rely, and intend to continue to rely, on third parties to conduct our clinical studies, they are not our employees, and we are responsible for ensuring that each of these clinical studies 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.

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 study protocols or to regulatory requirements, or if they otherwise fail to comply with clinical study protocols or meet expected deadlines, the clinical studies of our product candidates may not meet regulatory requirements. The FDA enforces GCP regulations through periodic inspections of clinical study sponsors, principal investigators and study sites. If we or our CROs fail to comply with applicable GCPs or other regulatory requirements, the clinical data generated in our clinical studies 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 studies 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 partnerships with other companies to assist in the research, development and commercialization of our ADC platforms and ADC product candidates. If our existing partners do not perform as expected, this may negatively affect our ability to commercialize our ADC product candidates, generate revenues through technology licensing, or otherwise negatively affect our business.

We have established strategic partnerships and intend to continue to establish strategic partnerships with third parties to research, develop and commercialize our platforms and existing and future product candidates. We entered into a collaboration agreement with Merck KGaA for the development and commercialization of other product candidates. For certain of these programs, we will depend on our partners to design and conduct their clinical studies. As a result, we may not be able to conduct these programs in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations. In addition, if any of these partners 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 partners 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 partners may devote to products utilizing or incorporating our technology. Moreover, our relationships with our partners 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 partners 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 partners 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 partners terminate or breach our agreements with them, or otherwise fail to complete their obligations in a timely manner, 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 partners do not prioritize and commit sufficient resources to programs associated with our product candidates or collaboration product candidates, we or our partners may be unable to commercialize these product candidates, which would limit our ability to generate revenue and become profitable.

Our partners may separately pursue competing products, therapeutic approaches or technologies to develop treatments for the diseases targeted by us or our partners. Competing products, either developed by the partners or to which the partners have rights, may result in the withdrawal of partner support for our product candidates. Even if our partners continue their contributions to the strategic partnerships, they may nevertheless determine not to actively pursue the development or commercialization of any resulting products. Additionally, if our partners 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 partners for a substantial portion of our revenue. The loss of any one of these partners could result in a material decline in our revenue.

We have strategic partnerships with a limited number of companies. To date, a substantial portion of our revenue has resulted from payments made under agreements with our strategic partners, and we expect that a portion of our revenue will continue to come from strategic partnerships. The loss of any of our partners, or the failure of our partners 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 partnerships 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 not be successful in establishing and maintaining additional strategic partnerships, which could adversely affect our ability to develop and commercialize products, negatively impacting our operating results.

We continue to strategically evaluate our partnerships and, as appropriate, we expect to enter into additional strategic partnerships in the future, including potentially with major biotechnology or biopharmaceutical companies. We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships 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 partnership agreements related to our product candidates could delay the development and commercialization of such candidates and reduce their competitiveness even if they reach the market. If we are not able to generate revenue under our strategic partnerships 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 partnerships related to our unpartnered product candidates, 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 were not successful in seeking additional financing, hiring additional employees or developing additional expertise, 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 unpartnered product candidate.

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, our lead product candidate, XMT-1592, 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 studies;
- 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 that are in the same class of drugs or have a similar mechanism of action. 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 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 epithelial ovarian cancer and non-squamous NSCLC with NaPi2b expression are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our drug candidates, are based on estimates. The total addressable market opportunity for UpRi or XMT-1592 for the treatment of epithelial ovarian cancer and non-squamous NSCLC with NaPi2b expression will ultimately depend upon, among other things, the diagnosis criteria included in the final label for UpRi or XMT-1592, if our drug candidates are approved for sale for these indications, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients who can be treated with our drug candidates may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

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.

In the future, we expect to build a focused sales and marketing infrastructure to market UpRi, our lead product candidate, XMT-1592, and any other current or future product candidates in the United States and certain foreign jurisdictions, if and when they are approved. 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, our lead product candidate, XMT-1592, 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 study or other studies 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 partners. 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 partners and the potential profitability of our product candidates in those countries would be negatively affected.

The impact of health care reform legislation and other changes in the health care industry and in health care spending on us is currently unknown and may adversely affect our business model.

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

Within the United States, there have been ongoing government efforts at the federal and state levels to reform the provision or control the cost of health care. There have been a number of legislative and regulatory changes to the healthcare system, such as the enactment and subsequent modification of the Health Care Reform Act, that could affect our future results of operations or the commercial success of our products, if approved. See "Business-Government regulation - Healthcare reform". We continue to evaluate the effect that healthcare reform efforts may have on our business, but expect that healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates, if approved. Healthcare reform efforts to contain or reduce costs of health care may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

We cannot predict the ultimate content, timing or effect of any such reforms.

In addition, other legislative changes have been proposed and adopted that affect health care spending. The Budget Control Act of 2011, includes provisions to reduce the federal deficit. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare payments to providers which began in April 2013, and will remain in effect through 2030 (except May 1, 2020 to March 31, 2021) unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on our results of operations.

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

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 or noncompetitive. 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 Astellas, AstraZeneca, Daiichi Sankyo, ImmunoGen, Immunomedics, Pfizer and SeaGen. These companies or their partners, including AbbVie, Genentech and Takeda, may develop product candidates which compete in the same indications as our current and future product candidates. We expect to compete on improved efficacy, safety and tolerability compared to other product candidates and if our products are not demonstrably superior in these respects compared to other approved therapeutics, we may not be able to compete effectively.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical studies, 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. Smaller or early-stage companies may also prove to be

significant competitors, particularly through strategic partnerships 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 Health Care Reform Act establishes a pathway for the FDA approval of follow-on biologics and provides twelve years 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 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 partnerships 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 and XMT-1592. 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, which could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. 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, only 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, our lead product candidate, XMT-1592, 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, our lead product candidate, XMT-1592, 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 partnership 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 license with Recepta Biopharma S.A., or Recepta, for intellectual property covering the NaPi2b antibody in UpRi and XMT-1592, 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 agreement with Recepta, the license for the rights covering the NaPi2b antibody in UpRi and XMT-1592, 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 partners; 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 partners 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 cover 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 partners. 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 partners, 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 partners, 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 our business and industry

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our ADC product candidates, conduct our clinical studies 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 studies 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 expect that we will need to manage additional relationships with various strategic partners, 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 studies 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.

As a pharmaceutical manufacturer, 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 or EKRA, 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 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 FDCA, 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, 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.

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 health care 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 health care 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 studies, 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. 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.

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 allegedly causes injury or is found to be otherwise unsuitable during product 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 study participants;
- costs to defend the related litigations;
- a diversion of management's time and our resources;
- substantial monetary awards to study 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 studies 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 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.

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 partners, 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 partners, 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 study 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. 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 studies of our current or future product candidates, including UpRi and XMT-1592;
- results of clinical studies 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 partnership 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;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us (including pursuant to the pre-funded warrants described below), 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.

Our principal stockholders and management own a significant percentage of our stock and are able to exercise significant influence over matters subject to stockholder approval.

As of December 31, 2020, our executive officers, directors and stockholders who own more than 5% of our outstanding common stock, together with their respective affiliates, beneficially owned a significant amount of our common stock, including shares subject to outstanding options and warrants that are exercisable within 60 days after such date. Accordingly, these stockholders are able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management or board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

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 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, 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, 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 and 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 and amended and restated by-laws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

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, 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, 2020, 2019 and 2018, the Company recorded no income tax benefit for the net operating losses incurred in each year, due to the uncertainty of realizing a benefit from those items. The Company has incurred net operating losses (NOLs) since its inception. As of December 31, 2020, the Company had federal NOLs of approximately $250.4 million and state NOLs of approximately $184.8 million. Of the $250.4 million of federal NOLs, $34.2 million expire at various dates through 2037. The remaining $216.2 million of federal NOLs do not expire. The state NOLs will expire at various dates through 2040. As of December 31, 2020, the Company had Federal and State research and development tax credit carryforwards of approximately $4.6 million and $1.5 million, respectively, which expire at various dates through 2040. Under the 2017 Tax Act, federal NOLs incurred in 2019 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 2017 Tax Act. In

addition, under Section 382 of the Internal Revenue 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. The Company has 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 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 the foreseeable future; thus, we do not know whether or 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.

Our amended and restated certificate of incorporation 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 provides that, subject to limited exceptions, the state or federal courts within the State of Delaware will be exclusive forums 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 or our amended and restated by-laws or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. 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 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.

General risk factors

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

In March 2020, the World Health Organization, or the WHO, declared the COVID-19 outbreak a pandemic and recommended containment and mitigation measures worldwide. On March 13, 2020, the U.S. President announced a National Emergency relating to the disease. The widespread infection 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 the Company's 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 studies 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 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, shipping of investigation 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.

- We have requested that most of our personnel work remotely, restricted on-site staff to only those personnel and contractors who must perform essential activities that must be completed on-site and limited the number of staff in any given research and development laboratory. 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 trial 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 Investigational New Drug (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 coronavirus pandemic. The U.S. Food and Drug Administration, or 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 and study 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 coronavirus pandemic and could result in delays to our clinical trials.

- The trading prices for our common shares and other biopharmaceutical companies have been highly volatile as a result of the coronavirus pandemic. As a result, we may face difficulties raising capital through sales of our common shares 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 shares.

The COVID-19 pandemic continues to evolve rapidly. 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 ultimate geographic spread of the disease, 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 the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy.

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 accidents or incidents that result 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 have significant negative consequences on our financial and operating conditions. Loss of access to these facilities 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.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our corporate headquarters are located in Cambridge, Massachusetts. We occupy approximately 35,000 square feet of office and laboratory space that we lease in a multi-tenant building in which our corporate headquarters are located. 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 be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. 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. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

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 23, 2021, there were approximately 26 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.

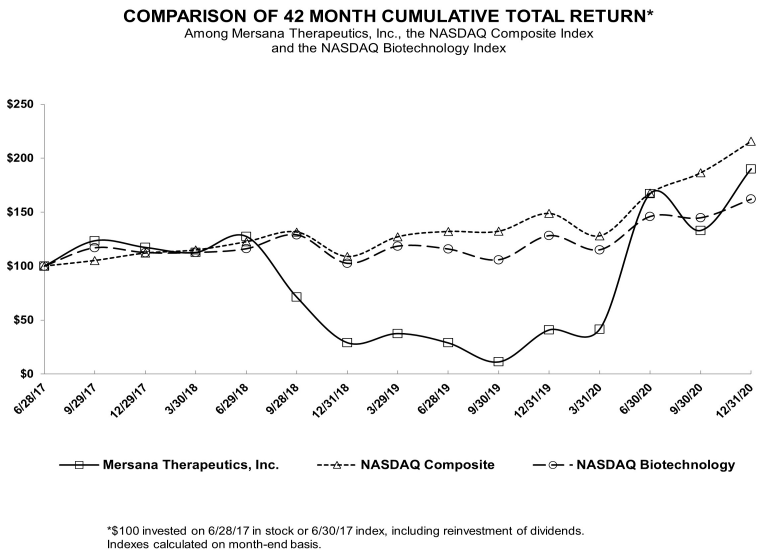
Dividend Policy

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. 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 June 28, 2017 (the first date that shares of our common stock were publicly traded) through December 31, 2020, 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 June 28, 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.



ITEM 6. SELECTED FINANCIAL DATA

You should read the following selected financial data together with our financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K and the information under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations." We have derived the statement of operations data for the years ended December 31, 2020, 2019 and 2018 and the balance sheet data as of December 31, 2020 and 2019 from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The historical statement of operations data for the years ended December 31, 2017 and 2016 and the historical balance sheet data as of December 31, 2018, 2017 and 2016 have been derived from audited financial statements not included in this Annual Report on Form 10-K. All financial information presented has been consolidated and reflects the operations of Mersana Therapeutics Inc. and its wholly-owned subsidiaries. Our historical results are not necessarily indicative of results expected in any future period. The selected historical financial information in this section is not intended to replace our consolidated financial statements and the related notes thereto.

	Year Ended December 31,				
	2020	2019	2018	2017	2016
	(in thousands, except share and per share data)				
Statements of Operations Data:					
Collaboration revenue	$ 828	$ 42,123	$ 10,594	$ 17,545	$ 25,171
Operating expenses:					
Research and development	67,036	55,040	59,915	46,700	32,008
General and administrative	21,902	17,283	16,334	10,462	6,984
Total operating expenses	88,938	72,323	76,249	57,162	38,992
Other income (expense):					
Interest income	424	2,226	1,398	910	121
Interest expense	(359)	(234)	—	—	—
Total other income (expense), net	65	1,992	1,398	910	121
Net loss	$ (88,045)	$ (28,208)	$ (64,257)	$ (38,707)	$ (13,700)
Net loss attributable to common stockholders — basic and diluted(1)	$ (88,045)	$ (28,208)	$ (64,257)	$ (38,707)	$ (13,700)
Net loss per share attributable to common stockholders — basic and diluted(1)	$ (1.43)	$ (0.65)	$ (2.79)	$ (3.22)	$ (10.82)
Weighted-average number of shares of common stock used in net loss per share attributable to common stockholders — basic and diluted(1)	61,485,205	43,492,113	23,032,250	12,022,733	1,266,758

	Year Ended December 31,				
	2020	2019	2018	2017	2016
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 255,094	$ 99,790	$ 70,131	$ 125,216	$ 100,297
Working capital(2)	228,577	77,256	4,880	85,662	73,787
Total assets	273,399	107,541	78,502	130,715	105,087
Long-term debt, net of discount	4,977	4,201	—	—	—
Convertible preferred stock	—	—	—	—	94,450
Total stockholders' equity (deficit)	228,087	78,318	8,795	69,994	(55,619)

(1) See Note 2 to our financial statements appearing elsewhere in this Annual Report on Form 10-K for further details on the calculation of basic and diluted net loss per share applicable to common stockholders.

(2) We define working capital as current assets less current liabilities.

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 the 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 SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company focused on developing antibody drug conjugates, or ADCs, that offer a clinically meaningful benefit for cancer patients with significant unmet need. We have leveraged over 20 years of industry learning in the ADC field to develop proprietary and differentiated technology platforms that enable us to design ADCs to have improved efficacy, safety and tolerability relative to existing ADC therapies.

We believe that our innovative platforms which include Dolaflexin and Dolasynthen, delivering our DolaLock payload, as well as Immunosynthen, delivering a novel stimulator of interferon genes, or STING, agonist, compose a highly efficient product engine that has enabled a robust discovery pipeline for us and our partners. Our ADCs in preclinical and clinical studies include first-in-class molecules that target multiple tumor types with high unmet medical need and have exhibited improved safety and efficacy compared to ADCs developed using first-generation technology.

Our goal is to become a leading oncology company by leveraging the potential of our innovative and differentiated ADC technologies and the experience and competencies of our management team to identify, acquire and develop promising ADC product candidates and to commercialize cancer therapeutics that are improvements over existing treatments.

Upifitamab rilsodotin (UpRi, XMT-1536), our 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. The NaPi2b antigen is broadly expressed in NSCLC adenocarcinoma and ovarian cancer with limited expression in normal tissue. We are actively recruiting and dosing patients with ovarian cancer and NSCLC adenocarcinoma, where a majority of patients express NaPi2b in a Phase 1 clinical trial. We expect to initiate a single-arm registration strategy in platinum-resistant ovarian cancer, UPLIFT, and a combination dose escalation study, UPGRADE, in ovarian cancer in 2021.

XMT-1592 was created using our Dolasynthen platform and also targets NaPi2b. XMT-1592 comprises the same proprietary NaPi2b antibody and potent auristatin DolaLock payload with controlled bystander effect as UpRi, with the additional features of homogeneous, site-specific bioconjugation and precise DAR. XMT-1592 is in a Phase 1 dose escalation study in patients with ovarian cancer and NSCLC adenocarcinoma.

Our early stage programs include, XMT-1660, a potentially first-in-class B7-H4-targeted DolaLock ADC, as well as XMT-2056, a STING-agonist ADC developed using our novel Immunosynthen platform. Our objective in 2021 is to rapidly progress these candidates through IND-enabling studies and scale up manufacturing activities with third parties. These development candidates provide significant opportunities for development in areas of high unmet need such as breast cancer, NSCLC and ovarian cancer.

In addition, we have established strategic research and development partnerships with Merck KGaA and Asana Biosciences for the development and commercialization of additional ADC product candidates against a limited number of targets selected by our partners based on our Dolaflexin platform. We believe the potential of our ADC technologies, supported by our world class management team and protected by our robust intellectual property portfolio, will allow us to discover and develop life-changing antibody-drug conjugates 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 study material and conducting clinical studies, 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 partnerships, private placements of our convertible preferred stock and public offerings of our common stock. In April 2020, we sold approximately 10.9 million shares of common stock pursuant to an at-the-market, or the ATM, equity offering program and received net proceeds of $63.0 million. In addition, in June 2020, we sold 9.2 million shares of common stock in a follow-on offering and received net proceeds of $164.0 million.

Since inception, we have incurred significant cumulative operating losses. Our net losses were $88.0 million, $28.2 million and $64.3 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of $280.4 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 activities for our lead product candidates, UpRi and XMT-1592;
- develop a companion or complementary diagnostic for the NaPi2b biomarker;
- complete IND-enabling studies for our preclinical development candidates XMT-2056 and XMT-1660;
- continue activities to discover, validate and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio; and
- hire additional research, development and general and administrative personnel.

Impact of COVID-19 on Our Business

We are continuing to monitor the impact of the COVID-19 pandemic on our operations and ongoing clinical and preclinical development, as well as discovery efforts. Mitigation activities to minimize COVID-19-related operation disruptions are ongoing and include:

- In line with guidance from the U.S. Centers for Disease Control and Prevention (CDC) and the Commonwealth of Massachusetts, we have implemented work from home measures for all non-laboratory employees and have suspended all business travel. We have also prioritized laboratory activities and implemented staggered schedules in the interest of safety and efficiency for laboratory-based employees. We will continue to modify and adapt our measures to align with guidance as the pandemic evolves.
- We are currently enrolling patients at investigational sites in different geographic areas across the United States, Canada and Australia in the UpRi Phase 1 study and within the United States in the XMT-1592 Phase 1 dose escalation study. We are in the process of initiating additional clinical sites both inside and outside the United States to increase enrollment, which could additionally mitigate potential regional impacts from COVID-19. Consistent with FDA guidance, we issued an administrative letter to allow for remote patient monitoring and remote testing, when possible.
- To the best of our knowledge, our contract manufacturing partners continue to operate their manufacturing facilities at or near normal levels, and we have not experienced any COVID-related delays in our manufacturing to date. We believe we have sufficient inventory of UpRi and XMT-1592 to support our ongoing clinical studies. We have planned manufacturing runs to address all currently anticipated future needs. At this time, and subject to further COVID-19 implications, we do not anticipate any disruptions to our clinical supply.

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. While the pandemic did not materially affect our financial results and business operations in the year ended December 31, 2020, we are unable to predict the impact that COVID-19 will have on our financial position and operating results in future periods due to numerous uncertainties. Management is actively monitoring this situation and the possible effects on our financial condition, operations, suppliers, industry, and our employees. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, our financial condition or our results of operations, see "Part I, Item 1A—Risk Factors" in this Annual Report on Form 10-K.

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 partnerships.

In June 2014, we entered into an agreement with Merck KGaA for the development and commercialization of ADC product candidates utilizing Fleximer for up to six target antigens. Merck KGaA is responsible for generating antibodies against the target antigens and we are responsible for generating Fleximer and our proprietary payloads and conjugating this to the antibody 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 with Merck KGaA for the supply of materials that could be used for IND-enabling studies and clinical trials.

For the years ended December 31, 2020, 2019 and 2018, we recognized revenue of $0.8 million, $2.1 million and $2.4 million, respectively, related to the Merck KGaA agreements.

In January 2016, we entered into collaboration agreements with Takeda for the development and commercialization of XMT-1522, a HER2-targeted ADC, and up to seven ADC product candidates utilizing Fleximer. The Company's collaboration agreements with Takeda were terminated during the first quarter of 2019. We recognized the remaining deferred revenue of $40.0 million related to the termination of the Takeda agreements in the first quarter of 2019. We do not expect to have any further revenue related to these agreements.

We have provided limited services to Asana BioSciences. We recorded no revenue for the year ended December 31, 2020, an immaterial amount of revenue for the year ended December 31, 2019 and revenue of $0.8 million for the year ended December 31, 2018, related to those services. In addition, we recognized revenue of $1.5 million related to a milestone achieved during the third quarter of 2018.

For the foreseeable future, we expect substantially all of our revenue to be generated from our collaboration agreements with Merck KGaA 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.

For information about our revenue recognition policy, see the notes to consolidated financial statements included in this Annual Report on Form 10-K.

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 studies 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 and clinical studies, are generally recognized based on an evaluation of the progress to completion of specific tasks. Costs for certain development activities, such as clinical studies, 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 total 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.

A significant portion of our research and development costs have been external costs, which we track on a program-by-program basis following nomination as a product candidate. We have not historically tracked all of our internal research and development expenses on a program-by-program basis as they are deployed across multiple projects under development. The following table summarizes our external research and development expenses, by program, following nomination as a clinical candidate for the years ended December 31, 2020, 2019 and 2018. All external research and development expenses not attributable to the UpRi, XMT-1592 and XMT-1522 programs are captured within preclinical and discovery costs. These costs relate to XMT-1592 prior to its designation in early 2020, as well as preclinical development candidates XMT-1660 and XMT-2056, additional earlier discovery stage programs and certain unallocated costs. We terminated the development of XMT-1522 in the first quarter of 2019. Our internal research and development costs are primarily personnel-related costs, stock-based compensation costs, and facility costs, including depreciation, and lab consumables.

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
UpRi external costs	$ 18,689	$ 9,461	$ 15,922
XMT-1592 external costs	7,180	—	—
XMT-1522 external costs	—	1,936	15,562
Preclinical and discovery costs	9,883	16,980	4,517
Internal research and development costs	31,284	26,663	23,914
Total research and development costs	$ 67,036	$ 55,040	$ 59,915

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 studies;
- 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.

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 anticipate that our general and administrative expenses will 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 income earned on cash equivalents and marketable securities. Interest expense is related to the credit facility that we entered into on May 9, 2019 and amended in August 2020, with Silicon Valley Bank. These borrowings bear a floating per annum rate interest, as well as a final payment of 5.5% of the amounts drawn, that is being recorded as interest expense over the term through the maturity date using the effective-interest method. Also included in interest expense is the amortization of the deferred financing costs and the accretion of debt discount relating to the credit facility.

Results of Operations

Comparison of Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019, together with the changes in those items:

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**Dollar Change**
Collaboration revenue	$ 828	$ 42,123	$ (41,295)
Operating expenses:			
Research and development	67,036	55,040	11,996
General and administrative	21,902	17,283	4,619
Total operating expenses	88,938	72,323	16,615
Other income (expense):			
Interest income	424	2,226	(1,802)
Interest expense	(359)	(234)	(125)
Total other income (expense), net	65	1,992	(1,927)
Net loss	$ (88,045)	$ (28,208)	$ (59,837)

Collaboration Revenue

Collaboration revenue was $0.8 million during the year ended December 31, 2020, compared to $42.1 million during the year ended December 31, 2019, a decrease of $41.3 million, primarily as a result of the termination of the Takeda agreements and the recognition of the remaining deferred revenue of $40.0 million in early 2019. Additionally, revenue of $2.1 million was recognized in connection with the Merck KGaA Agreement and Merck KGaA Supply Agreement in the year ended December 31, 2019. During the year ended December 31, 2020, $0.8 million was recognized as a result of completion of research services associated with a target included in the Merck KGaA Agreement.

Research and Development Expense

Research and development expense was $67.0 million for the year ended December 31, 2020, compared to $55.0 million for the year ended December 31, 2019. The overall increase of $12.0 million was primarily attributable to the following:

- an increase of $9.2 million related to manufacturing, clinical and regulatory activities for UpRi;
- an increase of $4.3 million related to employee compensation, primarily due to an increase in headcount supporting the growth of our research and development activities, and the increase in valuation of stock-based awards granted to employees;
- an increase of $1.8 million related to XMT-1592 clinical and regulatory expenses;
- an increase of $1.7 million related to manufacturing for preclinical and discovery stage programs including XMT-1660 and XMT-2056;
- an increase of $1.3 million related to other research services and supplies costs;
- an increase of $1.1 million related to advancement of companion diagnostic development efforts for the NaPi2b biomarker; and
- an increase of $0.4 million related to milestones paid for in-licensed technologies.

These increased costs were partially offset by the following:

- a decrease of $5.2 million related to preclinical development and manufacturing activities for XMT-1592;
- a decrease of $1.7 million related to the development and manufacturing activities for XMT-1522; and
- a decrease of $0.9 million to support partner programs.

We expect our research and development expenses to increase as we continue our clinical development UpRi and XMT-1592 and continue to advance our preclinical product candidate pipeline and invest in improvements in our ADC technologies.

General and Administrative Expense

General and administrative expense was $21.9 million for the year ended December 31, 2020, compared to $17.3 million for the year ended December 31, 2019. The overall increase of $4.6 million was primarily attributable to the following:

- an increase of $2.8 million related to consulting and professional fees;
- an increase of $1.3 million related to employee compensation, primarily due to the increase in valuation of stock-based awards granted to employees; and
- an increase of $0.5 million in facility-related costs as a result of the amendment of our lease in March 2020.

We expect that our general and administrative expense will increase in the future to support continued research and development activities. These increases will likely include legal, auditing and filing fees, additional insurance premiums and general compliance and consulting expenses.

Total Other Income (Expense), Net

Total other income (expense), net was $0.1 million and $2.0 million for the years ended December 31, 2020 and 2019, respectively. Other income consists primarily of interest income on cash equivalents and short-term marketable securities. Interest expense was related to our outstanding borrowings under the credit facility.

Comparison of Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018, together with the changes in those items:

(in thousands)	Year Ended December 31, 2019	2018	Dollar Change
Collaboration revenue	$ 42,123	$ 10,594	$ 31,529
Operating expenses:			
Research and development	55,040	59,915	(4,875)
General and administrative	17,283	16,334	949
Total operating expenses	72,323	76,249	(3,926)
Other income (expense):			
Interest income	2,226	1,398	828
Interest expense	(234)	—	(234)
Total other income (expense), net	1,992	1,398	594
Net loss	$ (28,208)	$ (64,257)	$ 36,049

Collaboration Revenue

Collaboration revenue was $42.1 million during the year ended December 31, 2019, compared to $10.6 million during the year ended December 31, 2018, a increase of $31.5 million, primarily as a result of the termination of the Takeda agreements and the recognition of the remaining deferred revenue of $40.0 million in early 2019. Additionally, revenue of $2.1 million was recognized in connection with the Merck KGaA Agreement and Merck KGaA Supply Agreement in the year ended December 31, 2019. This compares to the revenue recognized during the year ended December 31, 2018 for support of partner programs with Takeda, Merck KGaA and Asana BioSciences of $9.1 million and recognition of a milestone of $1.5 million achieved upon completion of a GLP toxicology study by Asana BioSciences.

Research and Development Expense

Research and development expense was $55.0 million for the year ended December 31, 2019, compared to $59.9 million for the year ended December 31, 2018. The overall decrease of $4.9 million was primarily attributable to the following:

- decrease of $13.5 million related to the development and manufacturing activities for XMT-1522; and
- decrease of $9.0 million related to manufacturing activities for UpRi.

These decreased costs were partially offset by the following:

- increase of approximately $8.3 million related to preclinical development and manufacturing activities for XMT-1592;
- increase of approximately $3.0 million related to UpRi clinical and regulatory expenses;
- increase of approximately $3.0 million related to research efforts to further platform development and evaluate potential product candidates;
- increase of $1.8 million related to employee compensation, including stock-based compensation expense;
- increase of $0.8 million related to advancement of companion diagnostic development efforts for the NaPi2B biomarker; and
- increase of $0.6 million related to a milestone paid upon dosing of the first patient in the expansion cohort of the UpRi clinical trial.

We expect our research and development expenses to increase as we continue our clinical development UpRi and XMT-1592 and continue to advance our preclinical product candidate pipeline and invest in improvements in our ADC technologies.

General and Administrative Expense

General and administrative expense was $17.3 million for the year ended December 31, 2019, compared to $16.3 million for the year ended December 31, 2018. The overall increase of $0.9 million was primarily attributable to the increase in stock-based compensation expense.

We expect that our general and administrative expense will increase in the future to support continued research and development activities. These increases will likely include legal, auditing and filing fees, additional insurance premiums and general compliance and consulting expenses.

Total Other Income (Expense), Net

Total other income (expense), net was $2.0 million and $1.4 million for the years ended December 31, 2019 and 2018, respectively. Other income consists primarily of interest income on cash equivalents and short-term marketable securities, which increased $0.6 million due to higher investable balances for the year ended December 31, 2019. Interest expense of $0.2 million was related to our outstanding borrowings under the credit facility.

Liquidity and Capital Resources

Sources of Liquidity

We have financed our operations primarily with the proceeds from our initial public offering, our follow-on public offerings in 2019 and 2020, and use of our at-the-market, or ATM, equity offering program in 2020. Our follow-on public offering was completed on March 5, 2019 and resulted in net proceeds of $92.2 million. On July 2, 2018, we established an ATM, or the 2018 ATM, pursuant to which we were able to offer and sell up to $75.0 million of our common stock from time to time at prevailing market prices. In April 2020, we sold approximately 10.9 million shares of common stock and received net proceeds of $63.0 million pursuant to our 2018 ATM. In addition, in June 2020, we sold 9.2 million shares of common stock in a follow-on public offering and received net proceeds of approximately $164.0 million.

In May 2020, we terminated the 2018 ATM and established a new ATM, or the 2020 ATM, pursuant to which we are able to sell up to $100.0 million of our common stock from time to time at prevailing market prices. As of December 31, 2020, we had not sold any shares under the 2020 ATM and had $100.0 million of availability under the program.

On May 8, 2019, we entered into a term-loan agreement which was subsequently amended on August 28, 2020. Pursuant to the amendment, we may be subject to certain conditions, borrow term loans in an aggregate amount of up to $30.0 million, of which $5.2 million were funded upon execution of the amendment. These proceeds were used to repay the existing balance and satisfy our existing obligations to Silicon Valley Bank, or SVB. No additional amounts have been drawn since the initial draw of $5.2 million.

As of December 31, 2020, we had cash and cash equivalents of $255.1 million.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2020, 2019 and 2018:

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Net cash used in operating activities	$ (74,696)	$ (67,744)	$ (55,216)
Net cash provided by (used in) investing activities	37,027	(27,293)	87,195
Net cash provided by financing activities	230,412	97,704	1,064
Increase in cash, cash equivalents and restricted cash	$ 192,743	$ 2,667	$ 33,043

Net Cash Used in Operating Activities

Net cash used in operating activities was $74.7 million for the year ended December 31, 2020 and primarily consisted of a net loss of $88.0 million adjusted for changes in our net working capital and other non-cash items including stock-based compensation of $7.2 million and depreciation of $1.0 million. Net cash used in operating activities was $67.7 million for the year ended December 31, 2019 and primarily consisted of a net loss of $28.2 million adjusted for non-cash items including

stock-based compensation of $4.9 million and depreciation of $1.2 million, as well as change in our net working capital and the decrease in deferred revenue of $41.4 million primarily related to the Takeda agreements. Net cash used in operating activities was $55.2 million for the year ended December 31, 2018 and primarily consisted of a net loss of $64.3 million adjusted for non-cash items including stock-based compensation of $3.9 million and depreciation of $1.3 million, as well as change in our net working capital and the decrease in deferred revenue of $6.2 million.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $37.0 million during the year ended December 31, 2020 compared to net cash used in investing activities of $27.3 million during the year ended December 31, 2019. Net cash provided by investing activities for the year ended December 31, 2020 consisted primarily of maturities of marketable securities. Net cash used in investing activities for the year ended December 31, 2019 consisted primarily of purchases of marketable securities, partially offset by maturities of marketable securities. Net cash provided by investing activities for the year ended December 31, 2018 consisted primarily of maturities of marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $230.4 million during the year ended December 31, 2020 compared to net cash provided by financing activities of $97.7 million during the year ended December 31, 2019. During the year ended December 31, 2020 cash provided by financing activities consisted primarily of $164.0 million related to the follow-on public offering in May 2020 and the proceeds from the use of the 2018 ATM of $63.0 million in April 2020 as well as proceeds from exercise of stock options of $3.1 million. During the year ended December 31, 2019 cash provided by financing activities consisted primarily of the proceeds from our follow-on public offering of our common stock and issuance of debt. During the year ended December 31, 2018 cash provided by financing activities consisted primarily of the proceeds from the exercise of stock options.

Funding Requirements

We expect our cash expenditures to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical studies of, and seek marketing approval for our product candidates. In addition, 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.

We believe our currently available funds will be sufficient to fund our current operating plan commitments for approximately the next two years. 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 studies 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 study 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 studies 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 equity offerings, debt financings, strategic partnerships 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 these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. We currently have access to an additional line of credit under the credit facility with SVB, along with funds to potentially be earned in connection with our agreements with Merck KGaA and Asana BioSciences, if development activities are successful under those agreements. 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 partnerships 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

The following table summarizes our significant contractual obligations as of payment due date by period at December 31, 2020:

(in thousands)	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 years
Lease commitments(1)	$ 15,739	$ 2,888	$ 5,929	$ 6,140	$ 782
Long-term debt obligations(2)	6,074	224	3,796	2,054	—
Total	$ 21,813	$ 3,112	$ 9,725	$ 8,194	$ 782

(1) Represents future minimum lease payments under our non-cancelable operating and finance leases, which expire through February 2024. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.

(2) Represents future debt principal plus interest and final payments under our term-loan, which is payable in full on November 1, 2024. Refer to footnote 8 in the Notes to the Consolidated Financial Statements.

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 purpose. Certain of these agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to the parties with whom we contract upon termination, primarily to reimburse them for their unrecoverable outlays incurred prior to cancellation and for wind-down activities. 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. At December 31, 2020, we had cancellable open purchase orders of $59.8 million in total under material agreements for preclinical, clinical, manufacturing, and other products and services for operating purposes. These amounts represent only our estimate of those items for which we had a contractual commitment to pay at December 31, 2020, assuming we would not cancel these agreements. The actual amounts we expect to pay in the future to the third parties under such agreements may differ from the cancellable open purchase order amounts.

In July 2015, we entered into a license agreement with Recepta Biopharma S.A., or Recepta, as amended, for the NaPi2b antibody. Under this agreement, 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 agreement will become fully-paid up and royalty-free. We have made $1.9 million in development milestone payments to date.

In January 2019, we entered into a license agreement with Synaffix B.V., or Synaffix, to develop, manufacture and commercialize ADC targets using Synaffix's proprietary technology for a total of six targets. At contract inception we designated the first target and paid an upfront, non-refundable license fee of $0.8 million. During the year ended December 31, 2020, we designated the next target and paid an upfront non-refundable reservation fee of $0.3 million. We are required to make milestone payments to Synaffix of up to an aggregate of $24.8 million in development and regulatory milestones, up to $20.0 million in one-time sales milestones based on the achievement of annual sales objectives for the first target. In addition, upon designation of additional targets, we will be obligated to pay in the range of $44.8 million to $62.0 million for issuance, development, regulatory and one time sales milestones. Finally, pursuant to the terms this license agreement, upon commencement of commercial sales of a product, if any, we are required to pay to Synaffix tiered royalties in the low-single digit percentages on net sales of the respective products. We have made $0.8 million in development milestone payments to Synaffix to date.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable Securities and Exchange Commission rules.

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, 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 Topic 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 Topic 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 Topic 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (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 arrangement 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 good 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 or 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 estimates 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 stand-alone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the stand-alone 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, adjusts 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 Topic 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. We consider the guidance in ASC Topic 606 in determining the appropriate treatment for the transactions between us and our collaborative partners 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 Topic 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, at times, 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

We are exposed to market risk-related to changes in interest rates. 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 and corporate bonds. 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 interest rates would not have a material effect on the fair market value of our investments portfolio.

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 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, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 26, 2021 expressed an unqualified opinion thereon.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases* (Topic 842), and the related amendments.

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 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. 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) relate 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 account or disclosure to which it relates.

Accrued Preclinical, Manufacturing and Clinical Expenses

Description of the Matter

The Company's accrual for preclinical, manufacturing and clinical expenses totaled $9.9 million at December 31, 2020. As discussed in Note 2 to the consolidated financial statements, the Company is required to estimate accruals for preclinical, manufacturing and clinical 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 accrual for preclinical, manufacturing and 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 the number of active sites, patient enrollment, and project timelines. 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

We obtained an understanding, evaluated the design, and tested the operating effectiveness of the controls over the Company's process for recording accrued preclinical, manufacturing and clinical expenses. These procedures included controls over management's review of inputs used, as well as the completeness and accuracy of the underlying data, in estimating the accrual.

To test the accruals for preclinical, manufacturing and clinical expenses, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used in the estimates and evaluating the various estimates and other inputs noted above that are used by management 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 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 accruals 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 accrual.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.
Boston, Massachusetts
February 26, 2021

Mersana Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 255,094	$ 62,351
Short-term marketable securities	—	37,439
Prepaid expenses and other current assets	3,486	1,536
Total current assets	258,580	101,326
Property and equipment, net	1,730	2,164
Operating lease right-of-use assets	10,936	2,598
Other assets	2,153	1,453
Total assets	$ 273,399	$ 107,541
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 8,340	$ 7,296
Accrued expenses	16,146	8,986
Deferred revenue	3,987	4,815
Operating lease liabilities	1,437	2,219
Short-term debt	—	667
Other liabilities	93	87
Total current liabilities	30,003	24,070
Operating lease liabilities	10,158	677
Long-term debt, net	4,977	4,201
Other liabilities	174	275
Total liabilities	45,312	29,223
Commitments (Note 14)		
Stockholders' equity		
Preferred stock, $0.0001 par value; 25,000,000 shares authorized; 0 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.0001 par value; 175,000,000 shares authorized; 68,841,288 and 45,388,023 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	7	5
Additional paid-in capital	508,499	270,662
Accumulated other comprehensive income	—	25
Accumulated deficit	(280,419)	(192,374)
Total stockholders' equity	228,087	78,318
Total liabilities and stockholders' equity	$ 273,399	$ 107,541

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,		
	2020	2019	2018
Collaboration revenue	$ 828	$ 42,123	$ 10,594
Operating expenses:			
Research and development	67,036	55,040	59,915
General and administrative	21,902	17,283	16,334
Total operating expenses	88,938	72,323	76,249
Other income (expense):			
Interest income	424	2,226	1,398
Interest expense	(359)	(234)	—
Total other income (expense), net	65	1,992	1,398
Net loss	$ (88,045)	$ (28,208)	$ (64,257)
Other comprehensive loss:			
Unrealized gain (loss) on marketable securities	(25)	33	141
Comprehensive loss	$ (88,070)	$ (28,175)	$ (64,116)
Net loss attributable to common stockholders — basic and diluted	$ (88,045)	$ (28,208)	$ (64,257)
Net loss per share attributable to common stockholders — basic and diluted	$ (1.43)	$ (0.65)	$ (2.79)
Weighted-average number of shares of common stock used in net loss per share attributable to common stockholders — basic and diluted	61,485,205	43,492,113	23,032,250

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, 2017	22,765,017	$ 3	$ 168,018	$ (149)	$ (97,878)	$ 69,994
Cumulative effect adjustment for adoption of ASC 606	—	—	—	—	(2,031)	(2,031)
Exercise of stock options	427,269	—	918	—	—	918
Purchase of common stock under ESPP	42,186	—	146	—	—	146
Stock-based compensation expense	—	—	3,884	—	—	3,884
Other comprehensive income	—	—	—	141	—	141
Net loss	—	—	—	—	(64,257)	(64,257)
Balance at December 31, 2018	23,234,472	$ 3	$ 172,966	$ (8)	$ (164,166)	$ 8,795
Issuance of common stock under public offering, net of issuance costs of $5,587	24,437,500	2	92,160	—	—	92,162
Exercise of stock options and warrants	150,978	—	175	—	—	175
Purchase of common stock under ESPP	140,073	—	489	—	—	489
Retirement of common stock in exchange for common stock warrant	(2,575,000)	—	(8,986)	—	—	(8,986)
Issuance of common stock warrant in exchange for retirement of common stock	—	—	8,986	—	—	8,986
Stock-based compensation expense	—	—	4,872	—	—	4,872
Other comprehensive income	—	—	—	33	—	33
Net loss	—	—	—	—	(28,208)	(28,208)
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

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,		
	2020	2019	2018
Cash flows from operating activities			
Net loss	$ (88,045)	$ (28,208)	$ (64,257)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,010	1,245	1,257
Loss on disposal of fixed assets	—	—	20
Net amortization of premiums and discounts on investments	(86)	(222)	(296)
Stock-based compensation	7,172	4,872	3,884
Change in deferred rent	—	—	110
Other non-cash items	148	103	—
Changes in operating assets and liabilities:			
Accounts receivable	—	459	325
Prepaid expenses and other current assets	(1,950)	2,179	(1,690)
Other assets	(700)	—	(1,132)
Accounts payable	942	(3,110)	7,375
Accrued expenses	7,280	(3,569)	5,431
Operating lease assets	1,642	1,771	—
Operating lease liabilities	(1,281)	(1,883)	—
Deferred revenue	(828)	(41,381)	(6,243)
Net cash used in operating activities	(74,696)	(67,744)	(55,216)
Cash flows from investing activities			
Maturities of marketable securities	37,500	27,000	88,565
Purchase of marketable securities	—	(53,688)	—
Purchase of property and equipment	(473)	(605)	(1,370)
Net cash provided by (used in) investing activities	37,027	(27,293)	87,195
Cash flows from financing activities			
Net proceeds from public offering of common stock	163,990	92,162	—
Net proceeds from use of ATM	63,036	—	—
Proceeds from exercise of stock options	3,138	175	918
Proceeds from purchases of common stock under ESPP	561	489	146
Proceeds from issuance of debt, net of issuance costs	(197)	4,965	—
Payments under capital lease obligations	(116)	(87)	—
Net cash provided by financing activities	230,412	97,704	1,064
Increase in cash, cash equivalents and restricted cash	192,743	2,667	33,043
Cash, cash equivalents and restricted cash, beginning of period	62,672	60,005	26,962
Cash, cash equivalents and restricted cash, end of period	$ 255,415	$ 62,672	$ 60,005
Supplemental disclosures of non-cash activities:			
Fair value of common stock retired in exchange for issuance of common stock warrant	$ —	$ 8,986	$ —
Purchases of property and equipment in accounts payable and accrued expenses	$ 102	$ —	$ 317
Debt financing costs in accrued expenses	$ —	$ 180	$ —
Cash paid for interest	$ 234	$ 132	$ —
Right-of-use assets obtained in exchange for operating lease liabilities	$ 9,980	$ 4,369	$ —
Right-of-use assets obtained in exchange for financing lease liabilities	$ —	$ 429	$ —
Adjustment to accumulated deficit and deferred revenue upon adoption of Topic 606	$ —	$ —	$ 2,031

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 20 years of industry learning in the ADC field to develop proprietary and differentiated technology platforms that enable it to design ADCs to have improved efficacy, safety and tolerability relative to existing ADC therapies. The Company's innovative platforms, which include Dolaflexin and Dolasynthen, each delivering its DolaLock payload, as well as Immunosynthen, delivering a novel stimulator of interferon genes (STING) agonist, provide an efficient product engine that has enabled a robust discovery pipeline for the Company and its partners. The Company's product candidates include upifitamab rilsodotin (UpRi, XMT-1536) and XMT-1592. The Company's early stage programs include a potentially first-in-class B7-H4-targeted DolaLock ADC, XMT-1660, as well as candidates leveraging the Immunosynthen platform, the most advanced of which is XMT-2056.

UpRi, an ADC utilizing the Company's Dolaflexin platform and targeting NaPi2b, an antigen broadly expressed in ovarian cancer and non-small cell lung cancer (NSCLC) adenocarcinoma, is currently in the expansion portion of a Phase 1 study in patients with ovarian cancer and NSCLC adenocarcinoma. XMT-1592 uses one of the Company's new platforms, Dolasynthen, and also targets NaPi2b. In the first half of 2020, the Company initiated the Phase 1 dose escalation study of XMT-1592 .

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 net losses since inception. The Company's net loss was $88,045, $28,208 and $64,257 for the years ended December 31, 2020, 2019 and 2018, respectively. The Company expects to continue to incur operating losses for at least the next several years. As of December 31, 2020, the Company had an accumulated deficit of $280,419. 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.

In April 2020, the Company sold 10,900,599 shares of common stock and received net proceeds of $62,976. In addition, in June 2020, the Company sold 9,200,000 shares of common stock and received net proceeds of $163,990. 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). All dollar amounts, except per share data in the text and tables herein, are stated in thousands unless otherwise indicated.

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 and clinical studies and related services;
- the cost of acquiring, developing and manufacturing ADC product candidates, clinical study 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 clinical studies 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 Accounting Standards Update (ASU) No. 2014-9, *Revenue from Contracts with Customers* (Topic 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 Topic 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 Topic 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (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 it is entitled to in exchange for the goods or services it transfers to the customer.

The promised good or services in the Company's arrangement 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 or whether the required expertise is readily available.

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 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. 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 stand-alone selling price for each performance obligation identified in the

contract. The Company utilizes key assumptions to determine the stand-alone 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 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.

Effective January 1, 2018, the Company adopted the provisions of Topic 606, using the modified retrospective transition method. Under this method, the Company recorded the cumulative effect of initially applying the new standard to all contracts in process as of the date of adoption. This standard applied to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. The adoption of the new revenue recognition guidance resulted in increases of $2,031 in deferred revenue and accumulated deficit as of January 1, 2018. For the years ended December 31, 2019 and 2018, revenue was not materially impacted as compared to the Company's prior revenue recognition methodology under ASC 605 Revenue Recognition.

Collaborative Arrangements

The Company records the elements of its collaboration agreements that represent joint operating activities in accordance with ASC Topic 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 considers the guidance in ASC Topic 606 in determining the appropriate treatment for the transactions between the Company and its collaborative partners 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 Topic 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 Topic 820 *Fair Value Measurement* (ASC 820) 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.

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.

	Year ended December 31, 2020		Year ended December 31, 2019	
	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	$ 62,351	$ 255,094	$ 59,634	$ 62,351
Restricted cash included in other assets, noncurrent	321	321	371	321
Total cash, cash equivalents and restricted cash per statement of cash flows	$ 62,672	$ 255,415	$ 60,005	$ 62,672

Marketable Securities

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. Amortization and accretion of discounts and premiums are recorded as interest income within other income. Prior to the adoption of ASU 2016-13, *Financial Instruments - Credit Losses*, unrealized gains and losses on available-for-sale securities were included in other accumulated comprehensive loss as a component of stockholders' equity until realized. Realized gains and losses and declines in value judged to be other than temporary are included as a component of other income (expense), net, based on the specific identification method. When determining whether a decline in value is other than temporary, the Company considers various factors, including whether the Company has the intent to sell the security, and whether it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis. Fair value is determined based on quoted market prices.

In accordance with the adoption of ASU 2016-13, the Company is required to determine whether any portion of the unrealized loss for any available-for-sale debt security is due to a credit loss, and if so, to measure the amount of the credit loss. The Company reviews each of its available-for-sale marketable securities for unrealized losses (declines in fair value below its amortized cost basis) at each balance sheet date presented in its financial statements and whenever events or changes in circumstances indicate that the amortized cost basis of an asset may not be recoverable.

Other Assets

The Company recorded other assets of $2,153 and $1,453 as of December 31, 2020 and 2019, respectively, comprised of $1,832 and $1,132, respectively, held by a service provider, and restricted cash of $321 and $321 at the end of each period held as a security deposit for a standby letter of credit related to a facility lease.

Accounting for Stock-based Compensation

The Company accounts for its stock-based compensation in accordance with ASC Topic 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. Due to the lack of a public market for the Company's common stock prior to completion of the 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 historical volatility is calculated based on a period of time commensurate with the expected term assumption. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. 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. For options granted to non-employees, the Company utilizes the contractual term of the 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, or RSU, at its grant date based on the closing market price of the Company's common stock on that date. 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.

Net Loss per Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding and 2,575,000 Exchange Warrants (as defined in footnote 9) outstanding during the period, without further consideration for potentially dilutive securities. In accordance with Accounting Standards Codification Topic 260, *Earnings Per Share*, the Exchange Warrants are included in the computation of basic net loss per share because the exercise price is negligible and they are fully vested and exercisable at any time after the original issuance date. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares 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 restricted stock units (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,		
	2020	2019	2018
Stock options	6,112,948	4,720,772	3,746,567
Unvested restricted stock units	716,767	447,336	—
Warrants	39,474	39,474	110,365
	6,869,189	5,207,582	3,856,932

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 assets disposed of 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, 2020, 2019 and 2018.

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 an impairment review is performed 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, an impairment charge is recognized 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, 2020, 2019 and 2018.

Leases

Consistent with ASC 842, 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 has lease agreements with lease and non-lease components, which are generally accounted for 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 Topic 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, 2020, 2019 and 2018, other comprehensive income (loss) consisted of changes in unrealized income and loss on marketable securities.

Concentration of Credit Risk and Off-balance Sheet Risk

The Company has no financial instruments with off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. 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 has not experienced any credit losses and does not believe this it is subject to any significant concentrations of credit risk from these financial instruments.

Recently Issued Accounting Pronouncements

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. The main provisions of ASU 2018-18 include: (i) clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue when the collaborative arrangement participant is a customer in the context of a unit of account and (ii) precluding the presentation of transactions with collaborative arrangement participants that are not directly related to sales to third parties together with revenue. This guidance is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those annual reporting periods, and early adoption is permitted. The guidance per ASU 2018-18 is to be adopted retrospectively to the date of initial application of Topic 606. The Company adopted the new standard effective January 1, 2020. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. Historically, U.S. GAAP delayed recognition of the full amount of credit losses until the loss was probable of occurring. Under this ASU, the income statement will reflect an entity's current estimate of all expected credit losses. The measurement of expected credit losses will be based upon historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down of the security. This ASU is effective for annual periods beginning after December 15, 2019, including interim periods within those annual reporting periods, and early adoption is permitted. The Company adopted the new standard effective January 1, 2020 using the modified retrospective method. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, as part of its initiative to reduce complexity in the accounting standards. The amendments in ASU 2019-12 eliminate certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. ASU 2019-12 also clarifies and simplifies other aspects of the accounting for income taxes. The amendments in ASU 2019-12 are effective for the fiscal years beginning after December 15, 2020. Early adoption is permitted, including adoption in any interim period. The Company is currently evaluating the potential impact ASU 2019-12 may have on its financial position and results of operations upon adoption.

3. Collaboration Agreements

Merck KGaA

In June 2014, the Company entered into a Collaboration and Commercial License Agreement with Merck KGaA (the Merck KGaA Agreement). Upon the execution of the Merck KGaA Agreement, Merck KGaA paid the Company a nonrefundable technology access fee of $12,000 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. All six targets were designated prior to 2018.

Under the terms of the 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 or cease development on the designated target.

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 $780,000 in future milestones related to all targets under the 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 $84,000; regulatory milestones $264,000; and sales milestones $432,000. 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.

Prior to 2018, the Company had received $3,000 related to development milestones under the Merck KGaA Agreement. There have been no additional milestone payments in the years ended December 31, 2019 or 2020. The next potential milestone payment the Company will be eligible to receive will be a development milestone of $500 on Merck KGaA's designation of a preclinical development candidate for any target. Revenue will be recognized when achievement of the milestone is considered probable.

Unless earlier terminated, the Merck KGaA Agreement will expire upon the expiration of the last royalty term for a product under the 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 Merck KGaA Agreement as preclinical development candidates, upon the expiration of the last to expire research program. Merck KGaA may terminate the 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 Merck KGaA Agreement in its entirety upon bankruptcy or similar proceedings of the other party or upon an uncured material breach of the 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 Merck KGaA Supply Agreement). Under the terms of the Merck KGaA Supply Agreement, the Company will provide Merck KGaA preclinical non-GMP ADC Drug Substance and clinical GMP Drug Substance for use in clinical trials associated with one of the antibodies designated under the Merck KGaA Agreement. The Company receives fees for its efforts under the 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 Merck KGaA Agreement.

Accounting Analysis

The Company identified the following performance obligations under the 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 plans 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 Topic 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, 2019, the total transaction price for the Merck KGaA Agreement was $21,500. During 2020, the Company revised its estimate for fees associated with research and development activities under the Merck KGaA Agreement to $6,325, a decrease of $175. The revised total transaction price for the Merck KGaA Agreement is $21,325. The transaction price of $21,325 was allocated to the performance obligations as follows: approximately $3,941 for each of the license and corresponding research and development services units of account for the first and second designated targets; $3,439 for each of the license and corresponding research and development services units of account for the third and sixth designated target; $3,152 for the license and corresponding research and development services unit of account for the fourth designated target; $2,746 for the license and corresponding research and development services unit of account for the fifth designated target; $425 for rights to future technological improvements; and $242 for joint research committee services.

The Company is recognizing revenue related to the exclusive license and research and development services performance obligation over the estimated period of the research and development services using a proportional performance model. The Company measures proportional performance based on the costs incurred relative to the total costs expected to be incurred. To the extent that the Company receives fees for the research services as they are preformed, 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, 2020, the Company has completed its research service obligations associated with four of the six designated targets. During the years ended December 31, 2020, 2019 and 2018, the Company recorded collaboration revenue of $828, $853 and $2,444, respectively, related to its efforts under the Merck KGaA Agreement. During the year ended December 31, 2019, the Company recognized collaboration revenue and corresponding research and development expense of $1,280 related to the Merck KGaA Supply Agreement. There were no amounts recognized during the years ended December 31, 2020 and 2018 related to the Merck KGaA Supply Agreement. There was no balance in accounts receivable related to the Merck KGaA Agreement and Merck KGaA Supply Agreement as of either December 31, 2020 or December 31, 2019.

As of December 31, 2020 and 2019, the Company had recorded $3,987 and $4,815, respectively, in deferred revenue related to the Merck KGaA Agreement and Merck KGaA Supply Agreement that will be recognized over the remaining performance period.

Takeda XMT-1522 Strategic Partnership

In January 2016, the Company entered into a Development Collaboration and Commercial License Agreement with Takeda's wholly owned subsidiary, Millennium Pharmaceuticals, Inc. for the development and commercialization of XMT-1522 (the XMT-1522 Agreement). Under the XMT-1522 Agreement, Takeda was granted the exclusive right to commercialize XMT-1522 outside of the United States and Canada. Under the XMT-1522 Agreement, the Company was responsible for conducting certain Phase 1 development activities for XMT-1522, including the ongoing Phase 1 clinical trial, at its own expense. The parties agreed to collaborate on the further development of XMT-1522 in accordance with a global development plan (Post-Phase 1 Development). On January 2, 2019, the Company received notice from Takeda stating that Takeda was exercising its right to terminate the XMT-1522 Agreement upon 30 days' prior written notice. The XMT-1522 Agreement terminated in accordance with its provisions, and the Company and Takeda wound down activities related to the XMT-1522 Agreement as of March 31, 2019. Under the XMT-1522 Agreement, the Company and Takeda shared equally all agreed Post-Phase 1 Development costs through the date of termination and for a period of 30 days after the effective termination date.

Takeda Strategic Research and Development Partnership

In March 2014, the Company entered into a Research Collaboration and Commercial License Agreement with Takeda's wholly owned subsidiary, Millennium Pharmaceuticals, Inc. (the 2014 Agreement). The 2014 Agreement was amended in January 2015 and amended and restated in January 2016 (the 2016 Restated Agreement). The agreements provided Takeda with the right to develop ADCs directed to a total of seven exclusive targets, designated by Takeda, over a specified period of time. On January 2, 2019, the Company received notice from Takeda stating that Takeda was exercising its right to terminate the 2016 Restated Agreement upon 45 days' prior written notice. The 2016 Restated Agreement terminated in accordance with its provisions, and the Company and Takeda wound down activities related to the 2016 Restated Agreement as of March 31, 2019.

Accounting Analysis

The Company's collaboration agreements with Takeda were terminated following receipt of written notices during the first quarter of 2019. As there are no further performance obligation, the Company recognized the remaining deferred revenue of $39,965 related to the termination of the Takeda agreements in the first quarter of 2019.

Prior to the termination of the agreements, the Company had identified 14 performance obligations in the agreements. The Company concluded that the license related to each of the designated targets was not distinct from the research services performed related to each of the designated targets as Takeda could not have obtain the benefit of the license without the related research services. Each license to a designated target and the related service performance obligation was considered distinct from every other license to a designated target and related services performance obligation as each research plan was pursued independent of the any other research plans for other designated targets. Further, the material rights provided were determined to be distinct from the other performance obligations in the arrangement as they were options in the contract Takeda agreements and not required for Takeda to obtain the benefit of the other promised goods or services in the arrangement. Similarly, the Company concluded that the XMT-1522 license and the related research and development services, including the Phase 1 development and the transfer of certain materials and know-how related to the Company's manufacturing processes, were one performance obligation. The license to the Company's intellectual property was not determined to be distinct from the research and related development services that the Company was obligated to perform. For the years ended December 31, 2019 and 2018, the Company recorded total revenue of $39,965 and $5,868, respectively, related to its efforts under the 2016 Restated Agreement and the XMT-1522 Agreement.

The Company concluded that the Post-Phase 1 Development activities under the XMT-1522 Agreement represented joint operating activities in which both parties were active participants and of which both parties were exposed to significant risks and rewards that are dependent on the commercial success of the activities. Accordingly, the Company accounted for the Post-Phase 1 Development activities in accordance with ASC 808. For the years ended December 31, 2019 and 2018, the Company was billed approximately $200 and $8,046, respectively, from Takeda representing Post-Phase 1 Development costs incurred by Takeda. These amounts have been reflected as research and development costs in the consolidated statement of operations. The Company did not perform any Post-Phase 1 Development activities or incur any associated costs prior to January 1, 2018. During the years ended December 31, 2019 and 2018, the Company billed Takeda $195 and $3,746, respectively, related to ASC 808 costs.

Summary of Contract Assets and Liabilities

The following table presents changes in the balances of our contract assets and liabilities during the years ended December 31, 2020 and December 31, 2019:

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Year ended December 31, 2020				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 4,815	$ —	$ 828	$ 3,987

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Year ended December 31, 2019				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 46,196	$ 210	$ 41,591	$ 4,815

During the year ended December 31, 2020, the Company recognized the following revenues as a result of changes in the contract asset and the contract liability balances in the respective periods.

	Year ended December 31,	
	2020	2019
Revenue recognized in the period from:		
Amounts included in the contract liability at the beginning of the period	$ 828	$ 41,591
Performance obligations satisfied in previous periods	$ —	$ —

Other Revenue

The Company has provided limited services for a collaboration partner, Asana BioSciences. For the years ended December 31, 2020, 2019 and 2018, the Company recorded revenue of $0, $25 and $782, respectively, related to these services. In addition, during the year ended December 31, 2018, the Company recognized revenue of $1,500 related to a milestone achieved upon the completion of a GLP toxicology study by Asana BioSciences. The next potential milestone the Company is eligible to receive is $2,500 upon dosing the fifth patient in a Phase 1 clinical study by Asana BioSciences. As of December 31, 2020, the Company considered this next milestone to be fully constrained as there is 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 is a high level of uncertainty in achieving this milestone, as this would require initiation of clinical trials by the collaboration partner. The Company reevaluates the probability of achievement of a milestone subject to constraint at each reporting period and as uncertain events are resolved or other changes in circumstances occur.

4. Fair Value Measurements

The following table presents information about the Company's assets and liabilities regularly measured and carried at a fair value and indicates the level within fair value hierarchy of the valuation techniques utilized to determine such value as of December 31, 2019. The Company had no marketable securities as of December 31, 2020:

	Fair Value	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2019				
Marketable securities:				
Commercial paper	$ 11,940	$ —	$ 11,940	$ —
Corporate bonds	12,010	—	12,010	—
U.S. Treasuries	13,489	13,489	—	—
	$ 37,439	$ 13,489	$ 23,950	$ —

There were no changes in valuation techniques or transfers between fair value measurement levels during the years ended December 31, 2020 and 2019.

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

As of December 31, 2020, the carrying value of the Company’s outstanding borrowing under the Credit Facility (as defined below) approximated fair value (a Level 2 fair value measurement), reflecting interest rates currently available to the Company. The Credit Facility is discussed more detail in Note 8, “Debt”.

5. Marketable Securities

The following table summarizes marketable securities held at December 31, 2019. The Company had no marketable securities as of December 31, 2020:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2019				
Commercial paper	$ 11,940	$ —	$ —	$ 11,940
Corporate bonds	11,990	20	—	12,010
U.S. Treasuries	13,484	5	—	13,489
	$ 37,414	$ 25	$ —	$ 37,439

6. Property and Equipment

Property and equipment consists of the following as of December 31, 2020 and 2019:

	December 31, 2020	December 31, 2019
Laboratory equipment	$ 6,520	$ 6,419
Leasehold improvements	1,886	1,886
Computer equipment and office equipment	959	1,068
Total property and equipment at cost	9,365	9,373
Less: Accumulated depreciation	(7,635)	(7,209)
	$ 1,730	$ 2,164

The Company recorded assets under finance leases of $429 as laboratory equipment during the year ended December 31, 2019. Financing leases are discussed in more detail in Note 11 “Leases”. Depreciation expense for the years ended December 31, 2020, 2019 and 2018 was $1,010, $1,245 and $1,257, respectively.

7. Accrued Expenses

Accrued expenses consist of the following as of December 31, 2020 and 2019:

	December 31, 2020	December 31, 2019
Accrued preclinical, manufacturing and clinical expenses	$ 9,902	$ 4,230
Accrued payroll and related expenses	5,412	4,037
Accrued professional fees	757	675
Accrued other	75	44
	$ 16,146	$ 8,986

8. Debt

On May 8, 2019, the Company entered into a loan and security agreement (the Original Agreement) with Silicon Valley Bank (SVB) pursuant to which the Company borrowed $5,000. The Original Agreement 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 Original Agreement had an interest-only period through August 31, 2020.

On August 28, 2020 (the Effective Date), the Company entered into a second amendment (the Amendment) to its existing loan and security agreement (as amended prior to the Amendment, the Existing Credit Facility) with SVB. Pursuant to the Amendment, the Company can borrow term loans in an aggregate amount of $30,000 (the Amended Credit Facility), at its option, (i) up to $25,000 in up to five principal advances through April 30, 2022, and (ii) an additional $5,000 in one principal advance, if the Company reaches certain development milestone events, as described in the Amendment, through April 30, 2022. The Company drew $5,200 upon execution of the Amendment, the proceeds of which were used to repay the Company’s existing balance and satisfy its obligations to SVB, including the final payment obligation under the Existing Credit Facility.

The Amended Credit Facility bears interest at a floating per annum rate equal to the greater of (i) 4.25% and (ii) 1.00% above the Prime Rate, as defined. The Company is obligated to make monthly interest-only payments on each outstanding term loan commencing on the first calendar day of the month following the funding date of such term loan, and continuing on the first calendar day of each month thereafter through May 31, 2022. The interest only period may be extended through January 31, 2023 upon the achievement of a regulatory milestone, as described in the Amendment. Following the interest-only period, the Company will be required to repay the outstanding principal balance under the term loans in equal monthly payments plus interest in arrears to SVB through November 1, 2024 (the Maturity Date).

The Company is also required to make a final payment to SVB equal to 5.5% 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 August 28, 2021, (b) 2.0% of the term loans then extended to the Company if the prepayment occurs after August 28, 2021 but on or prior to August 28, 2022, or (c) 1.0% of the term loans then extended to the Company if the prepayment occurs after August 28, 2022 but before November 1, 2024. The Amended 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 Amendment removed the requirement for the Company to maintain a minimum liquidity ratio. 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 Amended 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 SVB's demand and shall accrue interest at an additional rate of 5.0% per annum of the past due amount outstanding. As of December 31, 2020, the Company was in compliance with all covenants under the Credit Facility. As such, as of December 31, 2020, the classification of the loan balance as stated on the balance sheet was based on the timing of defined future payment obligations.

The unamortized issuance costs under the Existing Credit Facility were $139 as of the date of the Amendment. The Company incurred debt issuance costs paid to the lender in connection with the Amended Credit Facility of $17. The Company recorded such costs, including the settlement of the final payment obligation under the Existing Credit Facility as a discount from the carrying value of the term loans which are amortized as interest expense using the effective-interest method over the term of the Amended Credit Facility.

As of December 31, 2020, there was $5,200 outstanding under the Amended Credit Facility and the debt consisted of the following:

	December 31, 2020
Total debt	$ 5,200
Less: Current portion of long-term-debt	—
Total debt, net of current portion	5,200
Debt financing costs, net of accretion	(246)
Accretion related to final payment	23
Long-term debt, net	$ 4,977

As of December 31, 2020, the estimated future principal payments due are as follows:

2021	$ —
2022	1,213
2023	2,080
2024	1,907
Total debt	$ 5,200

During the year ended December 31, 2020 and 2019, the Company recognized $340 and $214, respectively, of interest expense related to the Existing Credit Facility and Amended Credit Facility, as applicable.

9. Stockholders' Equity

Preferred stock

As of December 31, 2020, the Company has 25,000,000 shares of authorized preferred stock. No shares of preferred stock have been issued.

At-the-market equity offering program

In July 2018, the Company established an at-the-market (ATM) equity offering program (the 2018 ATM) pursuant to which it could offer and sell up to $75,000 of its common stock from time to time at prevailing market prices. In April 2020, the Company sold 8,938,599 and 1,962,000 shares of common stock at $5.59 per share and $7.74 per share, respectively, to raise

aggregate gross proceeds of $65,153 through the 2018 ATM facility. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were approximately $62,976.

In May 2020, the Company terminated the 2018 ATM and established a new ATM equity offering program (the 2020 ATM) pursuant to which it is able to sell up to $100,000 of its common stock from time to time at prevailing market prices. As of December 31, 2020, the Company had not sold any shares under the 2020 ATM.

Follow-on offering

In June 2020, the Company sold 9,200,000 shares of common stock, in an underwritten public offering 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 $163,990.

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, 2020 and 2019 there were warrants to purchase 39,474 shares of common stock. During the year ended December 31, 2020, there were no exercises of warrants in exchange for shares of common stock.

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 Accounting Standards Codification 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 Accounting Standards Codification 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

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 (the Board).

As of December 31, 2020 and 2019 there were 6,869,189 and 7,782,582, respectively, shares of common stock reserved for the exercise of outstanding stock options and warrants.

	December 31, 2020	December 31, 2019
Stock options	6,112,948	4,720,772
Restricted stock units	716,767	447,336
Warrants	39,474	39,474
Exchange warrants	—	2,575,000
	6,869,189	7,782,582

10. Stock Options

Stock option plans

As of June 30, 2017, there were 3,141,625 options outstanding under the Company's 2007 Stock Incentive Plan. The 2007 Plan expired in June 2017. Any cancellations under the 2007 Stock Incentive Plan will increase the options available under the 2017 Stock Incentive Plan as described below.

In June 2017 the Company's shareholders approved the 2017 Stock Incentive Plan (the 2017 Plan or the Plan). Under the 2017 Plan initially, up to 2,255,000 shares of common stock may be granted to the Company's employees, officers, directors, consultants and advisors in the form of options, restricted stock units (RSUs) or other stock-based awards. The number of shares of common stock issuable under the Plan will be cumulatively increased annually by 4% of the outstanding shares or such lesser amount specified by the Board. The terms of the awards are determined by the Board, subject to the provisions of the Plan. As of December 31, 2020 there were 1,288,072 shares available for future issuance under the Plan, including 1,815,520 shares automatically added to the Plan on January 1, 2020.

Inducement awards

The Company granted its senior vice president of regulatory affairs an option to purchase up to 120,000 and its senior vice president and chief medical officer an option to purchase 200,000 shares of common stock on September 2, 2020 and November 30, 2020, respectively, as an inducement to employment in accordance with Nasdaq Listing Rule 5635(c)(4). No underwriters were involved in this issuance of securities. The securities were issued pursuant to Section 4(a)(2) under the Securities Act of 1933, as amended, relating to transactions by an issuer not involving any public offering. These options are subject to terms substantially the same as the 2017 Plan.

With respect to incentive stock options, the exercise price per share will equal the fair market value of the common stock on the date of grant, as determined by the Board, and the vesting period is generally four years. Nonqualified stock options will be granted at an exercise price established by the Board at its sole discretion (which has not been less than fair market value on the date of grant) and the vesting periods may vary. Options granted under the Plan expire no later than 10 years from the date of grant. The Board may accelerate vesting or extend the expiration of granted options in the case of a merger, consolidation, dissolution, or liquidation of the Company.

Stock option activity

A summary of the activity under the Plan is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2020	4,720,772	$ 5.24	7.3	$ 9,836
Granted	2,359,074	11.96		
Exercised	(697,428)	4.50		
Cancelled	(269,470)	7.05		
Outstanding at December 31, 2020	6,112,948	$ 7.84	7.3	$ 114,729
Exercisable at December 31, 2020	3,147,379	$ 5.14	6.1	$ 67,562

The weighted-average grant date fair value of options granted during the years ended December 31, 2020, 2019 and 2018, was $7.99, $2.47 and $8.78 per share, respectively.

Cash received from the exercise of stock options was $3,138, $175 and $918 for the years ended December 31, 2020, 2019 and 2018, respectively.

Restricted stock units

In July 2019, the Company issued RSUs with service conditions to employees. The awards cliff-vest two years after the grant date. In January 2020, the Company issued 324,932 RSUs with a service condition to employees for which the vesting term is annually over four years. Vesting of these awards is contingent on the fulfillment of the service conditions during the vesting term.

A summary of the RSU activity under the 2017 Plan is as follow:

	Number of Shares	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2020	447,336	1.5	$ 2,564	$ 4.00
Granted	361,932	—		8.14
Vested	—	—		—
Forfeited	(92,501)	—		4.68
Unvested at December 31, 2020	716,767	1.0	$ 19,073	$ 6.00

Stock-based compensation expense

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

The measurement date for employee awards is generally the date of grant. 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 statement of operations and comprehensive loss:

	Year ended December 31,		
	2020	2019	2018
Stock options	$ 5,725	$ 4,230	$ 3,754
Restricted stock units	1,187	410	—
Employee stock purchase plan	260	232	130
Stock-based compensation expense included in Total operating expenses	$ 7,172	$ 4,872	$ 3,884

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,		
	2020	2019	2018
Research and development	$ 3,841	$ 2,245	$ 1,788
General and administrative	3,331	2,627	2,096
Stock-based compensation expense included in Total operating expenses	$ 7,172	$ 4,872	$ 3,884

As of December 31, 2020, there was $19,487 and $2,699 of unrecognized compensation expense related to unvested stock options and unvested RSUs, respectively, that is expected to be recognized over a weighted average period of 2.8 years and 2.3 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,		
	2020	2019	2018
Risk-free interest rate	1.2 %	2.3 %	2.7 %
Expected dividend yield	— %	— %	— %
Expected term (years)	6.05	5.99	6.07
Expected stock price volatility	74 %	74 %	73 %

Expected volatility for the Company's common stock is determined based on 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.

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. During the years ended December 31, 2020 and 2019 the Company issued 80,267 and 140,073 shares, respectively, under the 2017 ESPP. As of December 31, 2020, there were 644,818 shares available for issuance, including 450,000 shares automatically added to the 2017 ESPP on January 1, 2020.

11. Leases

The Company has an operating lease for its office space in Cambridge, MA and operating and finance leases for certain equipment. In March 2020, the Company entered into the Seventh Amendment to the office space lease to extend the term of the lease through March 2026 and to provide the Company with a tenant improvement allowance of $172. The current rate per square foot that is in place through March 2021 (the original expiration date of the lease) did not change. After March 2021, there are predetermined fixed escalations of the rate as outlined in the amendment. The Company has an option to extend the lease term for an additional five years. The Company's exercise of this option was not considered reasonably certain as of December 31, 2020.

The extension is accounted for as a lease modification. The Company assessed the lease classification of the amended office space lease at the modification date and determined that the amended office space lease should be accounted for as an operating lease. The right-of-use asset and corresponding operating lease liability have been remeasured based on the present value of remaining lease payments over the remaining extended lease term, using the incremental borrowing rate applicable as of the lease modification date. The Company determined the appropriate incremental borrowing 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 right-of-use asset and liability and are reflected as an expense in the period incurred.

As a result of the modification in March 2020, the Company recorded an increase of $9,980 to its right-of-use (ROU) asset and lease liabilities in the first quarter of 2020.

In connection with the office lease, the Company had a letter of credit agreement for the benefit of its landlord in the amount of $321 as of each December 31, 2020 and 2019, collateralized by a money market account.

During the first quarter of 2019, the Company entered into finance leases for certain equipment. The Company recorded assets under finance leases of $429 as property and equipment.

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

The components of lease expense were as follows:

	Year ended December 31,	
	2020	2019
Operating lease cost	$ 2,755	$ 2,160
Finance lease cost:		
Amortization of right-of-use assets	$ 176	$ 75
Interest on lease liabilities	21	20
	$ 197	$ 95

Supplemental balance sheet information related to leases was as follows:

	Year ended December 31,	
	2020	2019
Operating leases:		
Operating lease right-of-use assets	$ 10,936	$ 2,598
Operating lease liabilities, current	1,437	2,219
Operating lease liabilities	10,158	677
Finance leases:		
Property and equipment, gross	$ 429	$ 429
Property and equipment, accumulated depreciation	(176)	(75)
Other liabilities, current	93	87
Other liabilities	174	275
Weighted-average remaining lease term:		
Operating leases	5.2 years	1.3 years
Finance leases	2.9 years	3.7 years
Weighted-average discount rate:		
Operating leases	10.8 %	10.3 %
Finance leases	6.9 %	6.9 %

Supplemental cash flow information related to leases was as follows:

	Year ended December 31,	
	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 2,394	$ 2,271
Operating cash flows from finance leases	21	20
Financing cash flows from finance leases	116	87

Rent expense was $2,644, $2,160 and $1,994 for the years ended December 31, 2020, 2019 and 2018, respectively.

Future minimum lease payments under non-cancellable leases as of December 31, 2020 were as follows:

	Operating leases	Finance leases
2021	$ 2,772	$ 116
2022	2,843	84
2023	2,928	74
2024	3,016	18
2025 and thereafter	3,888	—
Total lease payments	15,447	292
Present value adjustment	(3,854)	(25)
Present value of lease liabilities	$ 11,593	$ 267

12. Income Taxes

For the years ended December 31, 2020, 2019 and 2018, the Company recorded no income tax benefit for the net operating losses incurred in each year, due to its uncertainty of realizing a benefit from those items.

A reconciliation of income taxes computed using the U.S. federal statutory rate to that reflected in operations as of December 31, 2020, 2019 and 2018 are as follows:

	2020	2019	2018
Income tax computed at federal statutory tax rate	21.0 %	21.0 %	21.0 %
State taxes, net of federal benefit	6.7 %	6.1 %	6.5 %
Permanent differences	1.2 %	(2.0)%	0.6 %
General business credits	3.4 %	10.3 %	4.2 %
Impact of ownership shift	— %	(53.3)%	— %
Change in valuation allowance	(32.3)%	17.9 %	(32.3)%
	— %	— %	— %

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, 2020 and 2019 are as follows:

	2020	2019
Deferred tax assets:		
Net operating losses	$ 64,259	$ 40,554
Tax credit carryforwards	5,670	2,448
Accrued expenses	4,058	2,520
Lease liabilities	3,166	791
Licensed technology	1,534	1,402
Deferred revenue	1,088	1,315
Depreciation	502	492
Other	84	77
Total gross deferred tax assets	80,361	49,599
Valuation allowance	(77,375)	(48,889)
Net deferred tax assets less valuation allowance	2,986	710
Deferred tax liabilities		
Right-of-use assets	(2,986)	(710)
Total gross deferred tax liabilities	(2,986)	(710)
Net deferred taxes	$ —	$ —

The Company has incurred net operating losses (NOL) since inception. At December 31, 2020, the Company had Federal and State net operating loss carryforwards of approximately $250,367 and $184,781, respectively. Of the $250,367 of Federal net operating loss carryforwards, $34,149 expire at various dates through 2037. The remaining $216,218 of Federal net operating loss carryforwards do not expire. The State net operating loss carryforwards expire at various dates through 2040. At December 31, 2020, the Company had Federal and State research and development tax credit carryforwards of approximately $4,582 and $1,482, respectively, which expire at various dates through 2040.

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 $77,375 and $48,889 at December 31, 2020 and December 31, 2019, respectively. The valuation allowance increased by $28,468 and decreased by $5,051 during the years ended December 31, 2020 and 2019, respectively, primarily as a result of the Company's 382 limitation and net operating losses generated during the periods, respectively.

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 through November 4, 2019 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, 2020 and 2019, 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, 2020 and 2019, 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 two state jurisdiction. The Company did not have any foreign operations during the years ended December 31, 2020, 2019 and 2018. The statute of limitations for assessment by the Internal Revenue Service and state tax authorities is closed for tax years prior to 2016, although carryforward attributes that were generated prior to tax year 2015 may still be adjusted upon examination to the extent utilized in a future period. There are no federal or state audits currently in progress.

13. 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 are eligible to participate in the 401(k) Plan with no service requirement. Employees may contribute up to 75% of eligible pay on a pre–tax basis up to the federal annual limits. For the year ended December 31, 2018 and the period from January 1, 2019 to July 31, 2019, the Company matched the employees' contributions at 50% on the first 6% up to $6. For the period from August 1, 2019 to December 31, 2019 and for the year ended December 31, 2020, the Company matched the employees' contributions at 100% on the first 4% up to $7. For the years ended December 31, 2020, 2019 and 2018, the Company recorded expense of $486, $404 and $332, respectively, related to its contribution to its 401(k) Plan.

14. Commitments

License Agreements

During the years ended December 31, 2020, 2019 and 2018, the Company recorded research and development expense related to non-refundable upfront payments of $250, $750, and $0, respectively. Further milestone payments of $750, $600 and $0, respectively, were also recorded as research and development expense during the years ended December 31, 2020, 2019 and 2018.

See Note 11 for the Company's future obligations related to leases as of December 31, 2020.

15. Selected Quarterly Financial Data (unaudited)

The following table contains selected quarterly financial information for 2020 and 2019. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

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

	Three months ended			
	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020
Collaboration revenue	$ 11	$ 796	$ 11	$ 10
Operating expenses:				
Research and development	12,219	15,413	16,546	22,858
General and administrative	4,936	5,171	5,881	5,914
Total operating expenses	17,155	20,584	22,427	28,772
Other income:				
Interest income	306	89	19	10
Interest expense	(88)	(87)	(92)	(92)
Total other income (expense), net	218	2	(73)	(82)
Net loss	$ (16,926)	$ (19,786)	$ (22,489)	$ (28,844)
Net loss per share attributable to common stockholders — basic and diluted	$ (0.35)	$ (0.33)	$ (0.33)	$ (0.42)
Weighted-average number of common shares used in net loss per share attributable to common stockholders — basic and diluted	47,988,630	60,748,225	68,419,192	68,630,078

	Three months ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Collaboration revenue	$ 41,035	$ 202	$ 844	$ 42
Operating expenses:				
Research and development	15,143	13,766	13,701	12,430
General and administrative	4,443	4,192	4,436	4,212
Total operating expenses	19,586	17,958	18,137	16,642
Other income:				
Interest income	452	725	608	441
Interest expense	—	(40)	(107)	(87)
Total other income (expense), net	452	685	501	354
Net income (loss)	$ 21,901	$ (17,071)	$ (16,792)	$ (16,246)
Net income (loss) per share attributable to common stockholders — basic	$ 0.72	$ (0.36)	$ (0.35)	$ (0.34)
Net income (loss) per share attributable to common stockholders — diluted	$ 0.70	$ (0.36)	$ (0.35)	$ (0.34)
Weighted-average number of common shares used in net income (loss) per share attributable to common stockholders — basic	30,299,650	47,708,085	47,833,607	47,886,144
Weighted-average number of common shares used in net income (loss) per share attributable to common stockholders — diluted	31,461,696	47,708,085	47,833,607	47,886,144

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Management's Evaluation of our Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (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, 2020, 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. 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, 2020. 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, 2020, our internal control over financial reporting is effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is included herein.

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, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control over Financial Reporting

We have audited Mersana Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Mersana Therapeutics, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the 2020 consolidated financial statements of the Company and our report dated February 26, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, 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.

/s/ Ernst & Young LLP
Boston, Massachusetts
February 26, 2021

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders and is incorporated here by reference.

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

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Financial Statements

For a list of the consolidated financial statements included herein, see Index to the Consolidated Financial Statements in this Annual Report on Form 10-K, which is incorporated into this Item by reference.

Financial Statement Schedules

No financial statement schedules have been submitted 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.

Exhibits

See the Exhibit Index immediately before the signature page of this Annual Report on Form 10-K. The exhibits listed in the Exhibit Index are filed or incorporated by reference as part of this Annual Report on Form 10-K.

ITEM 16. FORM 10-K SUMMARY

None.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
3.1	Fifth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, File No. 001-38129, filed on July 10, 2017).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, File No. 001-38129, filed on July 10, 2017).
4.1	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.1 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
4.2	Third Amended and Restated Investor Rights Agreement, dated as of June 15, 2016, by and among Mersana Therapeutics, Inc. and the Stockholders listed therein (incorporated by reference to Exhibit 4.2 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
4.3	Form of Exchange Warrant (incorporated by reference to Exhibit 4.1 to the Company's Form 8-K, File No. 001-38129, filed on November 27, 2019).
4.4	Description of Registrant's Common Stock (incorporated by reference to Exhibit 4.4 to the Company's Form 10-K, File No. 001-38129, filed on February 28, 2020).
10.1†	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Company's Form S-1/A, File No. 333-218412, filed 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 Company's Form S-1, File No. 333-218412, filed 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 Company's Form 10-Q, File No. 001-38129, filed on May 8, 2020).
10.4+	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 Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
10.5+	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 Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
10.6+	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 Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
10.7+	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 Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
10.8	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 Company's Form 10-Q, File No. 001-38129, filed on August 14, 2018).
10.9+	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 Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
10.10	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 Company's Form 10-Q, File No. 001-38129, filed on November 6, 2019).

10.11+	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 Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
10.12+	Collaboration Agreement, dated as of July 25, 2012, by and between Adimab, LLC and Mersana Therapeutics, Inc. (incorporated by reference to Exhibit 10.10 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
10.13+	Amendment Number One to the Collaboration Agreement, dated February 21, 2013, by and between Adimab, LLC and Mersana Therapeutics, Inc. (incorporated by reference to Exhibit 10.11 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
10.14+	Amendment Number One, to the Collaboration Agreement dated June 17, 2014, by and between Adimab, LLC and Mersana Therapeutics, Inc. (incorporated by reference to Exhibit 10.12 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
10.15	Second Amendment to Amended and Restated Research Collaboration and Commercial License Agreement, as amended, dated August 2, 2017 by and between Mersana Therapeutics, Inc. and Millennium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q, File No. 001-38129, filed on August 11, 2017).
10.16	Third Amendment to the Amended and Restated Research Collaboration and Commercial License Agreement, as amended, dated October 30, 2017 by and between Mersana Therapeutics, Inc. and Millennium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q, file No. 001-38129, filed on November 13, 2017).
10.17	Exchange Agreement, dated November 26, 2019, by and between Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS, L.P. and Mersana Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K, File No. 001-38129, filed on November 27, 2019).
10.18	Loan and Security Agreement, dated May 8, 2019, by and between Silicon Valley Bank and Mersana Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q, File No. 001-38129, filed on May 9, 2019).
10.19	First Amendment to the Loan and Security Agreement, dated June 21, 2019 by and between Silicon Valley Bank and Mersana Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q, File No. 001-38129, filed on August 8, 2019).
10.20	Second Amendment to Loan and Security Agreement, dated August 28, 2020, by and between Mersana Therapeutics, Inc., and Silicon Valley Bank (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, File No. 001-38129, filed on September 3, 2020).
10.21†	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 Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
10.22†	Offer Letter, by and between Mersana Therapeutics, Inc. and Dirk Huebner, dated November 5, 2018 (incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q, File No. 001-38129, filed on May 8, 2020).
10.23†	Offer Letter, by and between Mersana Therapeutics, Inc. and Brian DeSchuytner, dated June 10, 2019 (incorporated by reference to Exhibit 10.3 to the Company's Form 10-Q, File No. 001-38129, filed on May 8, 2020).
10.24†	2007 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.19 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
10.25†	Form of Incentive Stock Option under the 2007 Stock Incentive Plan (incorporated by reference to Exhibit 10.20 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
10.26†	Form of Nonqualified Stock Option under the 2007 Stock Incentive Plan (incorporated by reference to Exhibit 10.21 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017).

10.27†	2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.22 to the Company's Form S-1/A, File No. 333-218412, filed on June 16, 2017).
10.28†	Form of Incentive Stock Option under the 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.23 to the Company's Form S-1/A, File No. 333-218412, filed on June 16, 2017).
10.29†	Form of Nonqualified Stock Option under the 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.24 to the Company's Form S-1/A, File No. 333-218412, filed on June 16, 2017).
10.30†	2017 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.25 to the Company's Form S-1/A, File No. 333-218412, filed on June 16, 2017).
10.31†	2017 Cash Bonus Plan (incorporated by reference to Exhibit 10.26 to the Company's Form S-1/A, File No. 333-218412, filed on June 16, 2017).
21.1*	Subsidiaries of Mersana Therapeutics, Inc.
23.1*	Consent of Ernst & Young LLP.
31.1*	Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Chief Executive Officer.
31.2*	Certification pursuant to Section 302 of Sarbanes Oxley Act of 2002 by Principal Financial Officer.
32.1**	Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Chief Executive Officer and Principal Financial Officer.
101	The following financial and related information from Mersana Therapeutics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline eXtensible Business Reportable Language (iXBRL) includes: (i) the Consolidated Balance Sheet; (ii) the Consolidated Statement of Operations and Comprehensive Loss; (iii) the Consolidated Statement of Changes in Stockholders' Equity; (iv) the Consolidated Statement of Cash Flows; and, (v) Notes to Consolidated Financial Statements.
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL (contained in Exhibit 101).

* Filed herewith.
** Furnished herewith.
† Indicates a management contract or compensatory plan.
+ Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been submitted separately to the Securities and Exchange Commission.

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 26, 2021

/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 26, 2021
/s/ BRIAN DESCHUYTNER Brian DeSchuytner	Senior Vice President, Finance & Product Strategy (Principal Financial Officer)	February 26, 2021
/s/ ASHISH MANDELIA Ashish Mandelia	Vice President, Controller (Principal Accounting Officer)	February 26, 2021
/s/ DAVID MOTT David Mott	Chairman of the Board	February 26, 2021
/s/ KRISTEN HEGE Kristen Hege, M.D.	Director	February 26, 2021
/s/ ANDREW A. F. HACK Andrew A. F. Hack, M.D., Ph.D.	Director	February 26, 2021
/s/ LAWRENCE M. ALLEVA Lawrence M. Alleva	Director	February 26, 2021
/s/ WILLARD H. DERE, M.D. Willard H. Dere, M.D.	Director	February 26, 2021
/s/ MARTIN H. HUBER, M.D. Martin H. Huber, M.D.	Director	February 26, 2021

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. 333-238140) of Mersana Therapeutics, Inc. and in the related Prospectus,
(2) 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,
(3) 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,
(4) Registration Statement (Form S-8 No. 333-222845) pertaining to the Mersana Therapeutics, Inc. 2017 Stock Incentive Plan, and
(5) 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 26, 2021, with respect to the consolidated financial statements of Mersana Therapeutics, Inc. and the effectiveness of internal control over financial reporting of Mersana Therapeutics, Inc. included in this Annual Report (Form 10-K) of Mersana Therapeutics, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 26, 2021

Exhibit 31.1

CERTIFICATIONS

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 26, 2021

By: /s/ Anna Protopapas

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

Exhibit 31.2

CERTIFICATIONS

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 26, 2021

By: /s/ Brian DeSchuytner

Brian DeSchuytner
Senior Vice President, Finance & Product Strategy
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS OF CEO AND CFO 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, 2020 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 26, 2021

By: /s/ Anna Protopapas

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

Date: February 26, 2021

By: /s/ Brian DeSchuytner

Brian DeSchuytner
Senior Vice President, Finance & Product Strategy
(Principal Financial Officer)