

**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, 2018.

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

(State or Other Jurisdiction of Incorporation or Organization)

04-3562403

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

840 Memorial Drive Cambridge, MA
(Address of Principal Executive Offices)

02139
(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	Name of each exchange on which registered
Common Stock \$0.0001 par value	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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§299.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of June 30, 2018, 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 \$262,605,135, based on the last reported sale price of such stock on the Nasdaq Global Select Market as of such date.

As of March 7, 2019, the registrant had 47,684,164 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 2019 Annual Meeting of Stockholders are incorporated by reference in Part III.

TABLE OF CONTENTS

	Page
<u>PART I</u>	
FORWARD LOOKING STATEMENTS	2
ITEM 1. BUSINESS	2
ITEM 1A. RISK FACTORS	32
ITEM 1B. UNRESOLVED STAFF COMMENTS	68
ITEM 2. PROPERTIES	68
ITEM 3. LEGAL PROCEEDINGS	68
ITEM 4. MINE SAFETY DISCLOSURES	68
<u>PART II</u>	
ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES	69
ITEM 6. SELECTED FINANCIAL DATA	70
ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	72
ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	86
ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA	87
ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	119
ITEM 9A. CONTROLS AND PROCEDURES	119
ITEM 9B. OTHER INFORMATION	120
<u>PART III</u>	
ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE	121
ITEM 11. EXECUTIVE COMPENSATION	121
ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS	121
ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE	121
ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES	121
<u>PART IV</u>	
ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES	122
ITEM 16. FORM 10-K SUMMARY	122
EXHIBIT INDEX	122
SIGNATURES	126

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 “anticipate,” “believe,” “estimate,” “expect,” “goal,” “intend,” “may,” “seek,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “possible,” “could,” “should,” “continue,” “contemplate” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

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

- the initiation, cost, timing, progress and results of our current and future research and development activities, preclinical studies and clinical trials;
- the timing of, and our ability to obtain and maintain, regulatory approvals for our product candidates;
- our ability to quickly and efficiently identify and develop additional product candidates;
- our ability to advance any product candidate into, and successfully complete clinical trials;
- our intellectual property position, including with respect to our trade secrets;
- the potential benefits of strategic partnership agreement and our ability to enter into selective strategic partnerships; and
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing.

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

The forward-looking statements contained herein represent our views as of the date of this Annual Report on Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, although we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. 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.

ITEM 1. BUSINESS

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 20 years of industry learning in the ADC field to develop proprietary technologies that enable us to design ADCs to have improved efficacy, safety and tolerability relative to existing ADC therapies. Our most advanced platform, Dolaflexin, has been used to generate a pipeline of proprietary ADC product candidates to address patient populations that are not currently amenable to treatment with traditional ADC-based therapies. Our lead product candidate, XMT-1536, is an ADC targeting NaPi2b,

[Table of Contents](#)

an antigen broadly expressed in ovarian cancer and non small cell lung cancer, or NSCLC. The first patient was dosed on XMT-1536 in late 2017 and the study is currently in Phase 1 dose escalation in ovarian cancer, NSCLC, and other orphan indications where a majority of patients express NaPi2b, including endometrial, papillary renal, papillary thyroid, and salivary duct. We plan to select a dose for use in the Phase 1 expansion studies and report data from the dose escalation study in the second quarter of 2019. Following dose escalation and establishment of a go forward dose we plan to expand into patient cohorts aimed at establishing proof of concept in platinum resistant ovarian cancer and NSCLC adenocarcinoma.

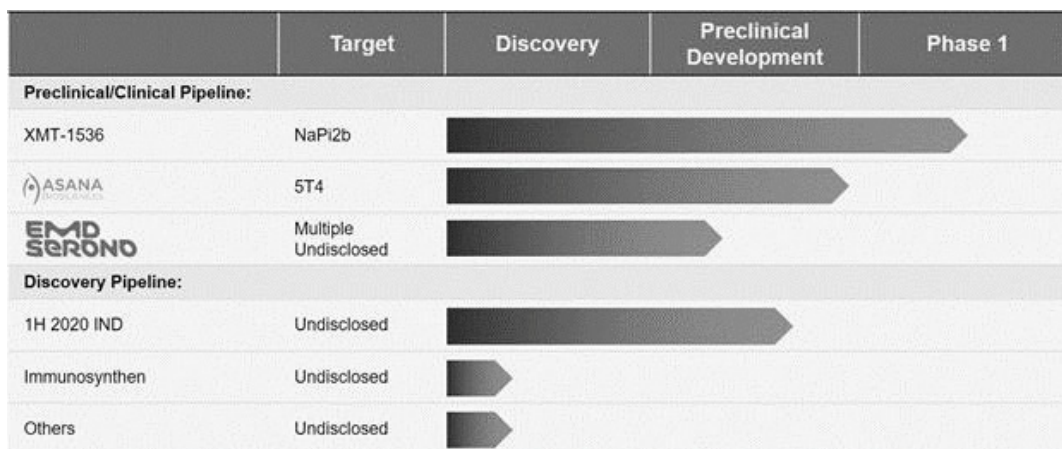
Beyond XMT-1536 and our Dolaflexin platform, we continue to work to identify earlier stage product candidates employing the platforms described below, and to advance our ADC platform technologies. We are leveraging our expertise to advance platform innovations that further expand the potential of our ADCs to deliver clinically meaningful benefit for cancer patients.

- *Dolasynten* is designed to be a novel, proprietary, homogeneous payload platform enabling the creation of ADCs with the ability to provide drug to antibody ratios, or DARs, ranging from 2-24.
- *Immunosynthen*, our emerging platform, is designed to be a novel, proprietary, immunostimulatory payload platform with the potential to create ADCs that can ideally address the challenge of systemic delivery and tolerability of immunomodulatory payloads.
- *Alkymer*, our DNA alkylation platform, has the potential to provide a broad therapeutic index for a DNA alkylating payload mechanism, and broaden addressable tumor indications to include those that are not responsive to anti-tubulin agents.

We plan to disclose the progress on the development of our platforms throughout 2019 and expect to announce our next ADC clinical candidate in the second half of 2019.

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 develop targeted and highly tailored therapies to help cancer patients become cancer survivors.

Our current pipeline is summarized in the chart below:



ADC Background

ADCs are an established therapeutic approach in oncology used to selectively deliver a highly potent chemotherapeutic payload directly to tumors thereby minimizing toxicity to surrounding healthy tissue. An ADC consists of an antibody attached to a “payload” via a molecule known as a linker. The antibody provides targeting capability against a distinct antigen expressed preferentially on a tumor cell, which results in the ADC binding only to those cells that express the target antigen. Upon binding to the tumor cell antigen, the ADC is internalized by the tumor cell and the payload is released, killing the cell in a targeted manner.

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:** Increases in the number of payload molecules delivered per antibody internalization event increases potency. However, the 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 ADC-based approaches, as the use of ADCs requires antigen targets to be highly expressed on tumor cells.
- **Bystander effect:** A released payload that is able to diffuse into and kill neighboring tumor cells, irrespective of antigen expression, is known as having a “bystander effect.” While the bystander effect has been shown to improve efficacy by killing adjacent tumor cells, it is also associated with indiscriminate healthy cell killing, which leads to dose limiting toxicities, such as neutropenia.

Our proprietary and highly differentiated Dolaflexin platform is designed to overcome these challenges and potentially achieve improved efficacy, safety and tolerability, hence improving the therapeutic index, compared to traditional ADC technologies. Unlike traditional ADCs, where the payload is attached directly to the antibody via a linker, our ADCs feature antibodies attached to multiple units of Dolaflexin, which each consist of our Fleximer polymer scaffold conjugated to several proprietary auristatin payload molecules. As a result, we believe our ADCs have the potential to offer the following benefits relative to traditional ADCs:

- **Improved linker stability:** Fleximer is a biodegradable, highly biocompatible and highly water soluble polymer scaffold. Fleximer creates a highly hydrophilic microenvironment, which protects the linker and the payload and results in a highly stable ADC in circulation. We have demonstrated in non-human primates that an ADC utilizing Dolaflexin is highly stable, with less than 0.05% of free payload detected in circulation.
- **Higher drug-to-antibody ratio:** The hydrophilic microenvironment of Fleximer shields the highly hydrophobic payload molecules and allows the ADC to achieve a DAR of 10 to 15 while maintaining acceptable pharmacokinetics and drug-like properties in animal models. In multiple preclinical models, our lead product candidate, XMT-1536, which is based on the Dolaflexin platform, has demonstrated that higher DAR results in

a significant increase in efficacy relative to traditional ADCs administered at comparable or even higher dose levels.

- **Expanded range of addressable target antigen expression levels:** As a result of higher DAR, our ADCs can deliver more payload to the tumor cell per antibody binding and internalization event. As a result, in preclinical models we have shown efficacy against tumors with lower levels of antigen expression. Our lead product candidate, XMT-1536, has demonstrated efficacy in animal models of low antigen-expressing tumors where alternative ADC platforms have shown either weak or no efficacy.
- **Controlled bystander effect:** We have designed our proprietary auristatin payload, used in the Dolaflexin platform, with a feature, referred to as DolaLock, that allows us to capture the benefits of the bystander effect while minimizing potential toxicities to healthy tissue. Specifically, the initial payload released from the ADC in the tumor is capable of a bystander effect. However, as the payload is metabolized over time, it loses the ability to diffuse into neighboring cells and becomes trapped in the cell, preventing further diffusion into healthy tissues.

The benefits of the Dolaflexin platform have resulted in tolerable doses in our preclinical models well in excess of the efficacious doses. Based on these findings, we have advanced XMT-1536 into Phase 1 development. 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.

We have assembled a management team with extensive, relevant experience, including specific ADC experience, from prior work at leading pharmaceutical companies such as Millennium Pharmaceuticals, Inc., Takeda, Biogen, Inc., MedImmune, Inc., Bayer AG, Genzyme and Vertex Pharmaceuticals, Inc. 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 platform, together with the team we have assembled, positions us well to generate best in class ADCs with the potential to transform the lives of cancer patients.

Our strategy

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

- **Rapidly advance the clinical development of XMT-1536.** Our lead product candidate, XMT-1536, is an ADC targeting NaPi2b and has demonstrated significant anti-tumor activity in preclinical models of ovarian cancer and NSCLC. XMT-1536 is currently in a Phase 1 dose escalation study in ovarian cancer and NSCLC and other orphan indications where a majority of patients express NaPi2b including papillary thyroid, papillary renal, endometrial, salivary duct. We plan to report data from the dose escalation portion of the study in the second quarter of 2019. Following dose escalation and establishment of a recommended go forward dose we plan to expand into cohorts aimed at establishing proof-of-concept in platinum resistant serous ovarian cancer and NSCLC adenocarcinoma.
- **Expand our ADC technology platform capabilities and build a pipeline of ADC candidates that address the significant unmet medical needs of cancer patients.** 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. Our areas of focus include the development of alternative scaffolds to drive homogeneity of our ADCs, alternative payloads to address additional indications and drug resistance. We believe these efforts may lead to the development of a robust pipeline of ADC candidates with improved efficacy and tolerability that have the potential to expand the addressable patient population.
- **Evaluate 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.

- **Attract and retain people that share our commitment to scientific excellence and patient care.** 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.

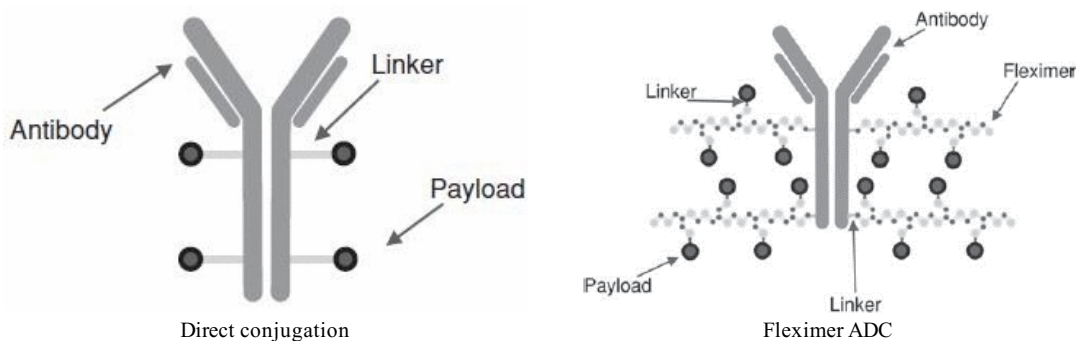
Our ADC technology platforms

ADCs for cancer traditionally consist of an antibody attached to a chemotherapeutic “payload” via a linker. The antibody provides targeting capability against a distinct antigen selectively expressed on a tumor cell, resulting in the ADC binding only to those cells that express the target antigen. Upon binding to the antigen, the ADC is internalized by the tumor cell and the payload is released through either cleavage of the linker or degradation of the antibody. Cell death results once the threshold level of payload has been internalized by the target cell. The individual components of an ADC dictate the efficacy, safety and tolerability of the treatment. Historically, ADC development has involved making compromises between features which may improve efficacy at the expense of safety and tolerability, and vice versa. The challenge of optimizing this balance is exemplified by the dearth of approved ADC products, despite the technology having existed for over 20 years.

Dolaflexin platform

Our proprietary and highly differentiated Dolaflexin platform is designed to increase the efficacy, safety and tolerability of ADCs by overcoming key limitations of existing technologies based on direct conjugation. Dolaflexin consists of Fleximer, a biodegradable, highly biocompatible, water soluble polymer, to which are attached multiple copies of our proprietary auristatin drug payload, using a linker specifically optimized for use with our polymer. The high water solubility of the Fleximer polymer compensates for the low solubility of the payload, surrounding the payload and protecting it from aggregation. Multiple copies of this Dolaflexin polymer-drug conjugate can then be attached to an antibody of choice, which significantly increases the payload capacity of the resulting ADC. As shown in the schematic in Figure 2, this approach differs from most other ADC technologies where the payload is directly conjugated to the antibody via a linker. Using the Dolaflexin platform, we have been able to generate ADCs with DAR between 10 to 15 while maintaining acceptable pharmacokinetics and drug-like properties in animal models. This represents a three to four fold increase in DAR relative to the traditional ADC approach.

Figure 2.

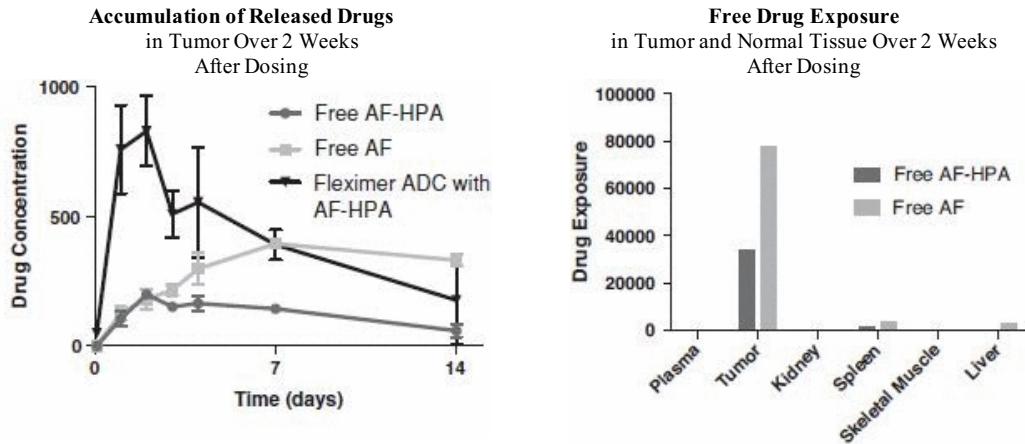


[Table of Contents](#)

Below is a summary of key advantages that we believe our proprietary Dolaflexin platform offers over other existing ADC technologies. We believe these properties will enable us to develop ADCs with an improved therapeutic index that may broaden the scope of addressable cancer patients for which ADC therapies are amenable.

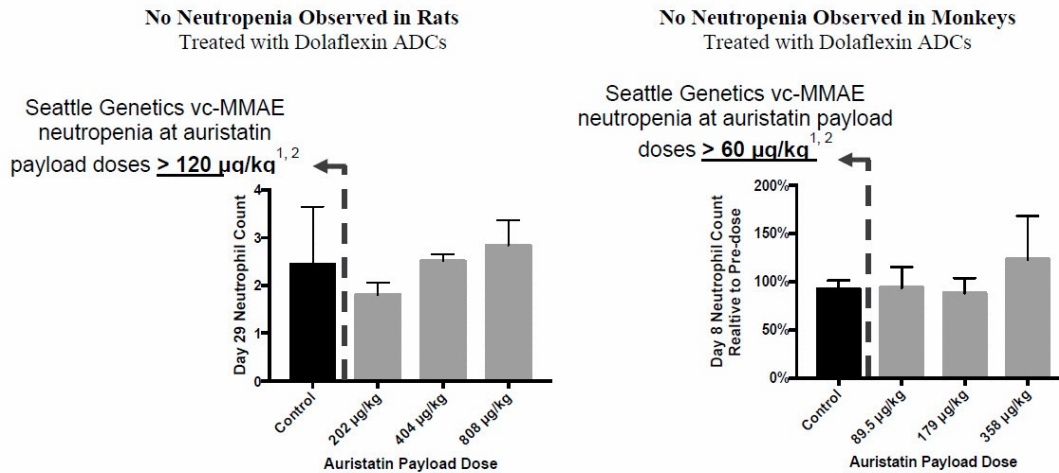
- **Improved linker stability:** There are two important linkers contributing to the stability of a Dolaflexin ADC: a non-cleavable linker attaching the Fleximer to the antibody and a cleavable linker attaching the payload to the Fleximer. The Fleximer provides for a highly hydrophilic and homogeneous microenvironment that stabilizes the payload-linker in circulation. However, the cleavable nature of the payload-linker results in rapid release of the payload upon internalization into the tumor cell.
- **Higher drug-to-antibody ratio:** Dolaflexin consists of Fleximer conjugated to up to four molecules of our proprietary auristatin payload. Our ADCs typically consist of three to four Dolaflexin units attached to each antibody, which allows us to achieve significantly higher DAR compared to other ADC approaches. For example, our lead proprietary product candidate, XMT-1536, can carry between 10 to 15 payload molecules per antibody, which we believe will result in greater efficacy than traditional ADCs with a lower DAR. Importantly, Fleximer is extremely water soluble, which helps maintain the pharmacokinetics and drug-like qualities of the ADC in animal models even at relatively high DARs.
- **Expanded range of addressable antigen expression levels:** The higher DAR enabled by our Dolaflexin platform results in more chemotherapeutic payload being released into the tumor cell for every binding and internalization event. As a result, we have demonstrated in animal models that Dolaflexin ADCs have efficacy against tumors with lower levels of antigen expression where traditional ADCs have not been effective.
- **Controlled bystander effect:** Our proprietary auristatin chemotherapeutic drug payload, has been specifically designed to maintain efficacy while improving safety and tolerability compared to payloads used in conventional ADCs. Upon internalization of the ADC into the tumor cell, cleavage of the linker occurs to release Auristatin F-hydroxypropylamide, or AF-HPA, as the primary chemotherapeutic payload. AF-HPA is a highly potent, freely cell-permeable anti-tubulin agent, which readily kills rapidly dividing tumor cells but is not toxic to non-dividing cells. Since AF-HPA is freely cell-permeable, it can diffuse into adjacent tumor cells and kill them in an antigen-independent manner through the bystander effect. However, release of AF-HPA into the systemic circulation can also lead to toxicity if taken up by normal healthy cells. To counteract this, our proprietary auristatin payload has been engineered with the DolaLock feature that causes AF-HPA to convert into the non-cell permeable chemotherapeutic, auristatin F, or AF, when metabolized over time inside the cell. While AF can still kill dividing cells if generated intracellularly, it is approximately 8-fold less potent than AF-HPA at killing dividing cells when outside the cell. Consistent with this, AF was significantly better tolerated than AF-HPA in rat safety studies. Figure 3 shows the accumulation of AF-HPA and its metabolite, AF, in a mouse tumor model demonstrating the conversion over time of AF-HPA to AF, the trapping of free AF in the tumor cells and its almost negligible accumulation in healthy tissues.

Figure 3. Accumulation of AF-HPA/AF in Tumor Consistent with Efficacy and Tolerability



The more limited exposure of free AF to healthy tissues corresponds to lower drug toxicities, such as neutropenia, seen in safety studies of Dolaflexin ADCs compared to competitor technologies (e.g., Seattle Genetics vc-MMAE), with seven out of nine ADCs that have reported Phase 1 results showing dose-limiting neutropenia. As shown in Figure 4, neutrophil counts did not decline in either rats or monkeys at Dolaflexin ADC doses above the maximum doses that can be administered of vc-MMAE ADCs, which are frequently dose-limited by neutropenia and sepsis.

Figure 4. Neutrophil Counts as a Function of Dolaflexin ADC Dose (in Auristatin Equivalents)



¹ Lin et al, Clin Cancer Res 2015, 21:5139-5150; ² FDA Pharmacology Review of Adcetris (BLA 125388)

Platform development

We intend to establish a leading position in the field of ADCs by continuing to advance our platform innovations that further broaden the potential of our ADCs to deliver clinically meaningful benefit for cancer patients. Our areas of focus include the development of alternative scaffolds to drive homogeneity of our ADCs and alternative payloads to address additional indications and drug resistance. We believe these efforts may lead to new product candidates with improved efficacy and tolerability as well as expansion of the addressable patient population. These platforms include:

- *Dolasynten*, a novel, fully homogeneous AF-HPA based payload platform is designed to enable the creation of ADCs with the ability to provide precise DARs ranging from 2 to 24. In preclinical studies optimized Dolasynten ADCs showed significant therapeutic index.
- *Immunosynten*, designed to be a novel, proprietary, immunostimulatory payload platform with the potential to create ADCs that can address the challenge of providing a local, tissue specific immunostimulatory response with a systemically administered medicine while maintaining a desirable tolerability profile and therapeutic index.
- *Alkymer*, our DNA alkylation platform, has the potential to provide a broad therapeutic index for a DNA alkylating payload mechanism, and broaden addressable tumor indications to include those that are not responsive to anti-tubulin agents such as those employed in our Dolaflexin and Dolasynten platforms.

We are planning to disclose the progress on the development of our platforms at scientific meetings throughout 2019.

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) and where the advantages of our platform may lead to a clinically superior therapeutic benefit. Our lead product candidate, XMT-1536, is in a Phase 1 dose escalation study. We plan to disclose our next ADC for clinical development in the second half of 2019. In addition, our partners have multiple ADC product candidates leveraging our technology in development.

XMT-1536: our NaPi2b-targeted ADC

Program description

Our lead product candidate, XMT-1536, is a Dolaflexin ADC targeting NaPi2b-expressing tumors. It is currently in the dose escalation portion of a Phase 1 clinical study. NaPi2b is an antigen highly expressed in 60% to 90% of both non-squamous NSCLC and epithelial ovarian cancer. However, the expression of NaPi2b in normal tissue is restricted to a limited subset of cell types, rendering it an ideal antigen for ADC development. XMT-1536 is composed of a proprietary anti-NaPi2b antibody, selected for its advantageous internalization properties. We are actively recruiting and dosing patients with ovarian cancer, NSCLC and other orphan indications where a majority of patients express NaPi2b, including papillary thyroid, papillary renal, endometrial, salivary duct. We plan to report data from the Phase 1 dose escalation portion of the study within the second quarter of 2019.

We believe this target to be clinically validated via Genentech's lifastuzumab vedotin, an ADC targeting NaPi2b utilizing the Seattle Genetics vc-MMAE platform, which provided encouraging results in Phase 1 studies in ovarian cancer. The clinical study had a 41% confirmed objective response rate by response evaluation criteria in solid tumors (RECIST criteria), which was achieved without evidence of target-mediated toxicities. However, in a randomized Phase 2 study in platinum-resistant ovarian cancer, lifastuzumab vedotin failed to demonstrate a statistically-significant benefit to liposomal doxorubicin, the comparator, on the primary endpoint of progression free survival, or PFS, despite a numerically superior response rate and improvement in median progression-free survival. Responses in NSCLC patients were also limited despite widespread expression of the NaPi2b target in the Phase 1 patients. Genentech has since discontinued development of lifastuzumab vedotin. The validation of the NaPi2b target provided by these studies forms the basis of our rationale to

[Table of Contents](#)

develop XMT-1536 as a potentially clinically meaningful ADC for the treatment of epithelial ovarian cancer and NSCLC adenocarcinoma. Based on our preclinical data, we believe that XMT-1536 may offer improved efficacy and a wider therapeutic index in these patients.

Unmet need and epidemiology

Ovarian cancer patients who progress during or within six months of completion of platinum-based therapy are considered to have platinum-resistant disease. These patients have limited treatment options including single agent taxanes and pegylated liposomal doxorubicin. Bevacizumab is also used to treat ovarian cancer patients but it is not always well-tolerated and has shown limited overall survival benefit. More recently, PARP inhibitors have been approved to treat ovarian cancer; however, they are predominantly used to treat BRCA1 and BRCA2 mutations and not all patients have benefitted from this treatment. We plan to initially test XMT-1536 in patients with platinum-resistant ovarian cancer. If proof-of-concept is established, there are opportunities to address treatment of first-line ovarian cancer and recurrent, platinum-sensitive disease where platinum-based chemotherapy regimens remain the standard of care.

Given the breadth of NaPi2b expression in NSCLC adenocarcinoma, we believe XMT-1536 also has the potential to treat a broad population of NSCLC adenocarcinoma patients. Initially, we plan to test XMT-1536 in platinum-resistant NSCLC adenocarcinoma patients. If proof-of-concept is established in this population, we believe that there are opportunities to move earlier in the treatment paradigm or consider combination treatment with PD-1/PD-L1 antibodies, the emerging standard of care in front line NSCLC. Our preclinical data indicating that the AF-HPA payload used in XMT-1536 induced immunogenic cell death support the potential for synergy with immune checkpoint inhibitors.

The following chart shows the initial therapeutic focus for our XMT-1536 product candidate:

	Ovarian Cancer	Non Small Cell Lung Cancer (NSCLC)
Incidence (U.S.)	~24,000 ¹	~189,000 ⁴
Deaths Per Year (U.S.)	~14,000 ²	~ 132,000 ⁵
Frontline SOC	Debulking surgery plus systemic chemotherapy	PD1 + chemotherapy
Area of Unmet Need	Resistant to platinum based therapy	Following PD1 + platinum treatment failure
Target Population	(Platinum Resistant OC)	(2 nd Line NSCLC Adenocarcinoma)
Treatment Options	Single agent chemotherapy, e.g. PLD, weekly Paclitaxel, Topotecan, Gemcitabine, PARP	Docetaxel, Premetrexed, Gemcitabine, or Docetaxel + Ramucirumab
Approximate Treatment Outcome	ORR ~10-20% ³ med PFS ~ 3-4 mos ³ med OS ~12 mos ³	ORR ~10-20% ³ med PFS ~ 3-4.5 mos ³ med OS ~ 8-10 mos ³

¹Based on CancerMPact[®] Patient Metrics for US, Western Europe, and Japan, accessed in March 2018. <https://www.cancermpact.com/cancer-mpact/>
²Hanna et al. JCO 2004 & Garon, Lahet 2014 & Pujade, JCO 2014 & Gordon, JCO 2001 & Rose, Gynecol Oncol 2003 & Sehouli, JCO 2011 & Mutch, JCO 2007 & Ferrandina, JCO 2008.
³Globalcan 2012 & SEER.
⁴Estimate based on 55% NSCLC incidence and total lung cancer death cases in the US in 2017 of 155900 deaths.

There are currently no FDA-approved tests to measure NaPi2b expression on tumor cells. Given the prevalence of its expression on epithelial ovarian and NSCLC adenocarcinoma tumors, however, our initial clinical studies of XMT-1536 are being conducted without prospective identification of patients with NaPi2b-expressing tumors. Nonetheless, we have developed and technically validated 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. If results are sufficiently robust, we believe there is an opportunity to develop XMT-1536 without the need for a companion diagnostic, or with the inclusion of the NaPi2b assay in the label as a complementary diagnostic to guide physician decision making. If a companion diagnostic is required for the label for XMT-1536, 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.

Clinical development plan and timeline

XMT-1536 is in a Phase 1, open label, multi-center study. We plan to report data from Phase 1 dose escalation study within the second quarter of 2019.

There are two parts to the Phase 1 study: (i) a dose escalation in patients with ovarian cancer, NSCLC and other orphan indications where a majority of patients express NaPi2b (papillary thyroid, papillary renal, endometrial, salivary duct) and (ii) a dose expansion focused on platinum-resistant ovarian cancer and NSCLC adenocarcinoma patient cohorts. The primary objective of the dose escalation part of the study is to establish the maximum-tolerated dose and a recommended go forward dose. The objective of the cohort expansion stage is to further assess tolerability at the recommended go forward dose, to estimate the objective response rate and durability of response and to further define patient selection criteria for pivotal studies.

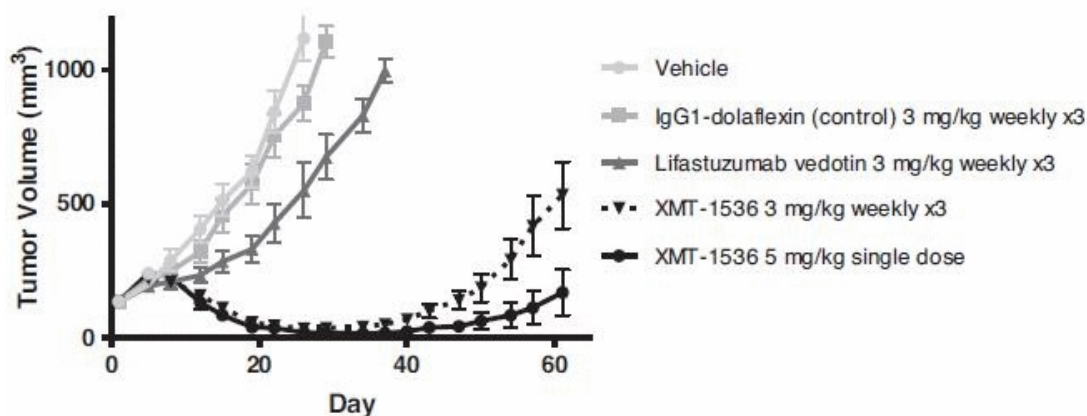
The dose escalation part of the study utilizes a modified 3+3 design. A Safety Review Committee will review the data after each dose cohort of three patients completes the DLT evaluation period and will recommend three patients be enrolled at the next dose level if a dose is reasonably well-tolerated. After the first cycle, patients may continue to receive XMT-1536 until disease progression, provided the drug is well-tolerated and patients continue to derive clinical benefit in the opinion of the investigator. Dose escalation started with a once every three week schedule which has been fully explored. Currently an evaluation of a once every four week regimen is ongoing.

Following dose escalation and establishment of a go forward dose, we plan to expand into patient cohorts aimed at establishing proof of concept in platinum resistant ovarian cancer and NSCLC adenocarcinoma. The expansion part of the study is designed to provide an initial estimate of the response rate for XMT-1536 in each cohort and the durability of the observed responses. These data will be used to support end-of-Phase 1 interactions with regulatory authorities and to inform the design of subsequent studies. We anticipate that observation of a clinically meaningful rate of durable responses in any of the cohorts could be used to support the initiation of pivotal studies to support approval in the indication.

Preclinical studies

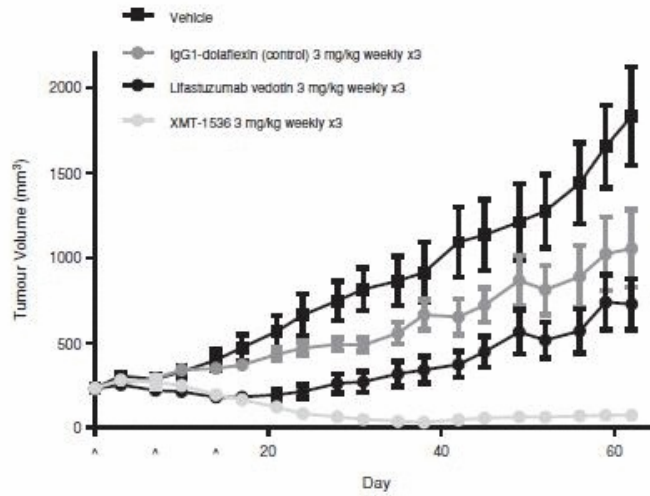
XMT-1536 induced complete tumor regressions in the OVCAR3 ovarian cancer model after a single dose of 5 mg/kg or three weekly doses of 3 mg/kg. In comparison, lifastuzumab vedotin administered via three weekly doses of 3 mg/kg failed to achieve tumor regressions (Figure 10). Genentech published regressions in this model at doses of 6 mg/kg and above, but, given the dose-limiting neutropenia seen in monkeys at doses above 3 mg/kg, these higher doses are unlikely to be translationally relevant.

Figure 10. Comparison of XMT-1536 to Lifastuzumab Vedotin in the OVCAR3 Ovarian Cancer Xenograft Model



Established CTG-0852 patient-derived NSCLC xenograft tumors were treated with XMT-1536, lifastuzumab vedotin or non-binding IgG1-dolaflexin control ADC at a 3 mg/kg dose once weekly for three weeks and tumor volume was measured for 60 days. XMT-1536 treatment resulted in nearly complete regression of the treated tumors that was durable for 45 days after cessation of treatment. In contrast, treatment with the non-binding ADC control or lifastuzumab vedotin led to modest tumor growth control without achieving tumor regression.

Figure 11. Comparison of XMT-1536 to Lifastuzumab Vedotin in the CTG-0852 NSCLC Xenograft Model



XMT-1536 was also tested in eight patient-derived tumor models of NSCLC adenocarcinoma, where it led to complete or near-complete tumor regressions in five of eight models and significant tumor growth delay in two of the remaining three models (Figure 12). All models were treated with three weekly doses of 3 mg/kg or less. The models were not pre-selected for NaPi2b expression and represented a range of tumor genotypes frequently observed in NSCLC adenocarcinoma, including RAS/RAF mutant tumors, EGFR mutant tumors, ALK-translocated tumors and tumors not carrying known oncogenic drivers. As with the data presented above, each column represents an individual tumor model, and the more negative the value, the greater the degree of XMT-1536 efficacy, with negative 100% representing complete tumor regression. In these experiments, the last dose of XMT-1536 was administered on Day 14 and tumor volumes were measured until Day 60 to evaluate durability of the regressions. The regressions were maintained until Day 60 in four of the five models achieving complete or near-complete regression after a 45 day treatment-free interval, indicating good durability of the tumor regressions (Figure 13).

Figure 12. Waterfall Plot of Best Tumor Response to XMT-1536 in Eight NSCLC Adenocarcinoma Models

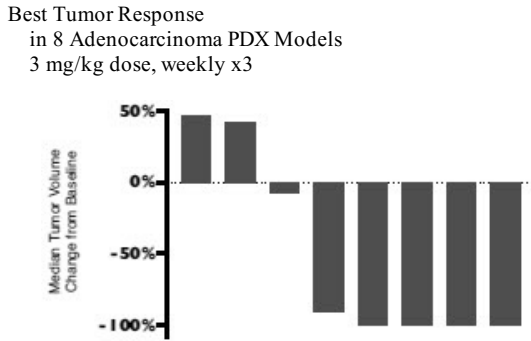
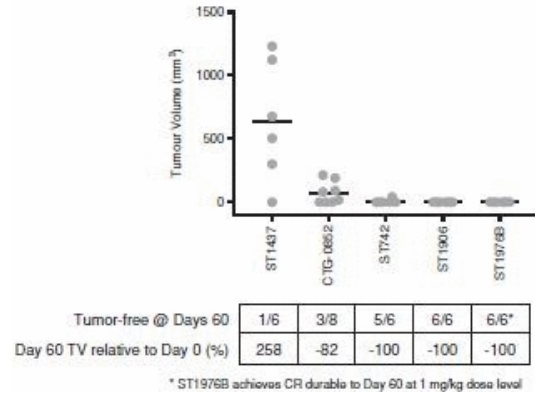


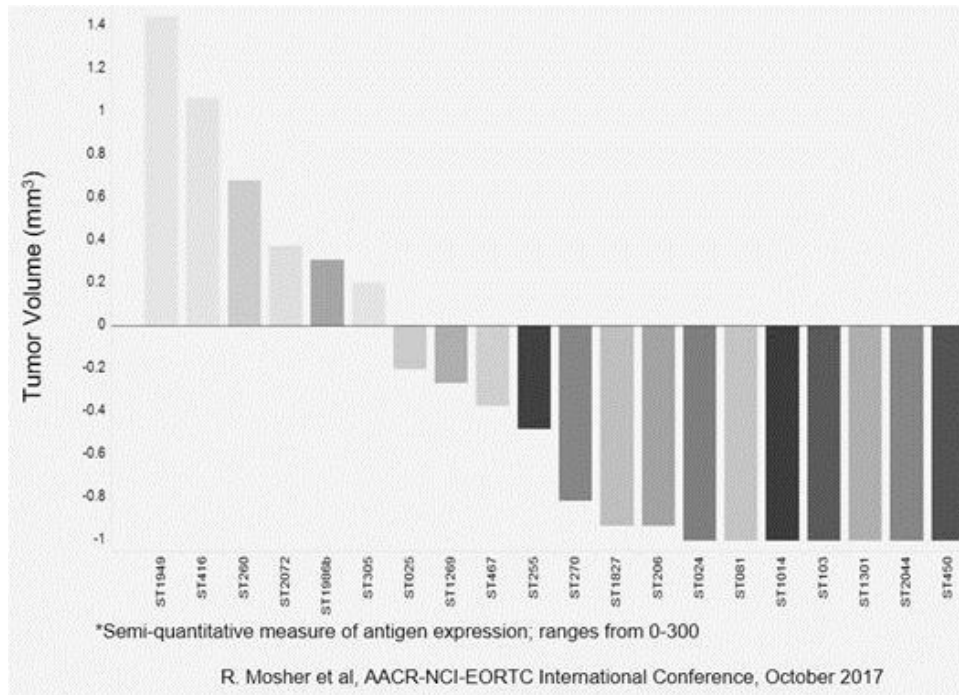
Figure 13. Day 60 Tumor Volumes in Models Achieving Complete or Near-Complete Regressions with XMT-1536



XMT-1536 was tested at 3 mg/kg three times weekly in a series of 19 human primary xenograft models derived from serous ovarian or fallopian tube cancers (n=3 animals/group). Models were not preselected for NaPi2B target expression. Growth effects were evaluated by calculating median best response relative to day 0, at any time-point. An immunohistochemistry (IHC) assay to detect NaPi2b was established using a primary anti-NaPi2b antibody, that consisted of a human/rabbit chimera of XMT-1535, the antibody included in XMT-1536. A tumor block from one untreated study animal, representing each tumor model, was evaluated to determine an efficacy/staining pattern relationship, and IHC values were reported as an “H” Score.

Median best response (Figure 14) calculation showed 10/19 models with a median best response of -50% to -100%. Considering models with a 50% or greater median best response after XMT-1536 treatment, all had a NaPi2b IHC H-score of ≥ 70 . Amongst tumors with H-score ≥ 70 , 10/12 (83%) models achieved 50% or greater reduction in tumor volume after XMT-1536 treatment, vs 0/7 (0%) models with H-score < 70 . There was an association between NaPi2b IHC H-score and tumor volume change after XMT-1536 treatment (Spearman rank coefficient 0.76).

Figure 14. XMT-1536 Effect in Primary Ovarian Cancer Xenograft Models was Associated with NaPi2b Expression



Preclinical tolerability data and therapeutic index

XMT-1536 is cross-reactive with cynomolgous monkey and rat NaPi2b, allowing an informative evaluation of whether XMT-1536 retains good tolerability in these commonly used safety species. In the exploratory repeat dose NHP study as well as the IND-enabling study, there was no evidence of neutropenia at payload doses that were at least four times the maximum tolerated dose of lifastuzumab vedotin and at least two times the dose that caused fatal neutropenia and sepsis in monkeys treated with lifastuzumab vedotin. Further, there was no evidence of significant pulmonary toxicity. We believe these data, combined with the strong efficacy data for XMT-1536 in models of NSCLC and ovarian cancer, are indicative of a favorable therapeutic index and supported moving into Phase 1 trials in cancer patients.

XMT-1522: HER2-targeted ADC

Program description

In January 2019, following a strategic evaluation by the Company of the competitive environment for HER2-targeted therapies, we and our former partner, Takeda, discontinued the development of XMT-1522 then being studied in the dose escalation of a Phase 1 clinical trial. The Company now wholly owns the asset and may choose to out license it to a development partner at a future date.

Strategic partnerships

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

We believe that our ADC platform has broad applicability across a number of targets. We have used strategic partnering to accelerate bringing Fleximer ADCs to patients. 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, 2018, 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 are entitled to receive future development, regulatory and commercial milestones of up to \$778 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 (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, 2018, we have received an upfront payment of \$0.8 million and milestone payments of \$3.0 million under this agreement.

Takeda XMT-1522 strategic partnership

In January 2016, we entered into a collaboration agreement with Takeda (formerly in partnership with Millennium Pharmaceuticals, Inc.) for the development and commercialization of XMT-1522. On January 2, 2019 we received a notice from Takeda that it was exercising its rights to terminate the Development Collaboration and Commercial License Agreement between the two parties for the global development and commercialization of XMT-1522. Takeda's delivery of the notice followed discussions between the two parties whereby we mutually agreed to terminate the co-development collaboration for XMT-1522 following a strategic evaluation of the competitive environment for HER2-targeted therapies. We are working with Takeda to wind down activities under the Development Collaboration and Commercial License Agreement. Through December 31, 2018, we have received an upfront payment of \$13.3 million and milestone payments of \$33.3 million under this agreement.

Takeda strategic research and development partnership

In March 2014, we entered into a collaboration agreement with Takeda (formerly in partnership with Millennium Pharmaceuticals, Inc.) for the development and commercialization of ADC product candidates utilizing Fleximer. On January 2, 2019, we received notice from Takeda stating that it was exercising its rights to terminate the Research Collaboration and Commercial License Agreement. Takeda's delivery of the notice followed discussions between the two parties whereby they mutually agreed to discontinue the Research Collaboration and License Agreement. We are in the process of winding down activities under Research Collaboration and Commercial License Agreement. Through December 31, 2018, we have received an upfront payment of \$24.8 million and milestone payments of \$0.8 million under this agreement.

Strategic partnerships to access antibodies to progress our proprietary pipeline

Our focus is to progress our proprietary pipeline of Fleximer based 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. These strategic partnerships have facilitated the acceleration of our proprietary pipeline.

Recepta license for the antibody in XMT-1536

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 XMT-1536 and granting Recepta the exclusive right to commercialize XMT-1536 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 XMT-1536, 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 XMT-1536, 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. 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.

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 clinical testing. In the future, we expect to use CMOs to manufacture commercial supply of our products. The Dolaflexin manufacturing process involves readily available starting materials and uses unit operations that are well-precedented in the field of chemical/pharmaceutical production. The current XMT-1536 supply chain utilizes the same vendors the company could use for commercialization.

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 testing, 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.

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 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 GCP;
- preparation and submission to the FDA of a Biologics License Application, or BLA;
- FDA acceptance, review and approval 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 audits of clinical study sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees, if any, for FDA review 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.

[Table of Contents](#)

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, obtaining informed consent from study subjects and approval and ongoing review of the study by an IRB at each site where the study will be conducted.

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

[Table of Contents](#)

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

[Table of Contents](#)

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 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 in accordance 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. To date, the FDA has approved a number of biosimilars and has issued several guidance documents outlining its approach to the review and approval of biosimilars.

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 is still being implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and meaning of the BPCIA is subject to significant uncertainty.

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

[Table of Contents](#)

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 USPTO, reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

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.

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 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

Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors are and will be subject to various federal, state and foreign fraud and abuse laws and other healthcare laws and regulations. These laws and regulations may impact, among other things, our arrangements with third-party payors, healthcare professionals who participate in our clinical research programs, healthcare professionals and others who purchase, recommend or prescribe our approved products and our proposed sales, marketing, distribution and education programs. The federal and state healthcare laws and regulations that may affect our ability to operate include, without limitation, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act, which imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

[Table of Contents](#)

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Physician Payments Sunshine Act, which require manufacturers of drugs, devices, biologics and medical supplies to report to the Centers for Medicare & Medicaid Services within the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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. As noted above, the U.S. Congress, state legislatures and foreign regulators from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products profitably. For example, the Health Care Reform Act substantially changed the way healthcare is financed by both governmental and private insurers. The law contains a number of provisions that affect coverage and reimbursement of drug products and/or that could potentially reduce the demand for our products such as:

- increasing rebates under state Medicaid programs for brand name prescription products and extending those rebates to Medicaid managed care;
- assessing a fee on manufacturers and importers of brand name prescription products reimbursed under certain government programs, including Medicare and Medicaid; and

[Table of Contents](#)

- requiring manufacturers to provide a 50% discount on Medicare Part D brand name prescription products sold to Medicare beneficiaries whose prescription product costs cause the beneficiaries to be subject to the Medicare Part D coverage gap (i.e., the so-called “donut hole”).

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Health Care Reform Act, and we expect there will be additional challenges and amendments to the Health Care Reform Act in the future. The current Presidential administration and members of the U.S. Congress have indicated that they may continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the Health Care Reform Act. Most recently, on December 22, 2017, the Tax Cuts and Jobs Act was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. It is uncertain the extent to which any such changes may impact our business or financial condition. We cannot predict the ultimate content, timing or effect of any changes to the Health Care Reform Act or other federal and state reform efforts. There is no assurance that federal or state healthcare reform will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the Health Care Reform Act was enacted. 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 2024 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.

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 patent 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, 2019, we owned, in all of our patent portfolios, 15 issued U.S. patents, 14 pending non-provisional U.S. patent applications (including one allowed U.S. patent application), 15 pending provisional U.S. patent applications, 35 issued foreign patents, six pending PCT patent applications and 105 pending foreign patent applications (including 10 allowed foreign patent applications) in a number of jurisdictions, including, but being not limited to, Australia, Brazil, Canada, China, Europe, Eurasia, Gulf Cooperation Council, Hong Kong, Israel, India, Indonesia, Iran, Japan, Mexico, Macau, New Zealand, Russia, South Korea, South Africa and Taiwan. Our eight 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 one issued U.S. patent covering our Dolaflexin ADC platform is projected to expire in 2034, excluding any additional term for patent term adjustments or patent term extensions; our two issued U.S. patents covering our XMT-1522 ADC are projected to expire in 2035, excluding any additional term for patent term adjustments or patent term extensions; our one issued U.S. patent covering our Alkymer ADC is projected to expire in 2037, excluding any additional term for patent term adjustments or patent term extensions; our additional two issued U.S. patents are projected to expire in 2033 and 2035, 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 2032 and 2039, in each case, excluding any additional term for patent term adjustments or patent term extensions. In addition, we have exclusively in-licensed three issued U.S. patents, one allowed U.S. patent application 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 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, 2019, we owned eight issued U.S. patents, two pending U.S. patent, 32 issued foreign patents and 16 pending foreign patent applications in a number of jurisdictions, including 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 June 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, 2019, we owned one issued U.S. patent, two pending U.S. applications and one pending PCT application, one issued foreign patent and 13 pending foreign patent applications in a number of jurisdictions, including Australia, Brazil, Canada, China, Eurasia, Europe, Israel, India, Japan, South Korea, Mexico and South Africa. Any U.S. or foreign patent issuing from the pending applications covering Dolaflexin ADC platform is projected to expire in October 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 June 2038, excluding any additional term for patent term adjustments or patent term extensions.

XMT-1536 ADC

The intellectual property portfolio for our NaPi2b ADC product candidate, XMT-1536, is directed to compositions of matter for our novel ADC based on exclusively in-licensed NaPi2b antibody and our Dolaflexin platform, as well as methods of using and making these novel conjugates. As of January 31, 2019, we owned six pending U.S. applications (including four pending provisional U.S. patent applications), 18 pending foreign patent applications, and one pending PCT application directed to the composition of matter for XMT-1536, methods of using and making same, companion diagnostics for XMT-1536 ADC and XMT-1536 dosing regimens. We also intend to enter the national/regional phase of the pending PCT patent application in foreign jurisdictions, including Australia, Brazil, Canada, China, Eurasia, Europe, Israel, India, Japan, South Korea, Mexico and South Africa. Any U.S. or foreign patent issuing from the pending applications covering XMT-1536 is projected to expire in March 2037, and any U.S. or foreign patent issuing from the pending applications covering XMT-1536 companion diagnostics is projected to expire in September 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 XMT-1536 dosing regimens is projected to expire in May 2039.

In addition, we have exclusively in-licensed three issued U.S. patents, one pending U.S. patent application 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.

Novel DNA Alkylators and Novel Scaffolds

The intellectual property portfolio for our novel DNA alkylators and novel scaffold platforms is directed to compositions of matter for the novel DNA alkylators, ADCs thereof, novel scaffolds, as well as methods of using and making these novel conjugates, scaffolds and compositions of matter. As of January 31, 2019, we owned one issued U.S. patent, nine pending U.S. patent applications (including six pending provisional U.S. patent applications), eight pending foreign patent applications, and three pending PCT patent applications. We intend to enter the national/regional phase of the PCT patent

applications in a number of jurisdictions, including 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 DNA alkylators and novel scaffold platforms is projected to expire between 2037 and 2039, 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, Dolasynten 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 aware of multiple companies with ADC technologies that may be competitive to our ADC platforms, including Astellas, AstraZeneca, Bristol-Myers Squibb, CytomX Therapeutics, Daiichi Sankyo, ImmunoGen, Immunomedics, Pfizer, Seattle Genetics and Sutro. These companies or their partners, including AbbVie, Genentech, Lilly, Novartis, Sanofi and Takeda, may develop ADCs based on these ADC technologies which compete in the same indications as our current and future ADC product candidates. We expect to compete on improved efficacy, safety and tolerability compared to other ADCs and if our products are not demonstrably superior in these respects compared to other approved therapeutics, we may not be able to compete effectively.

[Table of Contents](#)

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, less toxic, 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

As of January 31, 2019, we had 86 full time employees, including 65 with M.D., Ph.D. or other advanced degrees. Of these full time employees, 69 are engaged in research and development and 17 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.

Facilities

We occupy approximately 34,000 square feet of office and laboratory space in Cambridge, MA under a lease that expires in early 2021. We have an option to extend the lease term for an additional five years. 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.

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.

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 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 \$64.3 million for the year ended December 31, 2018. As of December 31, 2018, we had an accumulated deficit of \$164.2 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 and the receipt of funds through strategic partnerships with third parties. 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 XMT-1536, including our Phase 1 clinical study;
- seek regulatory approval for XMT-1536, 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 XMT-1536, our expenses could increase.

To become and remain profitable, we must succeed in developing our ADC 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

[Table of Contents](#)

impair our ability to raise capital, expand our business, discover or develop other ADC 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, cash equivalents and marketable securities were \$70.1 million as of December 31, 2018. 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 XMT-1536 and any future ADC 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 ADC product candidates. Our costs will increase if we experience any delays in our clinical studies for XMT-1536, 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 XMT-1536 and any other potential ADC product candidates and conducting preclinical studies and clinical studies;
- the timing of, and the costs involved in, obtaining regulatory approvals for XMT-1536 and any other potential ADC product candidates if preclinical studies and clinical studies are successful;
- the cost of manufacturing XMT-1536 and any other potential ADC product candidates for clinical studies in preparation for regulatory approval and in preparation for commercialization;
- the cost of commercialization activities for XMT-1536 and any other potential ADC product candidates, if any ADC 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 estimate that our existing cash, cash equivalents and marketable securities will be sufficient to fund our projected operating requirements through at least mid 2021 and to fund our Phase 1 clinical study for XMT-1536. 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 ADC 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 ADC 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. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional 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 ADC platforms, or ADC 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 XMT-1536 or any other ADC product candidate, or grant rights to third parties to develop and market ADC product candidates that we would otherwise prefer to develop and market ourselves.

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

Because we have limited financial and managerial resources, we focus on specific product candidates. As a result, we may forgo or delay pursuit of opportunities with other product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Failure to properly assess potential product candidates could result in our focus on product candidates with low market potential, which would harm our business and financial condition. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through 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 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 an early stage 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 preclinical results for XMT-1536 are not necessarily predictive of the results of our ongoing or future discovery programs or clinical studies. Promising results in preclinical studies 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 ADC 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 ADC product candidates, we may be prevented or delayed in obtaining marketing approval for our ADC 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.

We currently have only one ADC product candidate, XMT-1536, in a clinical study. A failure of this product candidate 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.

XMT-1536 is our only clinical-stage development product candidate. While we have certain other preclinical programs in development and we intend to develop other product candidates, it will take additional investment and time for such programs to reach the same stage of development as XMT-1536. In addition, we have other product candidates in our current pipeline that are based on the same ADC platform. If XMT-1536 fails in development as a result of any underlying problem with our ADC platform, then we may be required to discontinue development of the ADC product candidates that are based on the same technology. If we were required to discontinue development of XMT-1536 or if XMT-1536 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 ADC 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 terminate a clinical trial, which could prevent us from commercializing our ADC product candidates on a timely basis, or at all.

We cannot guarantee that clinical studies, including our ongoing Phase 1 clinical study and anticipated additional clinical studies for XMT-1536, 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, 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 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;

[Table of Contents](#)

- 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 ADC product candidates to the clinical sites;
- patients not completing participation in a study or not returning for post-treatment follow-up;
- 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 ADC 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 ADC product candidates or our partners' ADC 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 XMT-1536 or any other future ADC product candidate.

We may seek a Breakthrough Therapy Designation or Fast Track Designation by the FDA for any of our 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 product candidate would receive marketing approval.

We may seek a Breakthrough Therapy Designation or Fast Track Designation for any of our product candidates. 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. 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. 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.

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 product candidates, our business will be substantially harmed.

The preclinical studies and clinical studies of our product candidates are, and the manufacturing and marketing of our product candidates will be, 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 ADC product candidates, we or our partners must demonstrate through extensive preclinical studies and clinical studies that the ADC 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 ADC technology, 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 XMT-1536 or any other ADC product candidate in some but not all of the territories for which we seek approval or some but not all of the target indications, resulting in limited commercial opportunity for the approved ADC product candidates.

[Table of Contents](#)

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 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.

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 ADC product candidates, including XMT-1536, 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, an ADC 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 XMT-1536 in one or more significant foreign jurisdictions, then the commercial opportunity for XMT-1536 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 ADC product candidates may also 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 ADC product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion 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 ADC 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 ADC 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 ADC 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 ADC product candidates or those of our competitors, either before or after receipt of marketing

[Table of Contents](#)

approval, could have a material adverse effect on the development of our ADC product candidates and our business as a whole.

If we or others identify undesirable side effects caused by our ADC 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 ADC product candidates;
- regulatory authorities may withdraw or limit their approvals of our ADC 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 ADC 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 product candidates.

If a companion diagnostic is required for the label for XMT-1536 or any of our 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 XMT-1536 or any of our other 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 XMT-1536 and our product candidates, may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;

[Table of Contents](#)

- 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 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 an ADC 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

[Table of Contents](#)

do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our ADC 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 ADC 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 ADC 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 ADC 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 ADC product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our ADC 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:

- an inability to initiate or continue clinical studies of ADC product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for ADC 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 ADC product candidates; and
- in the event of approval to market and commercialize an ADC product candidate, an inability to meet commercial demands for our products.

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 ADC product candidates and commercialize any approved ADC 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 ADC product candidates in sufficient quality and quantity, the development, testing and clinical studies of that ADC 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 ADC product candidates, including XMT-1536, 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 ADC product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our ADC product candidates successfully.

We rely on third parties to conduct preclinical studies and clinical studies for our ADC product candidates, including XMT-1536, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for XMT-1536 or any other ADC product candidates that we may develop in the future.

We have designed the Phase 1 clinical study for XMT-1536 and intend to design any future clinical study for any future unpartnered ADC 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 ADC 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 ADC 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 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 ADC 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 ADC platforms and existing and future ADC product candidates. We entered into a collaboration agreement with Merck KGaA for the development and commercialization of other ADC 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 ADC 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 ADC product candidates based on our ADC platforms or technology, adverse events with their ADC product candidates could negatively affect our ADC 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 ADC product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner our ADC product candidates, potential partners must view these ADC 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 an ADC product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into strategic partnership agreements related to our ADC 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 ADC product candidates, we will bear all of the risk and costs related to the development of any such ADC 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 ADC product candidate development. This could negatively affect the development of any unpartnered ADC 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 XMT-1536 or any other ADC 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 medical 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' ADC products may negatively impact the market acceptance of our ADC 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 XMT-1536 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 XMT-1536, if our drug candidate is 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 XMT-1536 and other ADC 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 XMT-1536 or any future ADC 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 ADC 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.

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 ADC 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 ADC 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.

The United States and state governments continue to propose and pass legislation designed to reduce the cost of health care. In March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, or the Health Care Reform Act, which include changes to the coverage and reimbursement of drug products under government health care programs such as:

- increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care;
- extending discounted rates on drug products available under the Public Health Service pharmaceutical pricing program to additional hospitals and other providers;
- assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid; and
- requiring drug manufacturers to provide a 50% discount on Medicare Part D brand name prescription drugs sold to Medicare beneficiaries whose prescription drug costs cause the beneficiaries to be subject to the Medicare Part D coverage gap (i.e., the so-called “donut hole”).

It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing health care legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services 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.

The legislative landscape in the United States continues to evolve. There have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations or the commercial success of our

products, if approved. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. For example, under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the Healthcare Reform Act. For example, tax reform legislation was enacted at the end of 2017 that eliminates the tax penalty established under Healthcare Reform Act for individuals who do not maintain mandated health insurance coverage beginning in 2019. In a May 2018 report, the Congressional Budget Office estimated that, compared to 2018, the number of uninsured will increase by 3 million in 2019 and 6 million in 2028, in part due to the elimination of the individual mandate. The Healthcare Reform Act has also been subject to judicial challenge. In December 2018, a federal district court, in a challenge brought by a number of state attorneys general, found the Healthcare Reform Act unconstitutional in its entirety because, once Congress repealed the individual mandate provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. Pending appeals, which could take some time, the Healthcare Reform Act is still operational in all respects.

There have also been other reform initiatives under the Trump Administration, including initiatives focused on drug pricing. For example, in May of 2018, President Trump and the Secretary of the Department of Health and Human Services released a "blueprint" to lower prescription drug prices and out-of-pocket costs. Certain proposals in the blueprint, and related drug pricing measures proposed since the blueprint, could cause significant operational and reimbursement changes for the pharmaceutical industry. As another example, in October 2018, the Centers for Medicare & Medicaid Services solicited public comments on potential changes to payment for certain Medicare Part B drugs, including reducing the Medicare payment amount for selected Medicare Part B drugs to more closely align with international drug prices.

More generally, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Individual states in the United States have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price constraints and marketing cost disclosure and transparency measures. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We continue to evaluate the effect that the Health Care Reform Act, the repeal of the individual mandate, and any additional 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. We cannot predict the ultimate content, timing or effect of any such reforms.

In addition, other legislative changes have been proposed and adopted since the 2010 health care reform legislation. The Budget Control Act of 2011, as amended, or the Budget Control Act, includes provisions intended to reduce the federal deficit. The Budget Control Act resulted in the imposition of 2% reductions in Medicare payments to providers beginning in 2013. Legislation extends reductions through 2023. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, 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 anticipated product revenues.

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 ADC product candidates. It is possible that these competitors will succeed in developing technologies that are more effective than our ADC platforms or ADC product candidates or that would render our ADC 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 ADC platforms, including Astellas, AstraZeneca, Bristol-Myers Squibb, Daiichi Sankyo, ImmunoGen, Immunomedics, Pfizer and Seattle Genetics. These companies or their partners, including AbbVie, Genentech, Lilly, Novartis, Sanofi and Takeda, may develop ADC

[Table of Contents](#)

product candidates which compete in the same indications as our current and future ADC product candidates. There are approximately 75 ADC product candidates in active clinical development. There are currently four approved ADC therapies in the United States: brentuximab vedotin, marketed by Seattle Genetics and Takeda, ado-trastuzumab emtansine, marketed by Genentech, gemtuzumab ozogamicin, marketed by Pfizer; and inotuzumab ozogamicin, also marketed by Pfizer. We expect to compete on improved efficacy, safety and tolerability compared to other ADC 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 testing, 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 and an additional six months exclusivity period if pediatric studies are conducted. In December 2018, however, a federal district court judge, in a challenge brought by a number of state attorneys general, found the Health Care Reform Act unconstitutional in its entirety. Given the court's decision struck down the Health Care Reform Act in its entirety, the decision means numerous reforms enacted as part of the Health Care Reform Act, but not specifically related to health insurance, such as the BPCIA, are invalid as well. While the Trump administration and CMS have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, and other efforts to repeal and replace the Health Care Reform Act will impact the biosimilar framework created by the Health Care Reform Act and our Business.

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 ADC platforms and ADC product candidate, XMT-1536. 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 ADC platforms and ADC 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 ADC platforms and ADC 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 ADC 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 ADC platforms or our ADC 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 ADC 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 an ADC 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 an ADC drug under patent protection could be further reduced. Even if patents covering our ADC 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 ADC product candidates.

Issued patents covering XMT-1536 and any 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 XMT-1536 or any other 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 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

[Table of Contents](#)

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 XMT-1536 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 XMT-1536. 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 ADC 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 ADC product candidates. As the biopharmaceutical industries expand and more patents are issued, the risk increases that our ADC 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 ADC 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 ADC platforms or our ADC 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 ADC platforms, our ADC product candidates or the use or manufacture of our ADC 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 ADC technology or one or more of our ADC 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 ADC 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 ADC 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 ADC 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.

Our relationships with health care professionals, institutional providers, principal investigators, consultants, customers (actual and potential) and third-party payors are, and will continue to be, subject, directly and indirectly, to federal and state health care fraud and abuse, false claims, marketing expenditure tracking and disclosure, government price reporting and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face 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 business operations and activities may be directly or indirectly subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. If we obtain FDA approval for any of our ADC 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 may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government and state governments in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal health care program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud

any health care benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, health care benefits, items or services relating to health care matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose requirements on certain covered health care providers, health plans, and health care clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services reimbursed by Medicare or Medicaid if the physician or a member of the physician's family has a financial relationship with the entity, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;
- the federal Physician Payments Sunshine Act, created under Section 6002 of the Health Care Reform Act, and its implementing regulations requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members, with data collection required beginning August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services required by March 31, 2014 and by the 90th day of each subsequent calendar year;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, changed by the Health Care Reform Act to, among other things, increase the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offer such rebates to additional populations, that require us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement or discounts on our marketed drugs (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts);
- 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 equivalents of each of the above federal laws, such as anti-kickback, false claims, consumer protection and unfair competition laws which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving health care items or services reimbursed by any third-party payor, including commercial insurers; state laws that require biotech companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to health care providers; state laws that require drug manufacturers to file reports with states regarding marketing information, such as the tracking and reporting of gifts, compensation and other remuneration and items of value provided to health care professionals and entities (compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships, which could potentially have a negative

[Table of Contents](#)

effect on our business or increase enforcement scrutiny of our activities); and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects.

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.

The Health Care Reform Act, among other things, amended the intent standard of the federal Anti-Kickback Statute and criminal health care fraud statutes to a stricter standard such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

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 ADC 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 ADC product candidates. Even a successful defense

[Table of Contents](#)

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 ADC 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.

[Table of Contents](#)

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 CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product candidates' development programs.

Despite the implementation of security measures, our internal computer systems and those of our strategic partners, third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, 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 or our CROs' operations, it could result in a material disruption of our programs. 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. 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 and the further development of our product candidates could be delayed.

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.

Risks related to our common stock

We are an "emerging growth company," as defined in the JOBS Act, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding

[Table of Contents](#)

executive compensation in our periodic reports and proxy statements and (3) exemptions from the requirements of holding a non-binding advisory vote on executive compensation.

We could be an emerging growth company through 2022, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds \$700.0 million as of any June 30 before that time or if we have total annual gross revenue of \$1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than \$1.00 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them, and we cannot predict or estimate the amount or timing of such additional costs.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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 ADC product candidates, including XMT-1536;
- 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;

[Table of Contents](#)

- 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, 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. 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, 2018, our executive officers, directors and stockholders who own more than 5% of our outstanding common stock, together with their respective affiliates, beneficially owned a substantial majority 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 are incurring and will continue to incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance requirements and initiatives.

As a public company, we are incurring and will continue to incur significant legal, insurance, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules of the SEC and The Nasdaq Stock Market have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

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, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock.

[Table of Contents](#)

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.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, the U.S. President signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended (the Code). The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income in respect of net operating losses generated during or after 2018 and elimination of net operating loss carrybacks, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge you to consult with your legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding 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, 2018, 2017 and 2016, 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. At December 31, 2018, the Company had federal NOLs of approximately \$102.1 million and state NOLs of approximately \$102.4 million. Of the \$102.1 million of federal NOLs, \$34.1 million expire at various dates through 2037. The remaining \$68.0 million of federal NOLs do not expire. The state NOLs will expire at various dates through 2038. At December 31, 2018, the Company had Federal and State research and development tax credit carryforwards of approximately \$7.7 million and \$3.3 million, respectively, which expire at various dates through 2038. Under the newly enacted federal income tax law, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. 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 through December 31, 2015 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

We occupy approximately 34,000 rentable square feet of office and laboratory space in Cambridge, Massachusetts under a lease that expires on March 31, 2021. We have an option to extend the lease term for an additional five years. 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.

None.

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 March 7, 2019, there were approximately 32 holders of record of shares of our common stock.

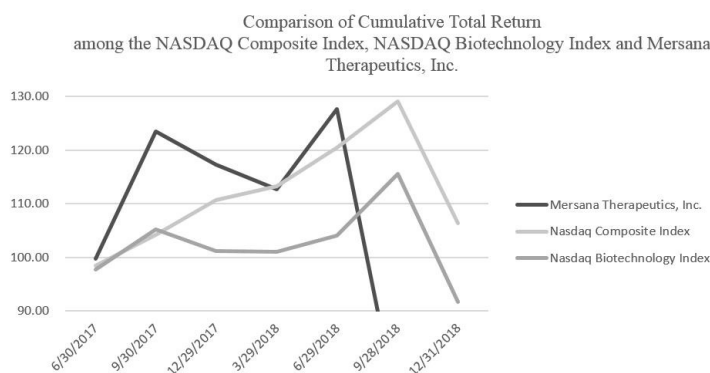
Dividend Policy

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, 2018, 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.



Use of Proceeds from Registered Securities

On July 3, 2017, we completed an initial public offering (IPO), in which we issued and sold 5,000,000 shares of our common stock at a public offering price of \$15.00 per share, for aggregate gross proceeds of \$75 million. We received \$67.4 million in net proceeds after deducting \$7.6 million of underwriting discounts and commissions and offering costs.

[Table of Contents](#)

On August 2, 2017, we issued and sold 51,977 shares of common stock at \$15.00 per share for gross proceeds of \$0.8 million upon the partial exercise of the underwriters' overallotment option. We received net proceeds of \$0.7 million after deducting \$0.1 million in underwriting discounts and commissions. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates.

All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-218412), which was declared effective by the SEC on June 27, 2017. J.P. Morgan Securities LLC, Cowen and Company, LLC and Leerink Partners LLC acted as joint book-running managers of the offering and as representatives of the underwriters. The offering commenced on June 27, 2017 and did not terminate until the sale of all of the shares offered.

As of December 31, 2018, we estimate that we have used all of the net proceeds from the IPO to fund manufacturing and clinical development activities for XMT-1522 and XMT-1536 and other research activities in support of our preclinical programs, and for working capital and other general corporate purposes. There was no material change in the use of the net proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) on June 29, 2017.

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, 2018, 2017 and 2016 and the balance sheet data as of December 31, 2018 and 2017 from our audited financial statements included elsewhere in this Annual Report on Form 10-K. We have derived the selected consolidated financial data for the year ended December 31, 2015 and the balance sheet data as of December 31, 2015 from audited financial statements that are not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that should be expected in the future.

	Year ended December 31,			
	2018	2017	2016	2015
(in thousands, except share and per share data)				
Statements of Operations Data:				
Collaboration revenue	\$ 10,594	\$ 17,545	\$ 25,171	\$ 10,359
Operating expenses:				
Research and development	59,915	\$ 46,700	\$ 32,008	\$ 21,353
General and administrative	16,334	10,462	6,984	5,347
Total operating expenses	76,249	\$ 57,162	\$ 38,992	\$ 26,700
Other income (expense):				
Other income (expense), net	1,398	910	121	(87)
Total other income (expense)	1,398	910	121	(87)
Net loss	\$ (64,257)	\$ (38,707)	\$ (13,700)	\$ (16,428)
Net loss attributable to common stockholders — basic and diluted	\$ (64,257)	\$ (38,707)	\$ (13,700)	\$ (16,428)
Net loss per share attributable to common stockholders — basic and diluted	\$ (2.79)	\$ (3.22)	\$ (10.82)	\$ (13.43)
Weighted-average number of common shares used in net loss per share attributable to common stockholders — basic and diluted(1)	23,032,250	12,022,733	1,266,758	1,223,457

	As of			
	<u>December 31,</u>	<u>December 31,</u>	<u>December 31,</u>	<u>December 31,</u>
	<u>2018</u>	<u>2017</u>	<u>2016</u>	<u>2015</u>
	(in thousands)			
Balance Sheet Data:				
Cash, cash equivalents and marketable securities	\$ 70,131	\$ 125,216	\$ 100,297	\$ 11,534
Working capital(2)	4,880	85,662	73,787	2,019
Total assets	78,502	130,715	105,087	14,409
Convertible preferred stock	—	—	94,450	36,296
Total stockholders' equity (deficit)	8,795	69,994	(55,619)	(42,692)

(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 20 years of industry learning in the ADC field to develop proprietary technologies that enable us to design ADCs to have improved efficacy, safety and tolerability relative to existing ADC therapies. Our most advanced platform, Dolaflexin, has been used to generate a pipeline of proprietary ADC product candidates to address patient populations that are not currently amenable to treatment with traditional ADC-based therapies. Our lead product candidate, XMT-1536, is an ADC targeting NaPi2b, an antigen broadly expressed in ovarian cancer and non small cell lung cancer (NSCLC). The first patient was dosed on XMT-1536 in early 2018 and the study is currently in Phase 1 dose escalation in ovarian cancer, NSCLC and other orphan indications where a majority of patients express NaPi2b including endometrial, papillary renal, papillary thyroid, and salivary duct. We plan to select a dose for use in the Phase 1 expansion studies and report data from the dose escalation study in the second quarter of 2019. Following dose escalation and establishment of a go forward dose we plan to expand into patient cohorts aimed at establishing proof of concept in platinum resistant ovarian cancer, and NSCLC adenocarcinoma.

Beyond XMT-1536 and our Dolaflexin platform, we continue to work to identify earlier stage product candidates employing the platforms described below, and to advance our ADC platform technologies. We are leveraging our expertise to advance platform innovations that further expand the potential of our ADCs to deliver clinically meaningful benefit for cancer patients.

- *Dolasynten* is designed to be a novel, proprietary, homogeneous payload platform enabling the creation of ADCs with the ability to provide drug to antibody ratios (DARs) ranging from 2-24.
- *Immunosynthen*, our emerging platform, is designed to be a novel, proprietary, immunostimulatory payload platform with the potential to create ADCs that can ideally address the challenge of systemic delivery and tolerability of immunomodulatory payloads.
- *Alkymer*, our DNA alkylation platform, has the potential to provide a broad therapeutic index for a DNA alkylating payload mechanism, and broaden addressable tumor indications to include those that are not responsive to anti-tubulin agents.

[Table of Contents](#)

We are planning to disclose the progress on the development of our platforms throughout 2019 and expect to announce our next ADC clinical candidate in the second half of 2019.

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 experienced management team and protected by our robust intellectual property portfolio, will allow us to develop targeted and highly tailored therapies to help cancer patients become cancer survivors.

Since inception, our operations have focused on building our platform, identifying potential product candidates, producing drug substance and drug product material for use in preclinical studies, conducting preclinical studies, including Good Laboratory Practice, or GLP, toxicology studies, manufacturing clinical trial material and conducting clinical trials, establishing and protecting our intellectual property, staffing our company and raising capital. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through our strategic partnerships, private placements of our convertible preferred stock and our initial public offering.

Since inception, we have incurred significant operating losses. Our net losses were \$64.3 million, \$38.7 million and \$13.7 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of \$164.2 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 candidate XMT-1536;
- continue activities to discover, validate and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional research, development and general and administrative personnel.

Financial Operations Overview

Revenue

To date, all of our revenue has been generated from strategic partnerships. We have not generated any revenue from product sales, and we do not expect to generate any revenue from product sales for the foreseeable future.

In March 2014, we entered into a collaboration agreement with Takeda for the development and commercialization of ADC product candidates utilizing Fleximer. On January 2, 2019, we received notice from Takeda stating that Takeda was exercising its right to terminate the collaboration agreement upon 45 days' prior written notice and the agreement terminated in February 2019. Under Topic 606, we have concluded that the performance obligations were not modified during the year ended December 31, 2018, and that we will account for the termination notice as an event in the first quarter of the fiscal year ended December 31, 2019. Under this agreement, as amended, Takeda had the right to select up to seven target antigens and selected four target antigens prior to terminating the arrangement. Takeda's responsibilities were generating antibodies against the target antigens and we were responsible for generating Fleximer and our proprietary payloads and conjugating this to the antibody to create the ADC product candidates. Takeda then had the exclusive right to and was responsible for the further development, manufacture and commercialization of these ADC product candidates, except that we had an option to co-develop and co-commercialize one product targeting one of Takeda's third through seventh target antigens and could have exercised such option with respect to an applicable product no later than 30 days after initiation of a Phase 2 clinical study for such product or at an earlier time if Takeda intended to grant rights to such product to a third party.

[Table of Contents](#)

In addition, in January 2016, we entered into a collaboration agreement with Takeda for the development and commercialization of XMT-1522. Under this agreement, Takeda was granted the exclusive right and responsibility to commercialize XMT-1522 outside the United States and Canada. We were also notified on January 1, 2019 that Takeda was exercising its right to terminate this agreement with 30 days' written notice and the agreement terminated in February 2019. We concluded that this termination should also be accounted for as a first quarter event.

For the years ended December 31, 2018, 2017 and 2016, we recognized revenue of \$5.9 million, \$13.8 million and \$21.4 million, respectively, related to the Takeda agreements.

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. 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 then has the exclusive right to and is responsible for the further development and commercialization of these ADC product candidates.

For the years ended December 31, 2018, 2017 and 2016, we recognized revenue of \$2.4 million, \$3.6 million and \$3.6 million, respectively, related to the Merck KGaA agreement.

We have provided limited services to Asana BioSciences. For the years ended December 31, 2018, 2017 and 2016, we recorded revenue of \$0.8 million, \$0.1 million and \$0.1 million, respectively, 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 agreement with Merck KGaA, Asana BioSciences and any other collaboration agreements we may enter into. Given the schedule of potential milestone payments and 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. Remaining revenue to be generated from our collaboration agreements with Takeda will be recognized in the first quarter of 2019.

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

Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research and development activities, including our drug discovery efforts, and the development of our product candidates, which include:

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

Research and development costs are expensed as incurred. Costs of certain activities, such as manufacturing, preclinical studies and clinical trials, are generally recognized based on an evaluation of the progress to completion of specific tasks. Nonrefundable advance payments for goods or services to be received in the future for use in research and development

[Table of Contents](#)

activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

We expect research and development costs to increase significantly for the foreseeable future as our product candidate development programs progress. 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. Our internal research and development costs are primarily personnel-related costs, facility costs, including depreciation and lab consumables. 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 development candidate for the years ended December 31, 2018, 2017 and 2016. Pre-development candidate expenses, unallocated costs and internal research and development costs have been stated separately.

(in thousands)	Year ended December 31,		
	2018	2017	2016
XMT-1536 external costs	\$ 15,922	\$ 8,647	\$ 3,971
XMT-1522 external costs	15,562	14,661	12,107
External costs for discovery stage programs and platform development	4,517	3,093	1,439
Internal research and development costs	23,914	20,299	14,491
Total research and development costs	<u>\$ 59,915</u>	<u>\$ 46,700</u>	<u>\$ 32,008</u>

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, material net cash inflows will commence from the development efforts associated with our product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

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

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

[Table of Contents](#)

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, business development, legal, 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 growth in research and development activities. This will likely include increased costs related to the hiring of additional personnel, fees to outside consultants and patent costs, among other expenses. We also anticipate increased expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services, director and officer insurance premiums and investor relations costs.

Other Income (Expense)

Other income (expense) consists primarily of interest income earned on cash equivalents and marketable securities.

Critical Accounting Policies 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 and stock-based compensation, discussed in the notes to consolidated financial statements included in this Annual Report on Form 10-K.

Revenue Recognition

Effective January 1, 2018, we adopted the provisions of Topic 606, using the modified retrospective transition method. Under this method, we recorded the cumulative effect of initially applying the new standard to all contracts in process as of the date of adoption. This standard applies 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.

We enter into collaboration agreements which are within the scope of 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-

[Table of Contents](#)

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 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 expenses include the costs incurred for services performed by our vendors in connection with 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 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 accrual or prepaid accordingly. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

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, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-based Compensation

We account for stock-based awards in accordance with ASC Topic 718, *Compensation—Stock Compensation*, or ASC 718. ASC 718 requires all stock-based compensation awards to employees, including grants of restricted stock and stock options, to be recognized as expense in the statements of operations based on their grant date fair values. We estimate the fair value of options granted using the Black-Scholes option pricing model.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (1) the expected stock price volatility, (2) the calculation of expected term of the award, (3) the risk-free interest rate, and (4) the expected dividend yield. Due to the lack of a public market for the trading of our common stock prior to the IPO and a lack of company-specific historical and implied volatility data, we have based our estimates of expected volatility on the historical volatility of a group of similar companies that are publicly traded. We calculate historical volatility based on a period of

[Table of Contents](#)

time commensurate with the expected term. We compute expected volatility based on the historical volatility of a representative group of companies with similar characteristics to us, including their stages of product development and focus on the life science industry. We use the simplified method as prescribed by the Securities and Exchange Commission's Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to non-employees, we utilize the contractual term of the arrangement as the basis for the expected term. We determine the risk-free interest rate based on a treasury instrument whose term is consistent with the expected term of the stock options. We use an assumed dividend yield of zero as we have never paid dividends and do not have current plans to do so.

The weighted-average assumptions used in the Black-Scholes option pricing model to determine the fair value of stock options granted to employees and directors were as follows:

	Year ended		
	December 31,		
	2018	2017	2016
Risk-free interest rate	2.7 %	2.2 %	1.5 %
Expected dividend yield	— %	— %	— %
Expected term (years)	6.07	6.21	6.25
Expected stock price volatility	73 %	67 %	69 %

We expense the fair value of stock-based awards granted to employees and directors on a straight-line basis over the associated service period, which is generally the period in which the related services are received. We measure stock-based compensation awards granted to non-employees at fair value as the awards vest and recognize the resulting value as stock-based compensation expense during the period the related services are rendered.

Through December 31, 2016, we were required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differed from our estimates. We used historical data to estimate post-vesting forfeitures and recorded stock-based compensation expense only for those awards that were expected to vest. To the extent that actual forfeitures differed from estimates, the difference was recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the financial statements is based on awards that were ultimately expected to vest. The fair value of stock-based payments was recognized as expense, net of estimated forfeitures, over the requisite service period which was generally the vesting period.

In the first quarter of 2017, we made an accounting policy election to recognize forfeitures as they occur upon adoption of guidance per ASU No. 2016-09. The adoption of this ASU did not have a material impact on our financial statements.

Results of Operations

Comparison of Years Ended December 31, 2018 and 2017

The following table summarizes our results of operations for the years ended December 31, 2018 and 2017, together with the changes in those items:

(in thousands)	Year ended December 31,		Dollar Change
	2018	2017	
Collaboration revenue	\$ 10,594	\$ 17,545	\$ (6,951)
Operating expenses:			
Research and development	59,915	46,700	13,215
General and administrative	16,334	10,462	5,872
Total operating expenses	76,249	57,162	19,087
Other income:			
Interest income	1,398	910	488
Total other income	1,398	910	488
Net loss	\$ (64,257)	\$ (38,707)	\$ (25,550)

Collaboration Revenue

The decrease in collaboration revenue from \$17.5 million during the year ended December 31, 2017 to \$10.6 million for the year ended December 31, 2018 was primarily the result of a decrease in efforts to support partner programs and a third quarter 2018 increase in total projected efforts associated with longer anticipated timelines, as a result of partial clinical hold, used to recognize XMT-1522 revenue. In addition, the year ended December 31, 2017 included a \$4.0 million increase in revenue relating to changes in estimates of the costs to complete services under the Takeda agreements.

Research and Development Expense

Research and development expense increased by \$13.2 million from \$46.7 million for the year ended December 31, 2017 to \$59.9 million for the year ended December 31, 2018, an increase of 28%.

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

- approximately \$2.3 million in increased employee compensation and \$0.7 million in increased lab consumables both primarily due to an increase in headcount as our programs progressed in clinical and preclinical studies;
- approximately \$9.3 million in increased external research and development expenses for manufacturing activities for XMT-1536 and XMT-1522, as well as research efforts to further platform development and evaluate potential product candidates;
- approximately \$2.9 million in increased external clinical and regulatory expenses due primarily to the commencement of our first in-human trials for XMT-1536; and
- approximately \$1.5 million in increased lab consumables and facilities costs;
- partially offset by a reduction of approximately \$2.8 million related to milestone payments in 2017 in connection with the XMT-1522 and XMT-1536 clinical trials, which were non-recurring events.

We expect our research and development expenses to increase as we continue our clinical development XMT-1536 and continue to advance our preclinical product candidate pipeline and invest in improvements in our ADC technologies.

[Table of Contents](#)*General and Administrative Expense*

General and administrative expense increased by \$5.9 million from \$10.5 million during the year ended December 31, 2017 to \$16.3 million for the year ended December 31, 2018, an increase of 56%.

The increase in general and administrative expense was primarily attributable to the following:

- approximately \$3.0 million in increased personnel costs primarily due to additional headcount as we built the infrastructure to support the growth of the research and development organization;
- approximately \$1.7 million in increased professional fees, including external legal fees, corporate communications and public relations costs to support operations as a growing public company; and
- approximately \$1.0 million in increased other costs, including insurance, software and franchise taxes.

We expect that our general and administrative expense will increase in future periods as we expand our operations and incur additional costs in connection with being a public company. These increases will likely include legal, auditing and filing fees, additional insurance premiums and general compliance and consulting expenses.

Other Income

Other income increased by \$0.5 million from \$0.9 million for the year ended December 31, 2017 to \$1.4 million for the year ended December 31, 2018. The change in other income was primarily due to increased interest income in the year ended December 31, 2018.

Comparison of Years Ended December 31, 2017 and 2016

The following table summarizes our results of operations for the years ended December 31, 2017 and 2016, together with the changes in those items:

(in thousands)	Year ended December 31,		Dollar Change
	2017	2016	
Collaboration revenue	\$ 17,545	\$ 25,171	\$ (7,626)
Operating expenses:			
Research and development	46,700	32,008	14,692
General and administrative	10,462	6,984	3,478
Total operating expenses	57,162	38,992	18,170
Other income:			
Interest income	910	121	789
Total other income	910	121	789
Net loss	<u>\$ (38,707)</u>	<u>\$ (13,700)</u>	<u>\$ (25,007)</u>

Collaboration Revenue

The decrease in collaboration revenue from \$25.2 million during the year ended December 31, 2016 to \$17.5 million for 2017 was primarily the result of a decrease in revenue due to the timing of activities performed under the XMT-1522 agreement, partially offset by a \$4.0 million increase in revenue during the quarter ended September 30, 2017, due to the impact of changes in estimates of the total costs to complete the research services under the Takeda agreements.

[Table of Contents](#)

Research and Development Expense

Research and development expense increased by \$14.7 million from \$32.0 million for the year ended December 31, 2016 to \$46.7 million for the year ended December 31, 2017, an increase of 46%.

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

- approximately \$4.8 million in increased employee compensation and \$0.6 million in increased lab consumables primarily due to an increase in headcount as our programs progressed in clinical and preclinical studies;
- approximately \$3.4 million in increased external research and development expenses for IND-enabling pre-clinical and toxicology studies related to XMT-1536 as well as the manufacturing activities for our two lead programs and research efforts to evaluate potential product candidates;
- approximately \$2.8 million in increased external clinical and regulatory expenses due to the commencement of our first in-human trials for our initial candidate XMT-1522 and our lead candidate XMT-1536; and
- approximately \$2.8 million related to milestone payments in connection with the XMT-1522 and XMT-1536 clinical trials.

General and Administrative Expense

General and administrative expense increased by \$3.5 million from \$7.0 million during the year ended December 31, 2016 to \$10.5 million for the year ended December 31, 2017, an increase of 50%.

The increase in general and administrative expense was primarily attributable to the following:

- approximately \$0.9 million in increased personnel costs primarily due to additional headcount as we build the infrastructure to support the growth of the research and development organization;
- approximately \$1.8 million in increased professional fees, including external legal fees, corporate communications and public relations costs to support operations as a public company; and
- approximately \$0.8 million in increased other costs, including insurance, software and franchise taxes.

Other Income (Expense), Net

Other income increased by \$0.8 million from \$0.1 million for the year ended December 31, 2016 to \$0.9 million for the year ended December 31, 2017. The change in other income was primarily due to increased interest income in the year ended December 31, 2017 due to higher investment balances.

Liquidity and Capital Resources

Sources of Liquidity

We have financed our operations primarily through private placements of our convertible preferred stock, strategic partnerships and the 2017 initial public offering of our common stock. As of December 31, 2018, we had cash, cash equivalents and marketable securities of \$70.1 million. On March 5, 2019, we announced the closing of a public offering resulting in gross proceeds of approximately \$97.8 million.

[Table of Contents](#)*Cash Flows*

The following table provides information regarding our cash flows for the years ended December 31, 2018, 2017 and 2016:

(in thousands)	Year ended December 31,		
	2018	2017	2016
Net cash provided by (used in) operating activities	\$ (55,216)	\$ (42,679)	\$ 31,588
Net cash provided by (used in) investing activities	87,195	(99,624)	(1,084)
Net cash provided by financing activities	1,064	68,597	58,259
Increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 33,043</u>	<u>\$ (73,706)</u>	<u>\$ 88,763</u>

Net Cash Provided by (Used in) Operating Activities

Net cash used in operating activities for the year ended December 31, 2018 was \$55.2 million as compared to \$42.7 million during the year ended December 31, 2017. We incurred losses during both periods. Net cash provided by operating activities was \$31.6 million during the year ended December 31, 2016. In 2016, we incurred losses, but they were offset by an increase in deferred revenue relating to upfront payments received from the 2016 Takeda agreements.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$87.2 million during the year ended December 31, 2018 compared to net cash used in operating activities of \$99.6 million during the year ended December 31, 2017. Net cash provided by investing activities for the year ended December 31, 2018 consisted primarily of maturities of marketable securities. Net cash used in investing activities for the year ended December 31, 2017 consisted primarily of purchases of marketable securities offset by maturities of marketable securities. Net cash used in investing activities for the year ended December 31, 2016 consisted primarily of purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$1.1 million during the year ended December 31, 2018 compared to net cash provided by financing activities of \$68.6 million during the year ended December 31, 2017. During the year ended December 31, 2018 cash provided by financing activities consisted primarily of the proceeds from exercise of stock options and purchases under ESPP. During the year ended December 31, 2017 cash provided by financing activities consisted primarily of the proceeds from our initial public offering. During the year ended December 31, 2016 cash provided by financing activities resulted from the proceeds received from sales of Series B-1 and C-1 Convertible Preferred Stock.

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 trials 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. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

[Table of Contents](#)

We expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating plan through at least mid 2021. Our future capital requirements will depend on many factors, including:

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, strategic partnerships and licensing arrangements. We do not have any committed external source of funds outside of those to be earned in connection with our agreement with Merck KGaA, if development activities are successful under this agreement. 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. 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, 2018:

(in thousands)	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 years
Lease commitments(1)	\$ 5,730	2,333	3,228	169	—

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

We enter into agreements in the normal course of business with contract research organizations for clinical trials and clinical supply manufacturing and with vendors for pre-clinical research studies, and other services and products for operating purposes. We have not included these payments in the table of contractual obligations above since the contracts are cancelable at any time by us, generally upon 30 days prior written notice to the vendor. Milestone payments associated with our license agreements have not been included in the above table of contractual obligations as we cannot reasonably estimate if or when they will occur. We do not expect any milestone payments for the year ended December 31, 2019 in connection with our development efforts.

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.

JOBS Act

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an “emerging growth company,” or an EGC, can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an EGC, we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an EGC until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

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

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	88
Consolidated Balance Sheets	89
Consolidated Statements of Operations and Comprehensive Loss	90
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)	91
Consolidated Statements of Cash Flows	92
Notes to Consolidated Financial Statements	93

Report of Independent Registered Public Accounting Firm

To the Shareholders 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, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

Adoption of ASU No. 2014-09

As discussed in Note 1 to the consolidated financial statements, the Company changed its method for recognizing revenue in 2018 due to the adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), 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 Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2013.
Boston, Massachusetts
March 8, 2019

Mersana Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 59,634	\$ 26,591
Short-term marketable securities	10,497	88,143
Accounts receivable	459	784
Prepaid expenses and other current assets	3,715	2,025
Total current assets	74,305	117,543
Property and equipment, net	2,694	2,319
Long-term marketable securities	—	10,482
Other assets	1,503	371
Total assets	<u>\$ 78,502</u>	<u>\$ 130,715</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 10,727	\$ 3,070
Accrued expenses	12,375	6,944
Deferred rent	127	232
Deferred revenue	46,196	21,635
Total current liabilities	69,425	31,881
Deferred rent, net of current portion	282	67
Deferred revenue, net of current portion	—	28,773
Total liabilities	<u>69,707</u>	<u>60,721</u>
Commitments (Note 13)		
Stockholders' equity		
Preferred stock, \$0.0001 par value; 25,000,000 shares authorized; 0 shares issued and outstanding at December 31, 2018 and 2017, respectively	—	—
Common stock, \$0.0001 par value; 175,000,000 shares authorized; 23,234,472 and 22,765,017 shares issued and outstanding at December 31, 2018 and 2017, respectively	3	3
Additional paid-in capital	172,966	168,018
Accumulated other comprehensive loss	(8)	(149)
Accumulated deficit	(164,166)	(97,878)
Total stockholders' equity	<u>8,795</u>	<u>69,994</u>
Total liabilities and stockholders' equity	<u>\$ 78,502</u>	<u>\$ 130,715</u>

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,		
	2018	2017	2016
Collaboration revenue	\$ 10,594	\$ 17,545	\$ 25,171
Operating expenses:			
Research and development	59,915	46,700	32,008
General and administrative	16,334	10,462	6,984
Total operating expenses	76,249	57,162	38,992
Other income:			
Interest income	1,398	910	121
Total other income	1,398	910	121
Net loss	\$ (64,257)	\$ (38,707)	\$ (13,700)
Other comprehensive loss:			
Unrealized gain (loss) on marketable securities	141	(149)	—
Comprehensive loss	\$ (64,116)	\$ (38,856)	\$ (13,700)
Net loss attributable to common stockholders — basic and diluted	\$ (64,257)	\$ (38,707)	\$ (13,700)
Net loss per share attributable to common stockholders — basic and diluted	\$ (2.79)	\$ (3.22)	\$ (10.82)
Weighted-average number of common shares used in net loss per share attributable to common stockholders — basic and diluted	23,032,250	12,022,733	1,266,758

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

Mersana Therapeutics, Inc.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(in thousands, except share and per share data)

	Series A-1 Convertible		Series B-1 Convertible		Series C-1 Convertible		Common Stock		Additional	Accumulated	Accumulated Deficit	Stockholders' Equity (Deficit)
	Preferred Stock		Preferred Stock		Preferred Stock		Shares	Amount	Paid-in Capital	Other Comprehensive Income (Loss)		
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2015	25,085,153	\$ 26,336	9,410,551	\$ 9,960	—	\$ —	1,223,457	\$ 1	\$ 2,778	\$ —	\$ (45,471)	\$ (42,692)
Issuance of Series B-1 convertible preferred stock, net of issuance costs of \$50	—	—	23,526,368	25,272	—	—	—	—	—	—	—	—
Issuance of Series C-1 convertible preferred stock, net of issuance costs of \$218	—	—	—	—	14,674,062	32,882	—	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	70,895	—	105	—	—	105
Stock-based compensation expense	—	—	—	—	—	—	—	—	668	—	—	668
Net loss	—	—	—	—	—	—	—	—	—	—	(13,700)	(13,700)
Balance at December 31, 2016	25,085,153	26,336	32,936,919	35,232	14,674,062	32,882	1,294,352	1	3,551	—	(59,171)	(55,619)
Issuance of common stock under initial public offering, net of issuance costs of \$7,580	—	—	—	—	—	—	5,000,000	—	67,420	—	—	67,420
Issuance of common stock under partial exercise of over-allotment option, net of issuance costs of \$55	—	—	—	—	—	—	51,977	—	725	—	—	725
Conversion of preferred stock into common stock	(25,085,153)	(26,336)	(32,936,919)	(35,232)	(14,674,062)	(32,882)	16,154,671	2	94,448	—	—	94,450
Exercise of stock options and warrants	—	—	—	—	—	—	264,017	—	452	—	—	452
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,422	—	—	1,422
Other comprehensive loss	—	—	—	—	—	—	—	—	—	(149)	—	(149)
Net loss	—	—	—	—	—	—	—	—	—	—	(38,707)	(38,707)
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 loss	—	—	—	—	—	—	—	—	—	141	—	141
Net loss	—	—	—	—	—	—	—	—	—	—	(64,257)	(64,257)
Balance at December 31, 2018	—	\$ —	—	\$ —	—	\$ —	23,234,472	\$ 3	\$ 172,966	\$ (8)	\$ (164,166)	\$ 8,795

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,		
	2018	2017	2016
Cash flows from operating activities			
Net loss	\$ (64,257)	\$ (38,707)	\$ (13,700)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation	1,257	928	655
Loss on disposal of fixed assets	20	—	—
Net amortization of premiums and discounts on investments	(296)	(293)	—
Stock-based compensation	3,884	1,422	668
Change in deferred rent	110	(159)	102
Changes in operating assets and liabilities:			
Accounts receivable	325	267	(411)
Prepaid expenses and other current assets	(1,690)	(1,200)	(245)
Other assets	(1,132)	60	(60)
Accounts payable	7,375	1,335	(325)
Accrued expenses	5,431	3,562	1,726
Deferred revenue	(6,243)	(9,894)	43,178
Net cash provided by (used in) operating activities	<u>(55,216)</u>	<u>(42,679)</u>	<u>31,588</u>
Cash flows from investing activities			
Maturities of marketable securities	88,565	47,220	—
Purchase of property and equipment	(1,370)	(1,143)	(1,084)
Purchase of marketable securities	—	(145,701)	—
Net cash provided by (used in) investing activities	<u>87,195</u>	<u>(99,624)</u>	<u>(1,084)</u>
Cash flows from financing activities			
Net proceeds from sale of Series B-1 convertible preferred stock	—	—	25,272
Net proceeds from sale of Series C-1 convertible preferred stock	—	—	32,882
Net proceeds from initial public offering	—	67,420	—
Net proceeds from issuance of common stock upon partial exercise of overallotment	—	725	—
Proceeds from exercise of stock options	918	452	105
Proceeds from purchases of common stock under ESPP	146	—	—
Net cash provided by financing activities	<u>1,064</u>	<u>68,597</u>	<u>58,259</u>
Increase (decrease) in cash, cash equivalents and restricted cash	33,043	(73,706)	88,763
Cash, cash equivalents and restricted cash, beginning of period	26,962	100,668	11,905
Cash, cash equivalents and restricted cash, end of period	<u>\$ 60,005</u>	<u>\$ 26,962</u>	<u>\$ 100,668</u>
Supplemental disclosures of non-cash activities:			
Conversion of preferred stock to common stock upon closing of initial public offering	\$ —	\$ 94,450	\$ —
Purchases of property and equipment included in accounts payable and accrued expenses	\$ 317	\$ 35	\$ 414
Purchases of property and equipment reimbursed by landlord	\$ —	\$ —	\$ 356
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 located in Cambridge, Massachusetts. The Company is focused on developing antibody drug conjugates, or ADCs, that offer a clinically meaningful benefit for cancer patients with significant unmet need. The Company leveraged 20 years of industry learning in the ADC field to develop proprietary technologies that enable it to design ADCs to have improved efficacy, safety and tolerability relative to existing ADC therapies. The Company's most advanced platform, Dolaflexin, has been used to generate a pipeline of proprietary ADC product candidates to address patient populations that are not currently amenable to treatment with traditional ADC-based therapies. The Company's lead product candidate, XMT-1536, is an ADC targeting NaPi2b, an antigen broadly expressed in ovarian cancer and non small cell lung cancer (NSCLC). The first patient was dosed on XMT-1536 in early 2018 and the study is currently in Phase 1 dose escalation in ovarian cancer, NSCLC and other orphan indications where a majority of patients express NaPi2b including endometrial, papillary renal, papillary thyroid, and salivary duct.

In January 2019, the Company announced that the development of XMT-1522 was being discontinued and the partnerships with Takeda were being terminated during the quarter ended March 31, 2019.

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 \$64,257, \$38,707 and \$13,700 for the years ended December 31, 2018, 2017 and 2016, respectively. The Company expects to continue to incur operating losses for at least the next several years. As of December 31, 2018, the Company had an accumulated deficit of \$164,166. The future success of the Company is dependent on 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. The Company's net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on the Company's stockholders' equity and working capital. The Company believes that its existing cash, cash equivalents and marketable securities as of December 31, 2018, and the \$97,800 in gross proceeds from the offering discussed in Note 15, will enable it to fund its operating plan through at least mid 2021.

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 United States generally accepted accounting principles 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.

Effective January 1, 2018, the Company adopted the requirements of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606) using the modified retrospective method as discussed below in Note 2. Summary of Significant Accounting Policies. All 2018 amounts and disclosures set forth in this Annual Report on Form 10-K reflect these changes.

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

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 separate units of accounting and best estimate of selling price of those units of accounting within its revenue arrangements, accrued 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 in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision-maker, the Company's chief executive officer, view the Company's operations and manage its business as a single operating segment, which is the business of discovering and developing ADCs.

Research and Development

The Company expenses all costs incurred in performing research and development activities. Research and development expenses include salaries and benefits, materials and supplies, preclinical expenses, manufacturing expenses, stock-based compensation expense, depreciation of equipment, contract services and other outside expenses. Costs of certain development activities, such as manufacturing, are recognized based on an evaluation of the progress to completion of specific tasks. 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 in the financial statements as prepaid or accrued research and development costs. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. Costs associated with collaboration agreements are included in research and development expense.

The Company may also incur costs associated with its collaboration agreements to supply ADC drug substance for which it has an enforceable right to recover such costs at the time the costs are incurred and it is probable the Company will receive some future benefit. Costs may include third party manufacturing and internal labor. The capitalized amounts are expensed when the related goods are delivered.

Revenue Recognition

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 applies to all contracts with customers, except for contracts

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

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 year ended December 31, 2018, revenue decreased by \$378, net loss increased by \$378 and basic and diluted net loss per share increased by \$0.02, based on revenue recognition under Topic 606, as compared to the Company's prior revenue recognition methodology under ASC 605 *Revenue Recognition*. These changes were primarily caused by the differences in determining and allocating transaction price under Topic 606.

The Company enters into collaboration agreements which are within the scope of 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.

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

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.

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

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

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		Year ended	
	December 31, 2018		December 31, 2017	
	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	\$ 26,591	\$ 59,634	\$ 100,297	\$ 26,591
Restricted cash included in other assets	371	371	371	371
Total cash, cash equivalents and restricted cash per statement of cash flows	<u>\$ 26,962</u>	<u>\$ 60,005</u>	<u>\$ 100,668</u>	<u>\$ 26,962</u>

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. Long-term marketable securities consist of investments with maturities greater than one year that are not expected to be used to fund current operations. 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. Unrealized gains and losses on available-for-sale securities are included in other comprehensive loss as a component of stockholders' equity (deficit) until realized.

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

Other Assets

The Company recorded other assets of \$1,503 and \$371 assets as of December 31, 2018 and 2017, respectively. The December 31, 2018 amount is comprised of restricted cash of \$371 held as security deposits for a standby letter of credit related to a facility lease and a corporate credit card program and \$1,132 held by a service provider. The December 31, 2017 amount is comprised of restricted cash.

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 and directors to be recognized as expense in the statements of operations based on their grant date fair values. Expense related to stock awards to non-employees is required to be recognized in the statement of operations based on the awards' vesting 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 IPO 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 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.

Through December 31, 2016, the Company was required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from its estimates. The Company used historical data to estimate post-vesting forfeitures and recorded stock-based compensation expense only for those awards that were expected to vest. To the extent that actual forfeitures differ from estimates, the difference was recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the financial statements is based on awards that were ultimately expected to vest. The fair value of stock-based payments was recognized as expense, net of estimated forfeitures, over the requisite service period which is generally the vesting period.

In the first quarter of 2017, the Company made an accounting policy election to recognize forfeitures as they occur upon adoption of guidance per ASU No. 2016-09. The adoption of this ASU did not have a material impact on the Company's financial statements.

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

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

For purposes of the diluted net loss per share calculation, convertible preferred stock, warrants to purchase common stock and options 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,		
	2018	2017	2016
Series A-1 Convertible Preferred Stock	—	—	5,574,467
Series B-1 Convertible Preferred Stock	—	—	7,319,307
Series C-1 Convertible Preferred Stock	—	—	3,260,897
Warrants	110,365	110,365	129,491
Stock options	3,746,567	3,205,485	2,901,985
	<u>3,856,932</u>	<u>3,315,850</u>	<u>19,186,147</u>

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 retirements or sales of assets during the years ended December 31, 2018, 2017 and 2016.

The Company reviews its property and equipment 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, 2018, 2017 and 2016.

Repairs and maintenance costs are expensed as incurred.

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.

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

Income Taxes

The Company accounts for income taxes using the liability method. The difference between the financial statement and tax basis of the assets and liabilities is determined annually. Deferred income tax assets and liabilities are computed using the tax laws and rates that are expected to apply for periods in which such differences reverse. Valuation allowances are established, if necessary, to reduce the deferred tax asset to the amount that will more likely than 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 greater than 50% likely of being realized. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs.

Comprehensive Income (Loss)

Comprehensive income (loss) is comprised of net loss and other comprehensive loss. For the years ended December 31, 2018 and 2017, other comprehensive loss consisted of unrealized income and loss on marketable securities. For the year ended December 31, 2016 comprehensive loss equaled net loss.

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 is not exposed to any significant concentrations of credit risk from these financial instruments.

Recently Issued Accounting Pronouncements

In January 2016, the FASB issued ASU No. 2016-01 *Financial Instruments* (ASU No. 2016-01) related to the recording of financial assets and financial liabilities. Under the amended guidance, equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) are to be measured at fair value with changes in fair value recognized in net income (loss). However, an entity has the option to measure equity investments without readily determinable fair values either (i) at fair value or (ii) at cost, adjusted for changes in observable prices minus impairment. Changes in measurement under either alternative will be recognized in net income (loss). The amended guidance became effective January 1, 2018. The Company adopted the new standard effective January 1, 2018. Based on the Company's current investment holdings, the adoption of this new standard did not have a material impact on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU No. 2016-02), which will replace the existing guidance in ASC 840, Leases. The updated standard aims to increase transparency and comparability among organizations by requiring lessees to recognize lease assets and lease liabilities on the balance sheet and requiring disclosure of key information about leasing arrangements. This standard is effective for the Company in the fiscal year beginning after December 15, 2018, but early adoption is permissible. The Company plans to adopt the standard effective January 1, 2019. The Company plans to use the modified retrospective method of adoption and to elect the available practical expedients. The standard is expected to have a material impact on the Consolidated Balance Sheets, but not have an impact on the Consolidated Statements of Operations. The most significant impact will be the recognition of right-of-use assets and lease liabilities for operating leases.

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

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments*. The new standard clarifies certain aspects of the statement of cash flows, including the classification of contingent consideration payments made after a business combination and several other clarifications not currently applicable to the Company. The new standard also clarifies that an entity should determine each separately identifiable source or use within cash receipts and cash payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. The Company adopted the new standard effective January 1, 2018. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows: Restricted Cash* (ASU No. 2016-18). The amendments in this update require that amounts generally described as restricted cash and restricted cash equivalents be included within cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted the new standard effective January 1, 2018. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*. This guidance is intended to provide clarity and reduce diversity in practice as to when changes to the terms or conditions of share-based payments are accounted for as modifications. Under this new guidance, entities will apply modification accounting if the fair value, vesting conditions or classification of the award changes. This guidance will be effective for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods, and early adoption is permitted. The guidance per ASU 2017-09 is to be adopted prospectively to an award modified on or after the adoption date. The Company adopted the new standard effective January 1, 2018. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. This guidance simplifies the accounting for share-based payments to non-employees by aligning it with the accounting for share-based payments to employees, with certain exceptions. This guidance will be effective for annual reporting periods beginning after December 15, 2018, including interim periods within those annual reporting periods, and early adoption is permitted. The guidance per ASU 2018-07 is to be adopted by using a modified retrospective approach with the cumulative effect of initially applying the new standard recognized at the date of initial application. The Company does not anticipate a material impact to the consolidated financial statements as a result of the adoption of this guidance.

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 will be 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 is currently evaluating the potential impact that ASU No. 2018-18 may have on its financial position and results of operations.

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

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 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 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 is also eligible to receive up to a total of \$780,000 in future milestones related to all targets under the 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 agreement. There have been no additional milestone payments in the year ended December 31, 2018. 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 upon achievement of the milestone.

Unless earlier terminated, the agreement will expire upon the expiration of the last royalty term for a product under the 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 agreement as preclinical development candidates, upon the expiration of the last to expire research program. Merck KGaA may terminate the 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 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 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 agreement.

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

Accounting Analysis

For periods prior to January 1, 2018, the Company applied the provisions of ASC 605 in accounting for this arrangement.

By applying the contract modification practical expedient, the Company has aggregated the effect of all modifications through the initial date of application of Topic 606 for the purposes of (i) identifying the satisfied and unsatisfied performance obligations, (ii) determining the transaction price and (iii) allocating the transaction price to the satisfied and unsatisfied performance obligations.

The Company identified the following performance obligations under the 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.

As of the date of initial application of Topic 606, the total transaction price for the Merck KGaA Agreement was \$22,875, which included approximately \$7,875 fees for research and development activities which have been or were expected to be received and \$3,000 of milestone payments previously earned. 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 milestone 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 Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. In the third quarter of 2018, the Company revised its estimate for fees associated with research and development activities under the Merck KGaA Agreement to \$7,070, a decrease of \$805. The revised total transaction price for the Merck KGaA Agreement is \$22,070.

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 transaction price as of the date of initial application of Topic 606 of \$22,875 was allocated to the performance obligations as follows: approximately \$4,226 for each of the license and corresponding research and development services

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

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, fourth, fifth and sixth 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.

During the years ended December 31, 2018, 2017 and 2016, the Company recorded revenue of \$2,444, \$3,636 and \$3,644, respectively, related to its efforts under the collaboration agreement. Included in accounts receivable as of December 31, 2018 and 2017 was \$450 and \$330, respectively, related to the Merck KGaA Agreement.

As of December 31, 2018 and 2017, the Company had recorded \$5,462 and \$6,634, respectively, in deferred revenue related to the Merck KGaA 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 study, at its own expense. Takeda had the option to conduct Phase 1 development activities at its own expense within its territory. The parties agreed to collaborate on the further development of XMT-1522 in accordance with a global development plan (Post-Phase 1 Development). The parties agreed to share equally all clinical stage manufacturing costs and any Post-Phase 1 Development costs incurred in the performance of activities for the purpose of obtaining regulatory approval in either the United States or Canada and in certain other major markets in the rest of the world. Each party was responsible for all Post-Phase 1 Development costs incurred in the performance of activities solely for the purpose of obtaining regulatory approval in such party's territory. Each party may conduct independent development of XMT-1522, subject to certain restrictions.

The Company received an upfront payment of \$26,500 upon execution of the XMT-1522 Agreement. In addition, the Company was entitled to a milestone payment of \$20,000 upon achievement of the IND Clearance Date (as defined therein). The Company achieved the IND Clearance Date in October 2016.

In addition to the milestone payment upon achievement of the IND Clearance Date, the Company is entitled to receive future development, regulatory and commercial milestones of up to \$288,000, consisting of \$87,000 of development milestones, \$128,000 of regulatory milestones and \$73,000 of commercial milestones, as well as royalties in the low to mid teens on net sales of XMT-1522 in Takeda's territory during the applicable royalty term. There are development milestones payable upon the achievement of nine separate events: the initiation of Phase 2 clinical trials and Phase 3 clinical trials for four separate specified patient populations and the initiation of a Phase 3 clinical trial for one additional unspecified patient population. There are 14 regulatory milestones, which are payable upon regulatory submissions, regulatory approvals and pricing approvals, as applicable, for the U.S., European Union and Japanese markets for up to four separate patient populations and multiple label indications. In addition, a regulatory milestone is payable upon the

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

receipt of regulatory and pricing approval in two specified markets other than the United States, the European Union or Japan. There are three individual commercial milestones, which are payable upon the attainment of certain thresholds for annual net sales. The next potential milestone the Company will be eligible to receive is a development milestone of \$12,000 related to the initiation of a Phase 2 clinical trial.

The XMT-1522 Agreement expires upon the expiration of the royalty term for XMT-1522, after which time, Takeda will have a perpetual, royalty-free license. However, Takeda may terminate the XMT-1522 Agreement in its entirety for convenience upon 30 days' prior written notice at any time up to the initiation of the first Phase 2 clinical study of XMT-1522 or upon 90 days' prior written notice following the initiation of the first Phase 2 clinical study of XMT-1522. Each party may terminate the XMT-1522 Agreement in its entirety upon bankruptcy or similar proceedings of the other party and in its entirety or on a country-by-country basis upon an uncured material breach of the agreement by the other party. Following termination, XMT-1522 will revert to the Company for further development and commercialization.

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 initially 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. Takeda was responsible for the product development and marketing of any products resulting from this collaboration. To date, the Company has received \$24,800 in non-refundable upfront fees, technology access fees or option exercise fees.

For the two targets initially under the 2014 Agreement, the Company initially granted a research license upon designation of a target. To receive a development and commercialization license for these designated targets, Takeda was required to pay an additional option exercise fee of \$1,300. For the remaining five targets, the Company grants a research, development and commercialization license upon the designation of a target.

For each designated target, the Company and Takeda develop research plans to evaluate Takeda's antibodies as ADCs incorporating the Company's technology. The Company receives service fees for its efforts under the research plans. The goal of the research plans is to provide Takeda with sufficient information to formally nominate a development candidate and begin Investigational New Drug Application (IND), enabling studies or cease development on the designated target.

As of December 31, 2018, Takeda had designated four targets and received development and commercialization licenses for the first, third and fourth designated targets and a research license for the second designated target. Takeda has limited replacement rights for two designated targets, subject to certain contractual restrictions. Takeda is required to pay \$500 to utilize the second limited replacement right.

As of December 31, 2018, if products are successfully developed and commercialized, the Company would be entitled to receive aggregate milestones of up to \$474,750 for all eligible designated targets consisting of \$50,250 in development milestones, \$153,000 in regulatory milestones, and \$271,500 in commercial milestones. The total milestones payable on each of the remaining eligible three targets are \$158,250. There are four individual development milestones per target, which are payable upon the filing of an IND application and the initiation of Phase 1 through Phase 3 clinical trials. There are eight individual regulatory milestones per target. These are payable upon regulatory submissions, regulatory approvals and pricing approvals, as applicable, for the U.S., European Union and Japanese markets and regulatory approvals for both a second and third indication. There are six individual commercial milestones, which are payable upon the first commercial sale in each of the U.S., European Union and Japanese markets and upon the attainment of three separate defined thresholds for annual net sales. The next potential milestone payment the Company will be eligible to receive is a development milestone of \$750 related to the filing of an IND. The Company is also entitled to receive royalties on product sales, if

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

any, during the applicable royalty term. Royalties payable on the remaining designated targets are in the mid to high single digits.

The Company may elect to exercise an option to co-develop and co-commercialize one product incorporating either Takeda's fifth, sixth or seventh target in the United States for a payment of \$15,000. If the Company elects to exercise the option to co-develop and co-commercialize a product, the Company will share in 50% of the profits related to the United States. The Company will be responsible for 50% of costs incurred specifically for the United States and 30% of global development costs. Any costs incurred specifically for a foreign country will be borne 100% by Takeda. If the Company elects to co-develop and co-commercialize a product, certain regulatory milestones and royalties related to the United States for that target would not be paid by Takeda.

Unless earlier terminated, the 2016 Restated Agreement will expire upon the expiration of the last royalty term for a product under the agreement, after which time, Takeda will have a perpetual, royalty-free license. Except with respect to the target antigen of a product for which the Company exercised its option to co-develop and co-commercialize in the United States, Takeda may terminate the 2016 Restated Agreement in its entirety or with respect to any target for convenience upon 45 days' prior written notice. Each party may terminate the 2016 Restated Agreement in its entirety upon bankruptcy or similar proceedings of the other party or upon an uncured material breach of the 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.

Accounting Analysis

For periods prior to January 1, 2018, the Company applied the provisions of ASC 605 in accounting for these arrangements.

Under ASC 605 and Topic 606, the Company has concluded that the 2016 Restated Agreement and the XMT-1522 Agreement should be accounted for as one arrangement due in part because the agreements are with the same party and were negotiated and executed contemporaneously. Further, in applying the contract modification practical expedient, the Company has aggregated the effect of all modifications through the initial date of application of Topic 606 for the purposes of (i) identifying the satisfied and unsatisfied performance obligations, (ii) determining the transaction price and (iii) allocating the transaction price to the satisfied and unsatisfied performance obligations.

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

The performance obligations and the allocated transaction price as of the date of initial application of Topic 606 are as follows:

Performance obligations	Allocated Transaction Price
XMT-1522 license and research services	\$ 49,828
Joint research committee services for XMT-1522	449
Exclusive license to the first designated target and research services	6,611
Research license to the second designated target and research services	1,017
Material right related to the exclusive license to the second designated target	526
Exclusive license to the third designated target and research services	4,974
Exclusive license to the fourth designated target and research services	3,678
Material right related to the license to the fifth designated target and research services	3,506
Material right related to the license to the sixth designated target and research services	3,506
Material right to license to the seventh designated target and research services	3,506
Material right related to first replacement right for a designated target	3,506
Material right related to the second replacement right to a designated target	3,116
Rights to future technological improvements	1,750
Joint research committee services	150
	<u>\$ 86,123</u>

The Company has concluded the license related to each of the designated targets is not distinct from the research services performed related to each of the designated targets as Takeda cannot obtain the benefit of the license without the related research services. Each license to a designated target and the related services performance obligation is considered distinct from every other license to a designated target and related services performance obligation as each research plan is pursued independent of the any other research plans for other designated targets. Further, the material rights provided in the agreement provide Takeda incremental rights for either no additional consideration or for additional fees that contain a significant discount. The material rights are distinct from the other performance obligations in the arrangement as they are options in the contract and are 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 certain materials and know how related to the Company's manufacturing processes are one performance obligation. The license to the Company's intellectual property is not distinct from the research and related development services that the Company is obligated to perform. Takeda would not have the ability to realize the value of the license without the Company performing the related services.

The Company has concluded that the Post-Phase 1 Development activities under the XMT-1522 Agreement represent joint operating activities in which both parties are active participants and of which both parties are exposed to significant risks and rewards that are dependent on the commercial success of the activities. Accordingly, the Company is accounting for the Post-Phase 1 Development activities in accordance with ASC 808 and they are not considered revenue elements under Topic 606. For the years ended December 31, 2018, 2017 and 2016, the Company was billed approximately \$8,046, \$3,408 and \$340, respectively, from Takeda representing the Company's share of 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,

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

2018. During the years ended December 31, 2018, 2017 and 2016, the Company billed Takeda \$3,746, \$0 and \$0, respectively, related to ASC 808 costs.

As of the date of initial application of Topic 606, the total transaction price for the 2016 Restated Agreement and the XMT-1522 Agreement was \$86,123, which included approximately \$14,023 of fees associated with research and development activities which had been or were expected to be provided. The Company utilizes the expected value approach to estimate the amount of consideration related to the 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 milestone payments, which had not 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 Takeda. 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 Company will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. In the third quarter of 2018, the Company revised its estimate for fees associated with research and development activities under the XMT-1522 Agreement to \$9,615. The revised total transaction price for the 2016 Restated Agreement and the XMT-1522 Agreement is \$86,289.

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 which include a license and research services, was 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 material rights and rights to future technological improvements were developed based on the estimated selling prices of a license or rights received and any fees payable upon exercise of the associated option, as well as considering the probability that additional technology would be made available or the probability the counterpart would utilize the technology or exercise the option. 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 will recognize revenue related to the performance obligations, which include research licenses or an exclusive development and commercialization license and the related research services, 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 estimated costs of the research. To the extent that the Company receives fees for the research services as they are performed, these amounts are recorded as deferred revenue. Revenue related to material rights will be recognized when the option is exercised, unless there are additional research services that the Company is required to perform related to the designated target (in which case revenue will be recognized based on the proportional performance model) or at the time the option right lapses. To the extent that the Company receives a fee upon exercise of the option, such amounts are recorded as deferred revenue. Revenue related to the material rights related to replacement rights will be recognized over the research term of the replacement target once the replacement right is exercised or at the time the right lapses unused. To the extent that the Company receives a fee upon exercise of the replacement right, such 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 approximates the time and cost incurred), which is expected to be ten years and six years, respectively. The Company will reassess the estimated remaining term at each subsequent reporting period.

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

For the years ended December 31, 2018, 2017 and 2016, the Company recorded total revenue of \$5,868, \$13,784 and \$21,401, respectively, related to its efforts under the 2016 Restated Agreement and the XMT-1522 Agreement. Included in accounts receivable as of December 31, 2018 and 2017 was \$9 and \$454, respectively, related to the Takeda agreements. Included in accounts payable as of December 31, 2018 was \$2,749 related to the Takeda agreements. During the quarter ended September 30, 2018, the Company revised its estimate of the total costs to complete research services under the 2016 Restated Agreement and the XMT-1522 Agreement, which changed the total consideration to be received under the agreements and the amount of revenue recognized during the year ended December 31, 2018. The Company recognized approximately \$1,535 less for the year ended December 31, 2018 as a result of the Company's change in estimate. The change in estimate increased the net loss by \$1,535, or \$0.07 per common share, for the year ended December 31, 2018.

As of December 31, 2018 and 2017, the Company had \$39,960 and \$43,579, respectively, of deferred revenue related to the Takeda agreements that will be recognized over the remaining performance periods for the applicable obligations.

On January 2, 2019, the Company received notices from Takeda stating that Takeda was exercising its right to: (a) terminate the 2016 Restated Agreement upon 45 days' prior written notice and (b) terminate the XMT-1522 Agreement upon 30 days' prior written notice. The Company and Takeda are working to wind down activities under the 2016 Restated Agreement and the XMT-1522 Agreement over the course of the applicable notice periods. The respective notice periods expired in February 2019 and the agreements were terminated. Under Topic 606, the Company has concluded that the performance obligations were not modified during the year ended December 31, 2018, and that the Company will account for the termination notice as an event in the first quarter of the fiscal year ended December 31, 2019.

Summary of Contract Assets and Liabilities

The following table presents changes in the balances of our contract assets and liabilities during the year ended December 31, 2018:

	Balance at Beginning				Balance at End of Period
	of Period	Additions	Deductions		
Year ended December 31, 2018					
Contract assets	\$ —	\$ —	\$ —	\$ —	\$ —
Contract liabilities:					
Deferred revenue	\$ 52,439	\$ 2,851	\$ 9,094	\$ 46,196	

The impact of the adoption of the new revenue recognition guidance is reflected within the balance as of the beginning of period.

During the year ended December 31, 2018, 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, 2018
Revenue recognized in the period from:	
Amounts included in the contract liability at the beginning of the period	\$ 8,704
Performance obligations satisfied in previous periods	\$ —

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

Other Revenue

The Company has provided limited services for a collaboration partner, Asana BioSciences. For the years ended December 31, 2018, 2017 and 2016, the Company recorded revenue of \$782, \$125 and \$125, 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.

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, 2018 and 2017:

	Fair Value	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2018				
Marketable securities:				
U.S. Treasuries	\$ 10,497	\$ 10,497	\$ —	\$ —
	<u>\$ 10,497</u>	<u>\$ 10,497</u>	<u>\$ —</u>	<u>\$ —</u>
	Fair Value	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2017				
Marketable securities:				
U.S. Treasuries	\$ 62,640	\$ 62,640	\$ —	\$ —
Commercial paper	24,931	—	24,931	—
Corporate bonds	11,054	—	11,054	—
	<u>\$ 98,625</u>	<u>\$ 62,640</u>	<u>\$ 35,985</u>	<u>\$ —</u>

There were no changes in valuation techniques or transfers between fair value measurement levels during the years ended December 31, 2018, 2017 and 2016. As of December 31, 2018 and 2017, cash and cash equivalents were comprised of cash and money market funds.

5. Marketable Securities

The following table summarizes marketable securities held at December 31, 2018 and 2017.

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2018				
U.S. Treasuries	\$ 10,505	\$ —	\$ (8)	\$ 10,497
	<u>\$ 10,505</u>	<u>\$ —</u>	<u>\$ (8)</u>	<u>\$ 10,497</u>

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2017				
U.S. Treasuries	\$ 62,777	\$ —	\$ (137)	\$ 62,640
Commercial paper	24,931	—	—	24,931
Corporate bonds	11,066	—	(12)	11,054
	<u>\$ 98,774</u>	<u>\$ —</u>	<u>\$ (149)</u>	<u>\$ 98,625</u>

As of December 31, 2018, the Company held three securities that were in an unrealized loss position. The aggregate fair value of securities held by the Company in an unrealized loss position at December 31, 2018 was \$10,497. These securities were held by the Company in an unrealized loss position for more than 12 months. As of December 31, 2018, the Company did not intend to sell, and would not be more likely than not required to sell, the securities in an unrealized loss position before recovery of their amortized cost basis. Furthermore, the Company has determined that there was no material change in the credit risk of these securities. As a result, the Company determined it did not hold any securities with any other-than-temporary impairment as of December 31, 2018.

There were no realized gains or losses on available-for-sale securities during the years ended December 31, 2018, 2017 and 2016.

6. Property and Equipment

Property and equipment consists of the following as of December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
Laboratory equipment	\$ 6,134	\$ 5,237
Computer equipment, office equipment and software	1,035	718
Leasehold improvements	1,886	1,504
Total property and equipment at cost	9,055	7,459
Less: Accumulated depreciation	(6,361)	(5,140)
	<u>\$ 2,694</u>	<u>\$ 2,319</u>

Depreciation expense for the years ended December 31, 2018, 2017 and 2016 was \$1,257, \$928 and \$655, respectively.

7. Accrued Expenses

Accrued expenses consist of the following as of December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
Accrued payroll and related expenses	\$ 3,042	\$ 3,041
Accrued preclinical, manufacturing and clinical expenses	8,314	3,183
Accrued professional fees	567	492
Accrued other	452	228
	<u>\$ 12,375</u>	<u>\$ 6,944</u>

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

8. Preferred Stock

As of December 31, 2018, the Company has 25,000,000 shares of authorized preferred stock. No shares of preferred stock have been issued.

9. Stockholders' Equity (Deficit)

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, 2018 and 2017 there were 3,856,932 and 3,315,850, respectively, shares of common stock reserved for the exercise of outstanding stock options and warrants.

	December 31, December 31,	
	2018	2017
Warrants	110,365	110,365
Stock options	3,746,567	3,205,485
	<u>3,856,932</u>	<u>3,315,850</u>

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. During the year ended December 31, 2017, the Company issued 19,071 shares of common stock upon the exercise of a warrant.

10. Stock Options

Stock Option Plan

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 awards 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, 2018 there were 2,085,048 shares available for future issuance under the Plan. In January 2019, the number of shares of common stock that might be issued under the Plan was increased by 929,378 shares.

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

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

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.

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

	Number of Shares	Weighted- Average Exercise Price	Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Options outstanding at January 1, 2018	3,205,485	\$ 3.44	7.8	\$ 41,709
Granted	1,273,115	13.33		
Exercised	(427,269)	2.15		
Cancelled	(304,764)	7.99		
Options outstanding at December 31, 2018	<u>3,746,567</u>	\$ 6.58	7.6	\$ 3,897
Options exercisable at December 31, 2018	<u>1,998,527</u>	\$ 3.57	6.6	\$ 3,460

The weighted-average grant date fair value of options granted during the years ended December 31, 2018, 2017 and 2016, was \$8.78, \$5.53 and \$2.34 per share, respectively.

Cash received from the exercise of stock options was \$918, \$452 and \$105 for the years ended December 31, 2018, 2017 and 2016, respectively.

Stock-Based Compensation

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

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.

For the years ended December 31, 2018, 2017 and 2016, the Company recorded stock-based compensation expense of \$3,828, \$1,366 and \$664, respectively, related to employee grants. The Company has an aggregate of \$10,289 of unrecognized stock compensation cost as of December 31, 2018 remaining to be amortized over the weighted-average period of 2.6 years. 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,		
	2018	2017	2016
Risk-free interest rate	2.7 %	2.2 %	1.5 %
Expected dividend yield	— %	— %	— %
Expected term (years)	6.07	6.21	6.25
Expected stock price volatility	73 %	67 %	69 %

Expected volatility for the Company's common stock was 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

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

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.

Prior to the Company's initial public offering in June 2017, the fair value of the common stock had been determined by the Board at each date of grant based on the variety of factors, including the Company's financial position and historical financial performance, the status of developments within the Company's research and development activities, the composition and ability of the current research and management team, an evaluation of the Company's competition, the current climate in the marketplace, the illiquid nature of the common stock, the effect of the rights and preferences of the preferred shareholders, and the prospects of the liquidity event, among others.

The Company granted stock option awards to non-employees. Total expense recorded during the years ended December 31, 2018, 2017 and 2016 related to these awards was \$56, \$56 and \$4, respectively.

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 year ended December 31, 2018 the Company issued 42,186 shares under the 2017 ESPP, with 182,814 available for issuance as of December 31, 2018. In January 2019, the number of shares of common stock for issuance under the 2017 ESPP was increased by 232,344 shares.

11. Income Taxes

For the years ended December 31, 2018, 2017 and 2016, 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, 2018, 2017 and 2016 are as follows:

	<u>2018</u>	<u>2017</u>	<u>2016</u>
Income tax computed at federal statutory tax rate	21.0 %	34.0 %	34.0 %
State taxes, net of federal benefit	6.5 %	5.1 %	5.1 %
Permanent differences	0.6 %	(0.8)%	(1.3)%
Research and development expenditures	— %	(2.3)%	— %
General business credits	4.2 %	8.2 %	12.9 %
Impact of tax reform	— %	(27.3)%	— %
Other	— %	— %	(0.1)%
Change in valuation allowance	(32.3)%	(16.9)%	(50.6)%
	<u>— %</u>	<u>— %</u>	<u>— %</u>

In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB No. 118), which allowed the Company to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. The Company's provisional estimate associated with the reduction in the U.S. federal corporate tax rate from 35% to 21% impacted the changes in the valuation allowance and change in tax rate component of the Company's effective tax rate reconciliation as well as its ending deferred tax assets and valuation allowance in the deferred tax footnote disclosure. In the fourth quarter of 2018, we completed our analysis to determine the effect of the Tax Act and recorded no adjustments as of December 31, 2018.

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

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, 2018 and 2017 are as follows:

	2018	2017
Deferred tax assets:		
Net operating losses	\$ 27,916	\$ 9,324
Tax credit carryforwards	10,178	7,516
Deferred revenue	12,410	13,718
Licensed technology	1,160	1,266
Depreciation	405	268
Accrued expenses	1,585	53
Deferred expenses	112	313
Unrealized loss	43	41
Other state credits	131	103
Total deferred tax assets	53,940	32,602
Valuation allowance	(53,940)	(32,602)
Net deferred tax assets	\$ —	\$ —

The Company has incurred net operating losses (NOL) since inception. At December 31, 2018, the Company had Federal and State net operating loss carryforwards of approximately \$102,112 and \$102,405, respectively. Of the \$102,112 of Federal net operating loss carryforwards, \$34,115 expire at various dates through 2037. The remaining \$67,997 of Federal net operating loss carryforwards do not expire. The State net operating loss carryforwards expire at various dates through 2038. At December 31, 2018, the Company had Federal and State research and development tax credit carryforwards of approximately \$7,708 and \$3,294, respectively, which expire at various dates through 2038.

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 these assets. Accordingly, the Company recorded a valuation allowance of \$53,940 and \$32,602 at December 31, 2018 and December 31, 2017, respectively. The valuation allowance increased by \$21,338 and \$6,611 during the years ended December 31, 2018 and 2017, respectively, primarily as a result of net operating losses generated during the periods.

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 December 31, 2015 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

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

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, 2018 and 2017, 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, 2018 and 2017, 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 one state jurisdiction. The Company did not have any foreign operations during the years ended December 31, 2018, 2017 and 2016. The statute of limitations for assessment by the Internal Revenue Service and state tax authorities is closed for tax years prior to 2015, 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.

12. 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. The Company matches the employees' contributions at 50% on the first 6% up to \$6. For the years ended December 31, 2018, 2017 and 2016, the Company recorded expense of \$332, \$273 and \$136, respectively, related to its contribution to its 401(k) Plan.

13. Commitments

Operating Leases

The Company leases office space in Cambridge, MA under an operating lease, which is effective through March 2021. The Company has an option to extend the lease term for an additional five years. The lease also provided the Company with a tenant improvement allowance of up to \$356. The Company fully utilized the allowance and recorded the assets acquired with the allowance as leasehold improvements. The Company recorded the tenant improvement allowance incurred as a deferred lease incentive and has amortized the deferred lease incentive through a reduction of rent expense ratably over the lease term.

In connection with the office lease, the Company has a letter of credit agreement for the benefit of its landlord in the amount of \$321 as of each December 31, 2018 and 2017, respectively, collateralized by a money market account.

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

In addition, the Company leases certain equipment under leases that expire through February 2024. Future minimum lease payments under leases, as amended, were as follows:

2019	\$ 2,333
2020	2,468
2021	760
2022	83
2023 and thereafter	86
	<u>\$ 5,730</u>

Rent expense was approximately \$1,994, \$1,834 and \$1,572 for the years ended December 31, 2018, 2017 and 2016, respectively.

The Company is recording rent expense on a straight-line basis over the term of the lease and has recorded deferred rent in the consolidated balance sheets accordingly.

License Agreements

Through December 31, 2018 the Company has licensed intellectual property from two biotechnology companies. The consideration included upfront payments and a commitment to pay annual license fees, milestone payments, and, upon product commercialization, royalties on revenue generated from the sale of products covered by the licenses. During the year ended December 31, 2017, the Company recorded expense related to milestone payments of \$2,750 related to these agreements.

14. Related Party Transactions

Included in Series C-1 financing and the Company's initial public offering were investments of \$10,000 and \$10,000, respectively, by Takeda.

15. Subsequent Events

The Company considered the events or transactions occurring after the balance sheet date, but prior to the issuance of the consolidated financial statements, for potential recognition or disclosure in its consolidated financial statements. All significant subsequent events have been properly disclosed in the consolidated financial statements.

On January 2, 2019, the Company received notices from Takeda stating that Takeda was exercising its right to: (a) terminate the 2016 Restated Agreement upon 45 days' prior written notice and (b) terminate the XMT-1522 Agreement upon 30 days' prior written notice.

On March 5, 2019, the Company completed a secondary public offering, in which the Company issued and sold an aggregate of 24,437,500 shares of its common stock at the public offering price of \$4.00 per share, which included the exercise in full of the underwriters' option to purchase additional shares of common stock. The gross proceeds from the offering were approximately \$97,800.

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

16. Selected Quarterly Financial Data (unaudited)

The following table contains selected quarterly financial information for 2018 and 2017. 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.

	Three months ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Collaboration revenue	\$ 3,064	\$ 4,191	\$ 2,151	\$ 1,188
Operating expenses:				
Research and development	12,256	12,663	15,180	19,816
General and administrative	3,571	4,231	4,380	4,152
Total operating expenses	15,827	16,894	19,560	23,968
Other income:				
Interest income	360	349	340	349
Total other income	360	349	340	349
Net loss	\$ (12,403)	\$ (12,354)	\$ (17,069)	\$ (22,431)
Net loss per share attributable to common stockholders — basic and diluted	\$ (0.54)	\$ (0.54)	\$ (0.74)	\$ (0.97)
Weighted-average number of common shares used in net loss per share attributable to common stockholders — basic and diluted	22,816,521	22,966,314	23,152,019	23,184,459

	Three months ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
Collaboration revenue	\$ 4,290	\$ 3,727	\$ 6,267	\$ 3,261
Operating expenses:				
Research and development	10,106	10,627	11,412	14,555
General and administrative	2,296	2,204	2,905	3,057
Total operating expenses	12,402	12,831	14,317	17,612
Other income:				
Interest income	51	158	318	383
Total other income	51	158	318	383
Net loss	\$ (8,061)	\$ (8,946)	\$ (7,732)	\$ (13,968)
Net loss per share attributable to common stockholders — basic and diluted	\$ (6.02)	\$ (6.33)	\$ (0.35)	\$ (0.61)
Weighted-average number of common shares used in net loss per share attributable to common stockholders — basic and diluted	1,338,475	1,412,308	22,242,129	22,750,425

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 chief executive officer and chief financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018, the end of the period covered by this Annual Report on Form 10-K. Based upon such evaluation, our chief executive officer and chief 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, 2018. 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

[Table of Contents](#)

management has concluded that, as of December 31, 2018, our internal control over financial reporting is effective based on those criteria.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting due to an exemption established by the Jumpstart Our Business Startups Act of 2012 for “emerging growth companies.”

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, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 under the captions “Executive Officers,” “Election of Directors” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our definitive proxy statement to be filed with the SEC with respect to our 2019 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 will be included under the captions “Executive and Director Compensation” and “Compensation Committee Interlocks and Insider Participation” in our definitive proxy statement to be filed with the SEC with respect to our 2019 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 under the Captions “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance Under Equity Compensation Plans” in our definitive proxy statement to be filed with the SEC with respect to our 2019 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 under the Captions “Employment Agreements,” “Potential Payments Upon Termination or Change in Control,” “Board Determination of Independence” and “Related Person Transactions” in our definitive proxy statement to be filed with the SEC with respect to our 2019 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 under the Captions “Audit Fees and Services” and “Pre-Approval Policies and Procedures” in our definitive proxy statement to be filed with the SEC with respect to our 2019 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 Form S-1, File No. 333-218412, filed on June 1, 2017).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 to the Company's Form S-1, File No. 333-218412, filed on June 1, 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).
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	Sixth Lease Extension and Modification Agreement, dated January 17, 2018, 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 15, 2018).

Table of Contents

- 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+ [Agreement Regarding LICR Technology, dated July 9, 2015, by and between Ludwig Institute for Cancer Research, Recepta Biopharma S.A. and Mersana Therapeutics, Inc. \(incorporated by reference to Exhibit 10.9 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017\).](#)
- 10.11+ [Collaboration Agreement, dated as of July 25, 2012, by and between Adimab, LLC and Mersana Therapeutics, Inc. \(incorporated by reference to Exhibit 10.10 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017\).](#)
- 10.12+ [Amendment Number One to the Collaboration Agreement, dated February 21, 2013, by and between Adimab, LLC and Mersana Therapeutics, Inc. \(incorporated by reference to Exhibit 10.11 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017\).](#)
- 10.13+ [Amendment Number One, to the Collaboration Agreement dated June 17, 2014, by and between Adimab, LLC and Mersana Therapeutics, Inc. \(incorporated by reference to Exhibit 10.12 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017\).](#)
- 10.14+ [Development Collaboration and Commercial License Agreement, dated January 29, 2016, by and between Mersana Therapeutics, Inc. and Millennium Pharmaceuticals, Inc. \(incorporated by reference to Exhibit 10.13 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017\).](#)
- 10.15+ [Amended and Restated Research Collaboration and Commercial License Agreement, dated as of January 29, 2016, by and between Mersana Therapeutics, Inc. and Millennium Pharmaceuticals, Inc. \(incorporated by reference to Exhibit 10.14 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017\).](#)
- 10.16+ [Amendment Number One to the A&R Research Collaboration and Commercial License Agreement, dated March 9, 2017, by and between Mersana Therapeutics, Inc. and Millennium Pharmaceuticals, Inc. \(incorporated by reference to Exhibit 10.15 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017\).](#)

[Table of Contents](#)

10.17	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).
10.19	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).
10.20†	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).
10.21†	Amended and Restated Offer Letter, by and between Mersana Therapeutics, Inc. and Timothy B. Lowinger, dated March 8 (incorporated by reference to Exhibit 10.18 to the Company's Form S-1, File No. 333-218412, filed on June 1, 2017).
10.22†	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).
10.23†	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).
10.24†	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).
10.25†	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).
10.26†	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).
10.27†	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).
10.28†	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).
10.29†	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 Chief Financial Officer.
32.1**	Certification of periodic financial report pursuant to Section 906 of Sarbanes Oxley Act of 2002 by Chief Executive Officer and Chief Financial Officer.

[Table of Contents](#)

101.*	XBRL Instance Document.
INS	
101.*	XBRL Taxonomy Extension Schema.
SCH	
101.*	XBRL Taxonomy Extension Calculation Linkbase.
CAL	
101.*	XBRL Taxonomy Extension Definition Linkbase.
DEF	
101.*	XBRL Taxonomy Extension Label Linkbase.
LAB	
101.*	XBRL Taxonomy Extension Presentation Linkbase.
PRE	

* 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.

Dated: March 8, 2019

/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
<u>/s/ ANNA PROTOPAPAS</u> Anna Protopapas	President, Chief Executive Officer and Director (Principal Executive Officer)	March 8, 2019
<u>/s/ DAVID A. SPELLMAN</u> David A. Spellman	Chief Financial Officer (Principal Financial Officer)	March 8, 2019
<u>/s/ WAYNE FOSTER</u> Wayne Foster	Vice President of Finance (Principal Accounting Officer)	March 8, 2019
<u>/s/ DAVID MOTT</u> David Mott	Chairman of the Board	March 8, 2019
<u>/s/ KRISTEN HEGE</u> Kristen Hege, M.D.	Director	March 8, 2019
<u>/s/ ANDREW A. F. HACK</u> Andrew A. F. Hack, M.D., Ph.D.	Director	March 8, 2019
<u>/s/ LAWRENCE M. ALLEVA</u> Lawrence M. Alleva	Director	March 8, 2019
<u>/s/ WILLARD H. DERE, M.D.</u> Willard H. Dere, M.D.	Director	March 8, 2019

Subsidiaries of the Registrant

Entity

State of Incorporation or Organization

Mersana Securities Corp.

Massachusetts

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. 333-226055) of Mersana Therapeutics, Inc. and in the related Prospectus,
- (2) Registration Statement (Form S-8 No. 333-222845) pertaining to the Mersana Therapeutics, Inc. 2017 Stock Incentive Plan, and
- (3) 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 March 8, 2019, with respect to the consolidated financial statements of Mersana Therapeutics, Inc. included in this Annual Report (Form 10-K) of Mersana Therapeutics, Inc. for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 8, 2019

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: March 8, 2019

By: /s/ Anna Protopapas
Anna Protopapas
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATIONS

I, David A. Spellman, 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: March 8, 2019

By: /s/ David A. Spellman
David A. Spellman
Chief Financial Officer
(Principal Financial Officer)

**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, 2018 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: March 8, 2019

By: /s/ Anna Protopapas
Anna Protopapas
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 8, 2019

By: /s/ David A. Spellman
David A. Spellman
Chief Financial Officer
(Principal Financial Officer)
