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

FORM 10-Q

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

For the quarterly period ended June 30, 2021

OR

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

Commission file number 001-38129

Mersana Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**04-3562403**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

840 Memorial Drive Cambridge, MA 02139
(Address of principal executive offices)
(Zip Code)

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

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	MRSN	The Nasdaq Global Select Market

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

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

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

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

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

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

There were 71,761,525 shares of Common Stock ($0.0001 par value per share) outstanding as of August 4, 2021.

Unless otherwise stated or the context requires otherwise, all references to "us," "our," "we," the "Company" and similar designations in this Quarterly Report on Form 10-Q refer to Mersana Therapeutics, Inc. and its consolidated subsidiary, Mersana Securities Corp.

FORWARD-LOOKING STATEMENTS

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

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

- the initiation, cost, timing, progress and results of our current and future research and development activities and preclinical and clinical studies;
- the adequacy of our inventory of upifitamab rilsodotin (UpRi, XMT-1536) and XMT-1592 to support our ongoing clinical studies, as well as the outcome of planned manufacturing runs;
- the timing of, and our ability to obtain and maintain, regulatory approvals for our product candidates;
- unmet need of ovarian cancer and non-small cell lung cancer;
- our ability to quickly and efficiently identify and develop additional product candidates;
- our ability to advance any product candidate into, and successfully complete, clinical studies;
- our intellectual property position, including with respect to our trade secrets;
- the potential benefits of strategic partnership agreements and our ability to enter into selective strategic partnerships;
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing; and
- the potential impact of the ongoing COVID-19 pandemic.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in our Annual Report on Form 10-K for the year ended December 31, 2020, and this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021, particularly in the "Risk factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

The forward-looking statements contained herein represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

RISK FACTORS SUMMARY

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

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

- We have incurred net losses since our inception, we have no products approved for commercial sale and we anticipate that we will continue to incur substantial operating losses for the foreseeable future.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- We have a credit facility that requires us to meet certain operating covenants and place restrictions on our operating and financial flexibility.
- We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.
- We only have two product candidates, upifitamab rilsodotin (UpRi, XMT-1536) and XMT-1592, in clinical studies. A failure of any of our product candidates in clinical development would adversely affect our business and may require us to discontinue development of other product candidates based on the same technology.
- We can provide no assurance that our clinical product candidates will obtain regulatory approval or that the results of clinical studies will be favorable.
- Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure. We can provide no assurance of the successful and timely development of new ADC products.
- If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our ADC product candidates, conduct our clinical studies and commercialize our ADC product candidates.
- We may encounter difficulties in managing our growth and expanding our operations successfully.
- Our activities, including our interactions with healthcare providers, third party payors, patients and government officials, are, and will continue to be, subject to extensive regulation involving health care, anti-corruption, data privacy and security and consumer protection laws. Failure to comply with applicable laws could result in substantial penalties, contractual damages, reputational harm, diminished revenues and curtailment or restructuring of our operations.
- We rely upon patents and other intellectual property rights to protect our technology. We may be unable to protect our intellectual property rights, and we may be liable for infringing the intellectual property rights of others.
- Our business is subject to risks arising from the outbreaks of disease, such as epidemics or pandemics, including the ongoing COVID-19 pandemic.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 227,388	$ 255,094
Prepaid expenses and other current assets	6,043	3,486
Total current assets	233,431	258,580
Property and equipment, net	1,901	1,730
Operating lease right-of-use assets	13,746	10,936
Other assets	4,607	2,153
Total assets	$ 253,685	$ 273,399
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 10,647	$ 8,340
Accrued expenses	23,383	16,146
Deferred revenue	3,966	3,987
Operating lease liabilities	2,173	1,437
Short-term debt	173	—
Other liabilities	129	93
Total current liabilities	40,471	30,003
Long-term operating lease liabilities	12,543	10,158
Long-term debt, net	4,870	4,977
Other long-term liabilities	288	174
Total liabilities	58,172	45,312
Commitments (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 25,000,000 shares authorized; 0 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	—	—
Common stock,$0.0001 par value; 175,000,000 shares authorized; 71,401,216 and 68,841,288 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	7	7
Additional paid-in capital	551,531	508,499
Accumulated deficit	(356,025)	(280,419)
Total stockholders' equity	195,513	228,087
Total liabilities and stockholders' equity	$ 253,685	$ 273,399

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Collaboration revenue	$ 11	$ 796	$ 21	$ 807
Operating expenses:				
Research and development	31,955	15,413	59,370	27,632
General and administrative	8,883	5,171	16,090	10,106
Total operating expenses	40,838	20,584	75,460	37,738
Other income (expense):				
Interest income	9	89	21	394
Interest expense	(95)	(87)	(188)	(175)
Total other income (expense), net	(86)	2	(167)	219
Net loss	(40,913)	(19,786)	(75,606)	(36,712)
Other comprehensive loss				
Unrealized gain (loss) on marketable securities	—	6	—	(23)
Comprehensive loss	$ (40,913)	$ (19,780)	$ (75,606)	$ (36,735)
Net loss attributable to common stockholders — basic and diluted	$ (40,913)	$ (19,786)	$ (75,606)	$ (36,712)
Net loss per share attributable to common stockholders — basic and diluted	$ (0.59)	$ (0.33)	$ (1.09)	$ (0.68)
Weighted-average number of shares of common stock used in net loss per share attributable to common stockholders — basic and diluted	69,616,467	60,748,225	69,303,899	54,368,429

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	45,388,023	$ 5	$ 270,662	$ 25	$ (192,374)	$ 78,318
Exercise of common stock warrant in exchange for common stock	2,574,971	—	—	—	—	—
Exercise of stock options	43,055	—	119	—	—	119
Stock-based compensation expense	—	—	1,609	—	—	1,609
Other comprehensive loss	—	—	—	(29)	—	(29)
Net loss	—	—	—	—	(16,926)	(16,926)
Balance at March 31, 2020	48,006,049	$ 5	$ 272,390	$ (4)	$ (209,300)	$ 63,091
Issuance of common stock from at-the-market transactions, net of issuance costs of $2,176	10,900,599	1	62,976	—	—	62,977
Issuance of common stock under public offering, net of issuance costs of $10,809	9,200,000	1	163,990	—	—	163,991
Purchase of common stock under ESPP	68,419	—	333	—	—	333
Exercise of stock options	206,143	—	1,296	—	—	1,296
Stock-based compensation expense	—	—	1,656	—	—	1,656
Other comprehensive income	—	—	—	6	—	6
Net loss	—	—	—	—	(19,786)	(19,786)
Balance at June 30, 2020	68,381,210	$ 7	$ 502,641	$ 2	$ (229,086)	$ 273,564
Exercise of stock options	88,871	—	317	—	—	317
Stock-based compensation expense	—	—	1,918	—	—	1,918
Other comprehensive loss	—	—	—	(2)	—	(2)
Net loss	—	—	—	—	(22,489)	(22,489)
Balance at September 30, 2020	68,470,081	$ 7	$ 504,876	$ —	$ (251,575)	$ 253,308
Exercise of stock options	359,359	—	1,406	—	—	1,406
Purchase of common stock under ESPP	11,848	—	228	—	—	228
Stock-based compensation expense	—	—	1,989	—	—	1,989
Net loss	—	—	—	—	(28,844)	(28,844)
Balance at December 31, 2020	68,841,288	$ 7	$ 508,499	$ —	$ (280,419)	$ 228,087
Exercise of stock options	148,472	—	764	—	—	764
Vesting of restricted stock units, net of employee tax obligations	61,678	—	(259)	—	—	(259)
Stock-based compensation expense	—	—	4,039	—	—	4,039
Net loss	—	—	—	—	(34,693)	(34,693)
Balance at March 31, 2021	69,051,438	$ 7	$ 513,043	$ —	$ (315,112)	$ 197,938
Issuance of common stock from at-the-market transactions, net of issuance costs of $746	2,271,074	—	33,287	—	—	33,287
Exercise of stock options	42,506	—	202	—	—	202
Purchase of common stock under ESPP	36,198	—	417	—	—	417
Stock-based compensation expense	—	—	4,582	—	—	4,582
Net loss	—	—	—	—	(40,913)	(40,913)
Balance at June 30, 2021	71,401,216	$ 7	$ 551,531	$ —	$ (356,025)	$ 195,513

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

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

	Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (75,606)	$ (36,712)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	432	494
Net amortization of premiums and discounts on investments	—	(86)
Stock-based compensation	8,621	3,265
Other non-cash items	77	74
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,418)	(163)
Other assets	(2,296)	(650)
Accounts payable	2,270	(377)
Accrued expenses	7,139	(2,349)
Operating lease assets	972	836
Operating lease liabilities	(660)	(706)
Deferred revenue	(21)	(807)
Net cash used in operating activities	(61,490)	(37,181)
Cash flows from investing activities		
Maturities of marketable securities	—	34,500
Purchase of property and equipment	(447)	(90)
Net cash provided by (used in) investing activities	(447)	34,410
Cash flows from financing activities		
Net proceeds from public offering of common stock	—	164,157
Net proceeds from the at-the-market (ATM) facility	33,338	63,129
Proceeds from exercise of stock options	966	1,415
Proceeds from purchases of common stock under ESPP	417	333
Payment of employee tax obligations related to vesting of restricted stock units	(259)	—
Proceeds from issuance of debt, net of issuance costs	—	(180)
Payments under capital lease obligations	(74)	(58)
Net cash provided by financing activities	34,388	228,796
Increase (decrease) in cash, cash equivalents and restricted cash	(27,549)	226,025
Cash, cash equivalents and restricted cash, beginning of period	255,415	62,672
Cash, cash equivalents and restricted cash, end of period	$ 227,866	$ 288,697
Supplemental disclosures of non-cash activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ 46	$ 10
Equity issuance costs in accounts payable and accrued expenses	$ 51	$ 321
Cash paid for interest	$ 122	$ 113
Right-of-use assets obtained in exchange for operating lease liabilities	$ 3,783	$ 9,980
Right-of-use assets obtained in exchange for financing lease liabilities	$ 213	$ —

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

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements
(in thousands, except share and per share data)
(unaudited)

1. Nature of business and basis of presentation

Mersana Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on developing antibody drug conjugates (ADCs) that offer a clinically meaningful benefit for cancer patients with significant unmet need. The Company has leveraged over 20 years of industry learning in the ADC field to develop proprietary and differentiated technology platforms that enable it to design ADCs to have improved efficacy, safety and tolerability relative to existing ADC therapies. The Company's innovative platforms, which include Dolaflexin and Dolasynthen, each delivering its DolaLock payload, as well as Immunosynthen, delivering a novel stimulator of interferon genes (STING) agonist, provide an efficient product engine that has enabled a robust discovery pipeline for the Company and its partners. The Company's clinical candidates include upifitamab rilsodotin (UpRi, XMT-1536) and XMT-1592. The Company's early-stage programs include XMT-1660, a potentially first-in-class Dolasynthen ADC targeting B7-H4, as well as XMT-2056, a Stimulator of Interferon Genes (STING) agonist ADC developed using the Company's Immunosynthen platform.

UpRi, an ADC utilizing the Company's Dolaflexin platform and targeting NaPi2b, an antigen broadly expressed in ovarian cancer and non-small cell lung cancer (NSCLC) adenocarcinoma, is being studied in UPLIFT, a single-arm registration strategy in patients with platinum-resistant ovarian cancer, as well as in UPGRADE, a Phase 1 combination dose escalation umbrella study to evaluate the safety and efficacy of UpRi in combination with other ovarian cancer therapies. The Company also continues to study UpRi in the expansion portion of a Phase 1 proof-of-concept clinical study. XMT-1592 uses the Company's Dolasynthen platform and also targets NaPi2b and is in the dose escalation portion of a Phase 1 proof-of-concept clinical study.

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 and clinical studies, the need to obtain marketing approval and reimbursement for any drug product candidate that it may identify and develop, the need to successfully commercialize and gain market acceptance of its product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development of technological innovations by competitors, reliance on third party manufacturers and the ability to transition from pilot-scale production to large-scale manufacturing of products.

The Company has incurred cumulative net losses since inception. For the six months ended June 30, 2021, the net loss was $75,606, compared to net loss of $36,712 in the six months ended June 30, 2020. The Company expects to continue to incur operating losses for at least the next several years. As of June 30, 2021, the Company had an accumulated deficit of $356,025. The future success of the Company is dependent on, among other factors, its ability to identify and develop its product candidates and ultimately upon its ability to attain profitable operations. The Company has devoted substantially all of its financial resources and efforts to research and development and general and administrative expense to support such research and development. Net losses and negative operating cash flows have had, and will continue to have, an adverse effect on the Company's stockholders' equity and working capital.

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

The Company's unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) and the rules and regulations of the Securities and Exchange Commission (SEC). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB). All dollar amounts, except per share data in the text and tables herein, are stated in thousands unless otherwise indicated. Certain information and footnote

disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2020 and the notes thereto, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on February 26, 2021.

The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company's management, the accompanying unaudited condensed consolidated financial statements contain all adjustments that are necessary to present fairly the Company's financial position as of June 30, 2021, the results of its operations for the three and six months ended June 30, 2021 and 2020, a statement of stockholders' equity for the three and six months ended June 30, 2021 and 2020 and cash flows for the six months ended June 30, 2021 and 2020. Such adjustments are of a normal and recurring nature. The results for the three and six months ended June 30, 2021 are not necessarily indicative of the results for the year ending December 31, 2021, or for any future period.

2. Summary of Significant Accounting Policies

Principles of Consolidation

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

Use of Estimates

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

Segment Information

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

Summary of Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements for the three and six months ended June 30, 2021 are consistent with those discussed in Note 2 to the consolidated financial statements in the Company's 2020 Annual Report on Form 10-K, except as otherwise noted below in "Recently Issued Accounting Pronouncements."

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
(in thousands, except share and per share data)
(unaudited)

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.

	Six Months Ended June 30, 2021		Six Months Ended June 30, 2020	
	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	$ 255,094	$ 227,388	$ 62,351	$ 288,376
Restricted cash included in other assets, noncurrent	321	478	321	321
Total cash, cash equivalents and restricted cash per statement of cash flows	$ 255,415	$ 227,866	$ 62,672	$ 288,697

Other Assets

The Company recorded other assets of $4,607 and $2,153 as of June 30, 2021 and December 31, 2020, respectively, comprised of $4,129 and $1,832, respectively, held by a service provider, and restricted cash of $478 and $321, respectively, held as a security deposit for a standby letter of credit related to a facility lease.

Net Loss per Share

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

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

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
(in thousands, except share and per share data)
(unaudited)

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

	Three and Six Months Ended June 30, 2021	Three and Six Months Ended June 30, 2020
Stock options	7,977,545	5,946,503
Unvested restricted stock units	1,070,311	742,128
Warrants	39,474	39,474
	9,087,330	6,728,105

Recently Issued Accounting Pronouncements

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, as part of its initiative to reduce complexity in the accounting standards. The amendments in ASU 2019-12 eliminate certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. ASU 2019-12 also clarifies and simplifies other aspects of the accounting for income taxes. The amendments in ASU 2019-12 are effective for the fiscal years beginning after December 15, 2020. The adoption of ASU 2019-12 did not have a material effect on our results of operations and financial position.

3. Collaboration agreements

Merck KGaA

In June 2014, the Company entered into a Collaboration and Commercial License Agreement with Merck KGaA (the Merck KGaA Agreement). Upon the execution of the Merck KGaA Agreement, Merck KGaA paid the Company a nonrefundable technology access fee of $12,000 for the right to develop ADCs directed to six exclusive targets over a specified period of time. No additional fees are due when a target is designated and the commercial license to the target is granted. Merck KGaA will be responsible for the product development and marketing of any products resulting from this collaboration. All six targets were designated prior to 2018. The next potential milestone payment that the Company is eligible to receive is a development milestone of $500 on Merck KGaA's designation of a preclinical development candidate for a target. Revenue will be recognized when achievement of the milestone is considered probable.

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

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

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
(in thousands, except share and per share data)
(unaudited)

Accounting Analysis

The Company identified the following performance obligations under the Merck KGaA Agreement: (i) exclusive license and research services for six designated targets, (ii) rights to future technological improvements and (iii) participation of project team leaders and providing joint research committee services.

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

As of June 30, 2021, the Company had completed its research service obligations associated with four of the six designated targets. During each of the three months ended June 30, 2021 and 2020, and the six months ended June 30, 2021 and 2020, the Company recorded collaboration revenue of $11, $796, $21, and $807, respectively, related to its efforts under the Merck KGaA Agreement. The Company did not recognize any collaboration revenue and corresponding research and development expense related to the Merck KGaA Supply Agreement during the three and six months ended June 30, 2021 and 2020.

As of June 30, 2021 and December 31, 2020, the Company had $3,966 and $3,987, respectively, in deferred revenue related to the Merck KGaA Agreement and Merck KGaA Supply Agreement that will be recognized over the remaining performance period.

Summary of Contract Assets and Liabilities

The following table presents changes in the balances of our contract assets and liabilities during the six months ended June 30, 2021 and 2020:

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Six months ended June 30, 2021				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 3,987	$ —	$ 21	$ 3,966

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Six months ended June 30, 2020				
Contract assets	$ —	$ —	$ —	$ —
Contract liabilities:				
Deferred revenue	$ 4,815	$ —	$ 807	$ 4,008

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
(in thousands, except share and per share data)
(unaudited)

During the three and six months ended June 30, 2021 and 2020, the Company recognized the following revenues as a result of changes in the contract asset and the contract liability balances in the respective periods:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue recognized in the period from:				
Amounts included in the contract liability at the beginning of the period	$ 11	$ 796	$ 21	$ 807
Performance obligations satisfied in previous periods	$ —	$ —	$ —	$ —

Other Revenue

The Company has provided limited services for a collaboration partner, Asana BioSciences. For each of the six months ended June 30, 2021 and 2020, the Company did not recognize revenue related to these services. The next potential milestone the Company is eligible to receive is $2,500 upon dosing the fifth patient in a Phase 1 clinical study by Asana BioSciences. As of June 30, 2021, the Company considers this next milestone to be fully constrained as there is considerable judgment involved in determining whether it is probable that a significant revenue reversal would occur. As part of its evaluation of the constraint, the Company considered numerous factors, including the fact that achievement of the milestone is outside the control of the Company and there is a high level of uncertainty in achieving this milestone, as this would require successful initiation of clinical trials by the collaboration partner. The Company reevaluates the probability of achievement of a milestone subject to constraint at each reporting period and as uncertain events are resolved or other changes in circumstances occur.

4. Fair value measurements

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

As of June 30, 2021 and December 31, 2020, the carrying value of the Company's outstanding borrowing under the Amended Credit Facility (as defined below) approximated fair value (a Level 2 fair value measurement), reflecting interest rates currently available to the Company. The Credit Facility is discussed in more detail in Note 6, "Debt".

5. Accrued expenses

Accrued expenses consisted of the following as of June 30, 2021 and December 31, 2020:

	June 30, 2021	December 31, 2020
Accrued preclinical, manufacturing and clinical expenses	$ 17,675	$ 9,902
Accrued payroll and related expenses	4,555	5,412
Accrued professional fees and insurance	1,030	757
Accrued other	123	75
	$ 23,383	$ 16,146

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
(in thousands, except share and per share data)
(unaudited)

6. Debt

On May 8, 2019, the Company entered into a loan and security agreement with Silicon Valley Bank (SVB), which has subsequently been amended on June 21, 2019, and August 28, 2020 (collectively, the Credit Facility) pursuant to which the Company can borrow term loans in an aggregate amount of $30,000, at its option, comprising (i) up to $25,000 in up to five principal advances through April 30, 2022, and (ii) an additional $5,000 in one principal advance, if the Company reaches certain development milestone events, as described in the Credit Facility, through April 30, 2022.

As of June 30, 2021, the Company was in compliance with all covenants under the Amended Credit Facility. As such, as of June 30, 2021, the classification of the loan balance as stated on the balance sheet was based on the timing of defined future payment obligations.

As of June 30, 2021, the Company had drawn a term loan of $5,200, and debt consisted of the following:

	June 30, 2021
Total debt	$ 5,200
Less: Current portion of long-term-debt	(173)
Total debt, net of current portion	5,027
Debt financing costs, net of accretion	(214)
Accretion related to final payment	57
Long-term debt, net	$ 4,870

As of June 30, 2021, the estimated future principal payments due are as follows:

2021 (excluding the six months ended June 30, 2021)	$ —
2022	1,213
2023	2,080
2024	1,907
Total debt	$ 5,200

During the three months ended June 30, 2021 and 2020, and the six months ended June 30, 2021 and 2020, the Company recognized $89, $51, $177, and $102, respectively, of interest expense related to the Existing Credit Facility and Amended Credit Facility, as applicable.

7. Stockholders' equity

Preferred stock

As of June 30, 2021, the Company had 25,000,000 shares of authorized preferred stock. No shares of preferred stock have been issued.

At-the-market equity offering program

In July 2018, the Company established an at-the-market (ATM) equity offering program (the 2018 ATM) pursuant to which it could offer and sell up to $75,000 of its common stock from time to time at prevailing market prices. In April 2020, the Company sold 8,938,599 and 1,962,000 shares of common stock at $5.59 per share and $7.74 per share, respectively, to raise aggregate gross proceeds of $65,153 through the 2018 ATM facility. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were approximately $62,976.

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
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In May 2020, the Company terminated the 2018 ATM and established a new ATM equity offering program (the 2020 ATM) pursuant to which it is able to sell up to $100,000 of its common stock from time to time at prevailing market prices. For the three months ended June 30, 2021, the Company sold 2,271,074 shares of common stock at an average price of $14.99 per share to raise aggregate gross proceeds of $34,033 through the 2020 ATM. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were approximately $33,287.

Follow-on offering

In June 2020, the Company sold 9,200,000 shares of common stock, in an underwritten public offering at a price to the public of $19.00 per share. Net proceeds to the Company after deducting fees, commissions and other expenses related to the offering were $163,990.

Warrants

In connection with a 2013 Series A-1 Preferred Stock issuance, the Company granted to certain investors warrants to purchase 129,491 shares of common stock. The warrants have a $0.05 per share exercise price and a contractual life of 10 years. The fair value of these warrants was recorded as a component of equity at the time of issuance. As of June 30, 2021, there were warrants to purchase 39,474 shares of common stock. During the quarter ended June 30, 2021, there were no exercises of warrants in exchange for shares of common stock.

Exchange warrants

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

On March 2, 2020, the Exchanging Stockholders exercised the Exchange Warrants in full on a net cashless exercise basis, resulting in the issuance of 2,574,971 shares of common stock.

Common stock

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

At June 30, 2021 and December 31, 2020, there were 9,087,330 and 6,869,189, respectively, shares of common stock reserved for the exercise of outstanding stock options and warrants.

	June 30, 2021	December 31, 2020
Stock options	7,977,545	6,112,948
Restricted stock units	1,070,311	716,767
Warrants	39,474	39,474
	9,087,330	6,869,189

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
(in thousands, except share and per share data)
(unaudited)

8. Stock options

Stock option plans

As of June 30, 2017, there were 3,141,625 stock options outstanding under the Company's 2007 Stock Incentive Plan (the 2007 Plan). The 2007 Plan expired in June 2017. Any cancellations 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 stockholders approved the 2017 Stock Incentive Plan (the 2017 Plan). Under the 2017 Plan initially, up to 2,255,000 shares of common stock may be granted to the Company's employees, officers, directors, consultants and advisors in the form of options, restricted stock units (RSUs) or other stock-based awards. The number of shares of common stock issuable under the 2017 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 2017 Plan. Any cancellations under the 2007 Plan, which expired in June 2017, would increase the number of shares that could be granted under the 2017 Plan. In January 2021, the number of shares of common stock issuable under the 2017 Plan was increased by 2,753,651 shares. As of June 30, 2021, there were 1,771,150 shares available for future issuance under the 2017 Plan. During the six months ended June 30, 2021, the Company granted 2,657,110 RSUs and options to purchase shares of common stock to employees under the 2017 Plan.

With respect to incentive stock options, the exercise price per share will equal the closing price of the common stock on the date of grant and the vesting period is generally four years. Nonqualified stock options will be granted at an exercise price established by the Board at its sole discretion (which has not been less than fair market value on the date of grant) and the vesting periods may vary. Options granted under the 2017 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.

Inducement awards

The Company grants to its employees, upon approval by the Board, options to purchase shares of common stock as an inducement to employment in accordance with Nasdaq Listing Rule 5635(c)(4). The securities are issued pursuant to Section 4(a)(2) under the Securities Act of 1933, as amended, relating to transactions by an issuer not involving any public offering. These options are subject to terms substantially the same as the 2017 Plan. As of June 30, 2021 there were 532,500 options to purchase shares of common stock granted as inducement awards outstanding.

Stock option activity

A summary of stock option activity is as follows:

	Number of Shares		Weighted-Average Exercise Price
Outstanding at January 1, 2021	6,112,948	$	7.84
Granted	2,325,657		19.27
Exercised	(190,978)		5.06
Cancelled	(270,082)		9.35
Outstanding at June 30, 2021	7,977,545	$	11.19
Exercisable at June 30, 2021	3,548,386	$	6.07

The weighted-average grant date fair value of options granted during the six months ended June 30, 2021 and 2020, was $13.45 and $4.06 per share, respectively.

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
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Cash received from the exercise of stock options was $966 and $1,415 for the six months ended June 30, 2021 and 2020, respectively.

Restricted stock units (RSUs)

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

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

	Number of Shares
Unvested at January 1, 2021	716,767
Granted	543,953
Vested	(73,954)
Forfeited	(116,455)
Unvested at June 30, 2021	1,070,311

Stock-based compensation expense

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

The measurement date for employee awards is generally the date of grant. Stock-based compensation expense is recognized over the requisite service period, which is generally the vesting period, using the straight-line method.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Stock options	$ 3,514	$ 1,272	$ 6,631	$ 2,505
Restricted stock units	949	318	1,755	627
Employee stock purchase plan	119	66	235	133
Stock-based compensation expense included in total operating expenses	$ 4,582	$ 1,656	$ 8,621	$ 3,265

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 2,502	$ 805	$ 4,803	$ 1,602
General and administrative	2,080	851	3,818	1,663
Stock-based compensation expense included in total operating expenses	$ 4,582	$ 1,656	$ 8,621	$ 3,265

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
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As of June 30, 2021, there was $42,433 and $11,070 of unrecognized stock compensation expense related to unvested stock options and unvested RSUs, respectively, that is expected to be recognized over a weighted-average period of 2.9 years and 3.3 years, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Risk-free interest rate	1.0 %	0.5 %	0.8 %	1.5 %
Expected dividend yield	— %	— %	— %	— %
Expected term (years)	5.97	6.00	6.04	6.04
Expected stock price volatility	83 %	80 %	83 %	70 %

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

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

Employee Stock Purchase Plan

During the year ended December 31, 2017, the Board adopted, and the Company's stockholders approved the 2017 employee stock purchase plan (the 2017 ESPP). The Company initially reserved 225,000 shares of common stock for issuance under the 2017 ESPP. The Company issued 36,198 shares under the 2017 ESPP during each of the three and six months ended June 30, 2021, and issued 68,419 shares under the 2017 ESPP during each of the three and six months ended June 30, 2020. As of June 30, 2021, there were 608,620 shares available for issuance. including 450,000 shares automatically added to the 2017 ESPP on January 1, 2020.

9. Leases

The Company has an operating lease for its office and lab space in Cambridge, MA and operating and finance leases for certain equipment. The operating lease for its office and lab space (the Office Lease) was amended in March 2020 and is effective through March 2026. The Company has an option to extend the lease term of the Office Lease for an additional five years.

On April 5, 2021, the Company entered into an Eighth Amendment (the Expansion Agreement) to the Office Lease. The Expansion Agreement granted the Company additional office space in its existing building for five years, beginning July 1, 2021, committing to lease payments of $4,983 over that period (the Expansion Lease). In connection with the Expansion Lease, the Company increased the balance of the security deposit by increasing the standby letter of credit for the benefit of its landlord by $156. The Expansion Agreement also provides the Company with a tenant improvement allowance of $51. Independent from the option under the Office Lease, the Company has an option to extend the lease term of the Expansion Lease for an additional five years. The Company's exercise of the options to extend the lease terms of both the Office Lease and Expansion Lease were not considered reasonably certain as of June 30, 2021.

(in thousands, except share and per share data)

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

As a result of the signing of the Expansion Agreement in April 2021, the Company recorded an increase of $3,783 to its right-of-use (ROU) asset and lease liabilities in the second quarter of 2021.

The Company had a standby letter of credit agreement for the benefit of its landlord in the amount of $478 in connection with the Office Lease and Expansion Lease as of June 30, 2021 and $321 in connection with the Office Lease as of December 31, 2020, collateralized by a money market account.

The Company has remaining finance lease terms of one year to five years for certain equipment, some of which include options to purchase at fair value. For the three and six month ended June 30, 2021 the Company recorded an asset under finance lease of $0 and $213, respectively, as property and equipment.

The components of lease expense were as follows:

	Operating leases	Finance leases
2021 (excluding the six months ended June 30, 2021)	$ 1,915	$ 82
2022	3,795	128
2023	3,909	121
2024	4,027	60
2025 and thereafter	5,457	56
Total lease payments	19,103	447
Present value adjustment	(4,387)	(30)
Present value of lease liabilities	$ 14,716	$ 417

10. Commitments

License agreements

The Company recorded research and development expense for a $900 milestone payment for the dosing of the first patient in UPLIFT during the three and six months ended June 30, 2021. The Company recorded research and development expense for a $750 milestone payment for the dosing of the first patient in the XMT-1592 trial during the three and six ended June 30, 2020.

See Note 9 for the Company’s future obligations related to leases as of June 30, 2021.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and the accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission (SEC) on February 26, 2021.

Our actual results and the 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 Quarterly Report. In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods.

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

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

Overview

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

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

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

Upifitamab rilsodotin (UpRi, XMT-1536), our first-in-class ADC targeting the sodium-dependent phosphate transport protein NaPi2b, utilizes the Dolaflexin platform to deliver about 10 DolaLock payload molecules per antibody. The NaPi2b antigen is broadly expressed in ovarian cancer and non-small cell lung cancer, or NSCLC, adenocarcinoma with limited expression in normal tissue. In April 2021, we initiated a single-arm registration strategy in platinum-resistant ovarian cancer, UPLIFT. In July 2021, we initiated UPGRADE, a Phase 1 combination dose escalation umbrella study to evaluate the safety and efficacy of UpRi in combination with other ovarian cancer therapies. The initial arm of this umbrella study is evaluating carboplatin in combination with UpRi followed by continuation of UpRi monotherapy in patients with recurrent platinum-sensitive ovarian cancer. We are continuing to study UpRi in the expansion portion of a Phase 1 proof-of-concept clinical study.

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

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

In addition, we have established strategic research and development partnerships with Merck KGaA and Asana Biosciences for the development and commercialization of additional ADC product candidates against a limited number of targets selected by our partners based on our Dolaflexin platform. We believe the potential of our ADC technologies, supported by our world class management team and protected by our robust intellectual property portfolio, will allow us to discover and develop life-changing ADCs for patients fighting cancer.

Since inception, our operations have focused on building our platforms, identifying potential product candidates, producing drug substance and drug product material for use in preclinical studies, conducting preclinical and toxicology studies, manufacturing clinical study material and conducting clinical studies, establishing and protecting our intellectual property, staffing our company and raising capital. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through our strategic partnerships, private placements of our convertible preferred stock and public offerings of our common stock. In April 2020, we sold approximately 10.9 million shares of common stock pursuant to an at-the-market, or ATM, equity offering program and received net proceeds of $63.0 million. In addition, in June 2020, we sold 9.2 million shares of common stock in a follow-on offering and received net proceeds of $164.0 million.

During the three months ended June 30, 2021, we sold approximately 2.3 million shares of common stock at an average price of approximately $15 per share pursuant to an ATM equity offering program and received net proceeds of $33.3 million.

Since inception, we have incurred significant cumulative operating losses. For the six months ended June 30, 2021, the net loss was $75.6 million, compared to net loss of $36.7 million in the six months ended June 30, 2020. As of June 30, 2021, we had an accumulated deficit of $356.0 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 clinical product candidates UpRi and XMT-1592;
- develop a diagnostic development effort for the NaPi2b biomarker;
- complete IND-enabling studies for our preclinical development candidates XMT-2056 and XMT-1660;
- continue activities to discover, validate and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio; and
- hire additional research, development and general and administrative personnel.

Impact of COVID-19 on Our Business

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

- We are currently enrolling patients at investigational sites in different geographic areas around the world in the UpRi Phase 1/2 studies, including UPLIFT and UPGRADE, and within the United States in the XMT-1592 Phase 1 dose escalation study. We are in the process of initiating additional clinical sites both inside and outside the United States to increase enrollment, which could additionally mitigate potential regional impacts from COVID-19. Consistent with FDA guidance, we issued an administrative letter to allow for remote patient monitoring and remote testing, when possible.

- To the best of our knowledge, our contract manufacturing partners continue to operate their manufacturing facilities at or near normal levels, though sourcing of raw materials that are globally being utilized for COVID-related vaccines and therapies has become an increasing challenge for our contract manufacturers. If such raw material sourcing challenges continue, we may experience associated delays in our manufacturing, although we have not experienced any such delays to date. We believe we currently have sufficient inventory of UpRi and XMT-1592 to support our ongoing clinical studies. We have planned manufacturing runs to address all currently anticipated future needs. At this time, and subject to further COVID-19 implications, we continue to monitor our clinical supply and ongoing operations of our contract manufacturers.

The ultimate impact of the coronavirus pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. While the pandemic did not materially affect our financial results and business operations in the second quarter ended June 30, 2021, we are unable to predict the impact that COVID-19 will have on our financial position and operating results in future periods due to numerous uncertainties. Management is actively monitoring this situation and the possible effects on our financial condition, operations, suppliers, industry, and our employees. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, our financial condition or our results of operations, see “Part II, Item 1A—Risk Factors” below.

Financial operations overview

Revenue

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

In June 2014, we entered into an agreement with Merck KGaA for the development and commercialization of ADC product candidates utilizing Fleximer for up to six target antigens. Merck KGaA is responsible for generating antibodies against the target antigens and we are responsible for generating Fleximer and our proprietary payloads and conjugating this to the antibody to create the ADC product candidates. Merck KGaA has the exclusive right to and is responsible for the further development and commercialization of these ADC product candidates. In May 2018, we entered into a supply agreement with Merck KGaA for the supply of materials that could be used for IND-enabling studies and clinical trials.

For each of the three and six months ended June 30, 2021, we recognized an immaterial amount of revenue related to the Merck KGaA Agreements. For the three and six months ended June 30, 2020, we recognized $0.8 million revenue related to the Merck KGaA Agreements.

We have provided limited services to Asana BioSciences. We did not record any revenue related to these services in the three and six months ended June 30, 2021 or 2020.

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

Operating expenses

Research and development expenses

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

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

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

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

A significant portion of our research and development costs have been external costs, which we track on a program-by-program basis following nomination as a product candidate. We have not historically tracked all of our internal research and development expenses on a program-by-program basis as they are deployed across multiple projects under development. The following table summarizes our external research and development expenses, by program, following nomination as a clinical candidate for the three and six months ended June 30, 2021 and 2020. All external research and development expenses not attributable to the UpRi and XMT-1592 programs are captured within preclinical and discovery costs. These costs relate to XMT-1592 prior to its designation in early 2020 as well as our preclinical development candidates XMT-1660 and XMT-2056, additional earlier discovery stage programs and certain unallocated costs. Our internal research and development costs are primarily personnel-related costs, stock-based compensation costs, and facility costs, including depreciation, and lab consumables.

(in thousands)	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
UpRi external costs	$ 10,671	$ 3,535	$ 20,049	$ 5,905
XMT-1592 external costs	1,676	2,672	4,144	3,845
Preclinical and discovery costs	7,346	2,022	11,859	3,530
Internal research and development costs	12,262	7,184	23,318	14,352
Total research and development costs	$ 31,955	$ 15,413	$ 59,370	$ 27,632

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

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

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

General and administrative expenses

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

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

Other income (expense)

Other income (expense) consists primarily of interest income earned on cash equivalents and marketable securities. Interest expense is related to borrowings under the credit facility that we entered into in May 2019 and amended in August 2020. These borrowings bear a floating per annum rate interest, as well as a final payment of 5.5% of the amounts drawn, that is being recorded as interest expense over the term through the maturity date using the effective-interest method. Also included in interest expense is the amortization of the deferred financing costs and the accretion of debt discount relating to the credit facility.

Results of Operations

Comparison of the three months ended June 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended June 30, 2021 and 2020, together with the changes in those items:

	Three Months Ended June 30,		
(in thousands)	**2021**	**2020**	**Dollar Change**
Collaboration revenue	$ 11	$ 796	$ (785)
Operating expenses:			
Research and development	31,955	15,413	16,542
General and administrative	8,883	5,171	3,712
Total operating expenses	40,838	20,584	20,254
Other income (expense):			
Interest income	9	89	(80)
Interest expense	(95)	(87)	(8)
Total other income (expense), net	(86)	2	(88)
Net loss	$ (40,913)	$ (19,786)	$ (21,127)

Collaboration Revenue

Collaboration revenue was immaterial during the three months ended June 30, 2021 and $0.8 million during the three months ended June 30, 2020. For the three months ended June 30, 2020 we recognized $0.8 million of revenue as a result of the completion of research services associated with a target included in the Merck KGaA Agreement, driving the decrease in collaboration revenue.

Research and Development Expense

Research and development expense increased by $16.6 million from $15.4 million for the three months ended June 30, 2020 to $32.0 million for the three months ended June 30, 2021.

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

- an increase of $6.5 million related to manufacturing, clinical and regulatory activities for UpRi;
- an increase of $4.3 million related to manufacturing for the preclinical and discovery stage programs XMT-1660 and XMT-2056;
- an increase of $3.2 million related to employee compensation (excluding stock-based compensation), primarily due to an increase in headcount supporting the growth of our research and development activities;

- an increase of $1.5 million related to our diagnostic development effort; and
- an increase of $0.2 million related to clinical and regulatory activities for XMT-1592.

These increased costs were partially offset by a decrease of $0.8 million related to manufacturing activities for XMT-1592.

Stock-based compensation expense included in research and development expenses increased by $1.7 million, related to an increase in headcount and the increased valuation of stock-based awards granted as a result of stock price appreciation.

We expect our research and development expenses to increase as we continue our clinical development of XMT-1536 and XMT-1592 and continue to advance our preclinical product candidate pipeline and invest in improvements in our ADC technologies.

General and Administrative Expense

General and administrative expense increased by $3.7 million from $5.2 million during the three months ended June 30, 2020 to $8.9 million during the three months ended June 30, 2021. The increase in general and administrative expense was primarily attributable to an increase of $1.7 million related to consulting and professional fees and an increase of $0.8 million related to employee compensation (excluding stock-based compensation), related to an increase in headcount. Stock-based compensation increased $1.2 million due to increased headcount and the increased valuation of stock-based awards as a result of stock price appreciation.

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

Total Other Income (Expense), net

Total other expense was $0.1 million for the three months ended June 30, 2021 and total other income was immaterial for the three months ended June 30, 2020. Other income consists primarily of interest income on cash equivalents and short-term marketable securities. Interest expense is related to our outstanding borrowings under the credit facility in both periods.

Comparison of the six months ended June 30, 2021 and 2020

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2020:

(in thousands)	Six Months Ended June 30, 2021	2020	Dollar Change
Collaboration revenue	$ 21	$ 807	$ (786)
Operating expenses:			
Research and development	59,370	27,632	31,738
General and administrative	16,090	10,106	5,984
Total operating expenses	75,460	37,738	37,722
Other income (expense):			
Interest income	21	394	(373)
Interest expense	(188)	(175)	(13)
Total other income (expense), net	(167)	219	(386)
Net income (loss)	$ (75,606)	$ (36,712)	$ (38,894)

Collaboration Revenue

Collaboration revenue was immaterial during the six months ended June 30, 2021 and $0.8 million during the six months ended June 30, 2020. For the six months ended June 30, 2020 we recognized $0.8 million of revenue as a result of the completion of research services associated with a target included in the Merck KGaA Agreement, driving the decrease in collaboration revenue.

Research and Development Expense

Research and development expense increased by $31.8 million from $27.6 million for the six months ended June 30, 2020 to $59.4 million for the six months ended June 30, 2021.

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

- an increase of $13.6 million related to manufacturing, clinical and regulatory activities for UpRi;
- an increase of $7.3 million related to manufacturing for the preclinical and discovery stage programs XMT-1660 and XMT-2056;
- an increase of $5.4 million related to employee compensation (excluding stock-based compensation), primarily due to an increase in headcount supporting the growth of our research and development activities;
- an increase of $1.5 million related to diagnostic development efforts; and
- an increase of $0.8 million related to manufacturing, clinical and regulatory activities for XMT-1592.

Stock-based compensation expense included in research and development expenses increased by $3.2 million, primarily related to and increase in headcount and the increased valuation of stock-based awards granted to employees as a result of stock price appreciation.

We expect our research and development expenses to increase as we continue our clinical development of XMT-1536 and XMT-1592 and continue to advance our preclinical product candidate pipeline and invest in improvements in our ADC technologies.

General and Administrative Expense

General and administrative expense increased by $6.0 million from $10.1 million during the six months ended June 30, 2020 to $16.1 million during the six months ended June 30, 2021. The increase in general and administrative expense was primarily attributable to an increase of $2.4 million related to consulting and professional fees and an increase of $1.4 million related to employee compensation (excluding stock-based compensation), primarily related to an increase in headcount. Stock-based compensation increased $2.2 million due to the valuation of stock-based awards granted to employees as a result of stock price appreciation.

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

Total Other Income (Expense), net

Total other expense was $0.2 million for the six months ended June 30, 2021 and total other income was $0.2 million for the six months ended June 30, 2020. Other income consists primarily of interest income on cash equivalents and short-term marketable securities. Interest expense was related to our outstanding borrowings under the credit facility in both periods.

Liquidity and Capital Resources

Sources of Liquidity

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

In May 2020, we terminated the 2018 ATM and established a new ATM, or the 2020 ATM, pursuant to which we are able to sell up to $100.0 million of our common stock from time to time at prevailing market prices. In the second quarter of 2021, we sold 2.3 million shares of common stock under the 2020 ATM for net proceeds of $33.3 million. As of the end of the quarter, we had $66.0 million of availability under the program.

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

As of June 30, 2021, we had cash and cash equivalents of $227.4 million.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2021 and 2020:

(in thousands)	Six Months Ended June 30, 2021	2020
Net cash used in operating activities	$ (61,490)	$ (37,181)
Net cash provided by (used in) investing activities	(447)	34,410
Net cash provided by financing activities	34,388	228,796
Increase (decrease) in cash, cash equivalents and restricted cash	$ (27,549)	$ 226,025

Net Cash Used in Operating Activities

Net cash used in operating activities was $61.5 million for the six months ended June 30, 2021 and primarily consisted of a net loss of $75.6 million adjusted for changes in our net working capital and other non-cash items including stock-based compensation of $8.6 million and depreciation of $0.4 million. Net cash used in operating activities was $37.2 million for the six months ended June 30, 2020 and primarily consisted of a net loss of $36.7 million adjusted for non-cash items including stock-based compensation of $3.3 million and depreciation of $0.5 million, as well as change in our net working capital.

Net Cash Provided by (Used in) Investing Activities

Net cash used in investing activities was $0.4 million during the six months ended June 30, 2021 and consisted of purchases of equipment. Net cash provided by investing activities was $34.4 million during the six months ended June 30, 2020 and consisted primarily of maturities of marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $34.4 million during the six months ended June 30, 2021 as compared to net cash provided by financing activities of $228.8 million during the six months ended June 30, 2020. During the six months ended June 30, 2021, cash provided by financing activities consisted primarily of proceeds from the use of our ATM of $33.3 million and from the exercise of stock options of $1.0 million, offset by $0.3 million from the payment of employee tax obligations related to vesting of restricted stock units. During the six months ended June 30, 2020 cash provided by financing activities consisted primarily of $164.2 million related to the follow-on public offering in May 2020 and the proceeds from the use of the ATM of $63.1 million in April 2020, as well as proceeds from exercise of stock options of $1.4 million, offset by the payment of $0.2 million of debt issuance costs.

Funding Requirements

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

We believe our currently available funds will be sufficient to fund our current operating plan commitments for approximately the next two years. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

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

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

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

If we raise funds through additional strategic partnerships or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Off-Balance Sheet Arrangements

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

Critical accounting policies and significant judgments 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. There were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on February 26, 2021.

Item 3. 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 in Asia and Europe and may be subject to fluctuations in foreign currency rates at that time.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

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

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2021, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended June 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be subject to 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 Quarterly Report on Form 10-Q, we do not believe we are party to any claim or litigation, the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks related to development and approval of our ADC product candidates

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

Our early clinical results for UpRi, our lead product candidate, our early preclinical results for XMT-1592 and the early results of any other current or future product candidates, are not necessarily predictive of the results of our ongoing or future discovery programs or clinical studies. Promising results in preclinical studies and early encouraging clinical results of a drug candidate may not be predictive of similar results in later-stage preclinical studies or in humans during clinical studies. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in 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 events in preclinical or 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 study results for one of our product candidates or for competitor products utilizing similar technology, may raise concerns about the safety or efficacy of other products in our pipeline. If the results of our ongoing or future clinical studies are inconclusive with respect to the efficacy of our product candidates or if we do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates. For example, patients in the Company's ongoing clinical studies have experienced serious adverse events, including without limitation death, pneumonitis, renal impairment, abdominal pain, fatigue, vomiting, sepsis, and pyrexia. We expect that certain patients in ongoing and future studies will experience additional serious adverse events, including those that may result in death, as the Company's product candidates progress through clinical development.

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. Accordingly, there is significant risk that our products may not receive FDA approval.

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

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

From time to time, we may publish interim, "top-line" or preliminary data from our clinical studies. Positive preliminary data may not be predictive of such study's subsequent or overall results. Interim data from clinical studies that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "top-line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

We currently have only two ADC product candidates, UpRi and XMT-1592, in clinical studies. A failure of any of our product candidates in clinical development would adversely affect our business and may require us to discontinue development of other ADC product candidates based on the same technology.

UpRi and XMT-1592 are currently our only clinical-stage development product candidates. While we have certain other preclinical programs in development and we intend to develop other product candidates, including XMT-1660 and XMT-2056, it will take additional investment and time for such programs to reach the clinical stage of development. In addition, we have other product candidates in our current pipeline that are based on the same platforms as UpRi and XMT-1592. If either product candidate fails in development as a result of any underlying problem with our platforms, then we may be required to discontinue development of the product candidates that are based on the same technologies. If we were required to discontinue development of UpRi or XMT-1592, or if UpRi or XMT-1592 were to fail to receive regulatory approval or were to fail to achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability.

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

We cannot guarantee that clinical studies, including our ongoing Phase 1b clinical study and anticipated additional clinical studies for UpRi, our lead product candidate, and our ongoing Phase 1 does escalation study of XMT-1592, will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing, and other events may cause us to temporarily or permanently cease a clinical study. Events that may prevent successful or timely commencement, enrollment or completion of clinical development include, among others:

- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching, or failing to reach, agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical study sites;

- difficulties in obtaining required Institutional Review Board, or IRB, or Ethics Committee, or EC, approval at each clinical study site;
- challenges in recruiting and enrolling suitable patients to participate in clinical studies that meet the criteria of the protocol for the clinical study;
- imposition of a clinical hold by regulatory agencies or IRBs or ECs for any reason, including safety concerns or after an inspection of clinical operations or study sites;
- failure by CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's good clinical practices, or GCP, or applicable regulatory guidelines in other countries;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical studies, including, for example, delays in the testing, validation, manufacturing or delivery of the product candidates to the clinical sites;
- patients not completing participation in a study or not returning for post-treatment follow-up, including as a result of the ongoing COVID-19 pandemic;
- clinical study sites or patients dropping out of a study;
- expected or unexpected safety issues, including occurrence of serious adverse events, or SAEs, associated with our product candidates in clinical studies that are viewed as outweighing the product candidate's potential benefits;
- changes in regulatory requirements or guidance that require amending or submitting new clinical protocols; or
- lack of adequate funding to continue the clinical study.

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

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

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

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the nature and complexity of the study protocol, including eligibility criteria for the study;
- the number of clinical study sites and the proximity of patients to those sites;
- standard of care in the diseases under investigation;
- the commitment of clinical investigators to identify eligible patients;

- competing studies; and
- clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

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

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

In August 2020, the FDA granted Fast Track Designation for UpRi for the treatment of patients with platinum-resistant high-grade serous ovarian cancer who have received up to three prior lines of systemic therapy or patients who have received four prior lines of systemic therapy regardless of platinum status. We may seek a Breakthrough Therapy Designation for UpRi, or we may seek Breakthrough Therapy Designation or Fast Track Designation for XMT-1592 or any of our product candidates. Fast Track Designation may be available if a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs that receive Breakthrough Therapy Designation or Fast Track Designation by the FDA may also be eligible for accelerated approval and/or priority review if they satisfy the criteria for those programs.

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

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

We may seek orphan drug designation status for one of our current or future product candidates, and we may be unsuccessful. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages and user-fee waivers. In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor. Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the European Medicines Agency or the FDA from approving another marketing application for the same drug and indication for a set time period, except in limited circumstances. Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the drug from competition because different drugs can be approved for the same condition, or the drug may be used off-label. Even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the other drug is clinically superior. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive

marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our current or future product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

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

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

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

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the number, design or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical studies;
- the data collected from clinical studies of our product candidates may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for marketing approval or may otherwise not be sufficient to support the submission of a new drug application or biologics license application, or other submission or to obtain regulatory approval in the United States or elsewhere;

- the FDA may not accept data generated at our preclinical studies and clinical study sites;
- the FDA may require us to conduct additional preclinical studies and clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- we or any third-party service providers may be unable to demonstrate compliance with current Good Manufacturing Practices, or cGMPs, to the satisfaction of the FDA or comparable foreign regulatory authorities, which could result in delays in or prevent regulatory approval or require us to withdraw or recall products and interrupt commercial supply of our products; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

We may seek approval of UpRi, XMT-1592 and any of our other current and future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of approval, the FDA requires that a sponsor of a product receiving accelerated approval perform a post-marketing confirmatory clinical study or studies. These confirmatory studies must be completed with due diligence. In addition, the FDA currently requires as a condition for accelerated approval preapproval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval. Accelerated approval may also be withdrawn if, among other things, a confirmatory study required to verify the predicted clinical benefit of the product fails to verify such benefit or if such study is not conducted with due diligence.

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

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

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

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

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical studies;
- refusal by the FDA or any other governing regulatory body to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

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

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

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

Patients in the Company's ongoing clinical studies have experienced serious adverse events, including without limitation death, pneumonitis, renal impairment, abdominal pain, fatigue, vomiting, sepsis, and pyrexia. We expect that certain patients in ongoing and future studies will experience additional serious adverse events, including those that may result in death, as the Company's product candidates progress through clinical development. These or additional undesirable side effects caused by our product candidates or those of our competitors, either before or after receipt of marketing approval, could result in a number of potentially significant negative consequences, including:

- our clinical studies may be put on hold;
- we may be unable to obtain regulatory approval for our product candidates;
- regulatory authorities may withdraw or limit their approvals of our product candidates;
- regulatory authorities may require the addition of labeling statements, such as a contraindication, black box warnings or additional warnings;
- the FDA may require development of a REMS with Elements to Assure Safe Use as a condition of approval or post-approval;
- we may decide to remove such product candidates from the marketplace;
- we may be subject to regulatory investigations and government enforcement actions;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

If a companion diagnostic is required for the label for UpRi, our lead product candidate, XMT-1592, or any of our other current or future product candidates, therefore conditioning our ability to market such product candidates on the commercial availability of an approved companion diagnostic, we may seek approval for our validated assay as a companion diagnostic or we may contract with third parties to create and obtain approval for a companion diagnostic. To be successful in developing and commercializing such a companion diagnostic, we need to address a number of scientific, technical and logistical challenges. We have little experience in the development and commercialization of diagnostics and may not be successful in developing and commercializing appropriate diagnostics to pair with UpRi, XMT-1592, or any of our other current or future product candidates. Companion diagnostics are subject to regulation by the FDA and equivalent foreign regulatory authorities as medical devices and require separate regulatory approval prior to commercialization. Given our limited experience in developing and commercializing diagnostics, we may rely in part or in whole on third parties for their design, manufacture and commercialization. We, our collaborators or such third parties may encounter difficulties in developing and obtaining approval for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility or clinical validation. Any delay or failure by us, our collaborators or such third parties to develop or obtain regulatory approval of the companion diagnostics could delay or prevent approval of our product candidates. If we, or any third parties that we may contract with to assist us, are unable to successfully develop and commercialize companion diagnostics for our product candidates, or experience delays in doing so:

- the development of UpRi, XMT-1592, and our other current or future product candidates, may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical studies;
- our product candidates may not receive marketing approval if safe and effective use of a therapeutic product candidate depends on the availability of an in vitro diagnostic; and
- we may not realize the full commercial potential of any product candidates that receive marketing approval if, among other reasons, we are unable to appropriately select patients who are likely to benefit from therapy with our products.

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

In addition, third-party collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion diagnostics fail to gain market acceptance, it would have an adverse effect on our ability to derive revenues from sales of our product candidates, if approved. In addition, any diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

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

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

Risks related to our financial position and need for additional capital

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

We have incurred net losses since our inception. Our net loss was $75.6 million for the six months ended June 30, 2021. As of June 30, 2021, we had an accumulated deficit of $356.0 million. We do not know when or whether we will become profitable. To date, we have not commercialized any products and therefore have never generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. Our losses have resulted principally from costs incurred in our discovery and development activities. Our net losses may fluctuate significantly from quarter to quarter and year to year.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities. To date, we have financed our operations primarily through the sale of equity securities, the receipt of funds through strategic partnerships with third parties and our credit facility. The amount of our future net losses will depend, in part, on the rate of our future expenditures. We have not completed pivotal clinical studies for any product candidate and only have one product candidate in a clinical study. It will be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market a product candidate, our future revenues would depend upon the size of the market or markets in which our product candidates received such approval and our ability to achieve sufficient market acceptance, reimbursement from third-party payors and adequate market share for our product candidates in those markets.

We expect to continue to incur significant expenses and increasing net losses for at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

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

If we are required by the United States Food and Drug Administration, or FDA, or any equivalent foreign regulatory authority to perform clinical studies or preclinical studies in addition to those we currently expect to conduct, or if there are any delays in completing the clinical studies of UpRi, XMT-1592, or any other current or future product candidates, our expenses could increase.

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

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

Our cash and cash equivalents were $227.4 million as of June 30, 2021. We have utilized substantial amounts of cash since our inception and expect that we will continue to expend substantial resources for the foreseeable future developing UpRi, our lead product candidate, XMT-1592, and any other current or future product candidates. These expenditures may include costs associated with research and development, conducting preclinical studies and clinical studies, potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any, and potentially acquiring new technologies. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical studies is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Our costs will increase if we experience any delays in our clinical studies for UpRi, XMT-1592 or any other current or future product candidates, including delays in enrollment of patients. We also incur costs associated with operating as a public company, hiring additional personnel and expanding our facilities.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing UpRi, XMT-1592 and any other current or future product candidates and conducting preclinical studies and clinical studies;
- the timing of, and the costs involved in, obtaining regulatory approvals for UpRi, XMT-1592 and any other current or future product candidates if preclinical studies and clinical studies are successful;
- the cost of manufacturing UpRi, XMT-1592 and any other current or future product candidates for clinical studies in preparation for regulatory approval and in preparation for commercialization;
- the cost of commercialization activities for UpRi, XMT-1592 and any other current or future product candidates, if any product candidates are approved for sale, including manufacturing, marketing, sales and distribution costs;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our future products, if any, or products developed by our partners.

Based on our current operating plan, we believe that our currently available funds will be sufficient to fund our operations through at least the next twelve months following the filing of this Quarterly Report on Form 10-Q. Our operating plan, however, may change as a result of many factors currently unknown to us and we may need additional funds sooner than planned. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical studies or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

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

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of such equity or convertible debt securities may include liquidation or other preferences that are senior to or otherwise adversely affect the rights of our common stockholders. Additional debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring future debt, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness, each of which could adversely impact our ability to conduct our business and execute our operating plan. If we raise additional funds through strategic partnerships with third parties, we may have to relinquish valuable rights to our technologies, including our platforms, or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for UpRi, our lead product candidate, XMT-1592, or any other current or future product candidates, or grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have a credit facility that requires us to meet certain operating and financial covenants and place restrictions on our operating and financial flexibility.

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

The Credit Facility includes customary covenants including covenants requiring us to maintain our corporate existence and governmental approvals, deliver certain financial reports and maintain insurance coverage. Additionally, we are restricted in our ability to transfer collateral, incur additional indebtedness, engage in mergers or acquisitions, pay dividends or make other distributions, make investments, create liens, sell assets and agree to a change in control. Upon the occurrence of an event of default, which includes our failure to satisfy our payment obligations under the Credit Facility, the breach of certain of the covenants under the Credit Facility, or the occurrence of a material adverse change in our business, SVB is entitled to increase the applicable interest rate, accelerate amounts due under the Credit Facility and dispose the collateral as permitted under applicable law. Any declaration by SVB of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

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

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

Risks related to our reliance on third parties

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

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

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

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

- a delay or inability to initiate or continue clinical studies of product candidates under development;
- delay in submitting regulatory applications, or delay or failure to receive regulatory approvals, for product candidates;
- loss of the cooperation of an existing or future strategic partner;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- a requirement to cease distribution or to recall batches of our product candidates;
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products; and
- fines, adverse publicity, and civil and criminal enforcement and sanctions.

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

In order to conduct clinical studies of our product candidates and commercialize any approved product candidates, we, or our manufacturing partners, will need to manufacture them in large quantities. We, or our manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical studies of that product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. We have evaluated which third-party manufactures to engage for scale-up to commercial supply of our product candidates, including UpRi, our lead product candidate and XMT-1592, and we have begun transfer and scale-up of certain manufacturing activities. If we are unable to obtain or maintain third-party manufacturing for commercial supply of our product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully.

We rely on third parties to conduct preclinical studies and clinical studies for UpRi and XMT-1592 and if such third parties do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for UpRi, XMT-1592, or any other current or future ADC product candidates.

We designed the Phase 1 clinical studies for UpRi, our lead product candidate, and XMT-1592, and we intend to design any future clinical studies for any future unpartnered product candidates that we may develop if preclinical studies are successful. However, we rely on CROs and other third parties to assist in managing, monitoring and otherwise carrying out many of these studies. As a result, we have less direct control over the conduct, timing and completion of these clinical studies and the management of data developed through clinical studies than would be the case if we were relying entirely upon our own staff. These CROs and other third parties are not our employees and we have limited control over the amount of time and resources that they dedicate to our programs. We compete with many other companies for the resources of these third parties. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with whom we contract might not be diligent, careful or timely in conducting our preclinical studies or clinical studies, resulting in the preclinical studies or clinical studies being delayed or unsuccessful.

The third parties on whom we rely generally may terminate their engagements at any time, and having to enter into alternative arrangements would delay development and commercialization of our product candidates. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

The FDA and comparable foreign regulatory authorities require compliance with regulations and standards, including GCP, for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical studies to assure that the data and results are credible and accurate and that the rights, integrity and confidentiality of study participants are protected. Although we rely, and intend to continue to rely, on third parties to conduct our clinical studies, they are not our employees, and we are responsible for ensuring that each of these clinical studies is conducted in accordance with its general investigational plan, protocol and other requirements. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities.

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

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

We have established strategic partnerships and intend to continue to establish strategic partnerships with third parties to research, develop and commercialize our platforms and existing and future product candidates. We entered into a collaboration agreement with Merck KGaA for the development and commercialization of other product candidates. For certain of these programs, we will depend on our partners to design and conduct their clinical studies. As a result, we may not be able to conduct these programs in the manner or on the time schedule we currently contemplate, which may negatively impact our business operations. In addition, if any of these partners withdraw support for these programs or proposed products or otherwise impair their development or experience negative results, our business and our product candidates could be negatively affected.

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

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

To date, we have depended on a small number of partners for a substantial portion of our revenue. The loss of any one of these partners could result in a material decline in our revenue.

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

We may not be successful in establishing and maintaining additional strategic partnerships, which could adversely affect our ability to develop and commercialize products, negatively impacting our operating results.

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

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

Risks related to commercialization of our ADC product candidates

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

Even if we obtain regulatory approval for UpRi, our lead product candidate, XMT-1592, or any other current or future product candidates that we may develop or acquire in the future, the product candidate may not gain market acceptance among physicians, health care payors, patients and the broader healthcare community. Market acceptance of any approved products depends on a number of factors, including:

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

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

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

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

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

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

In the future, we expect to build a focused sales and marketing infrastructure to market UpRi, our lead product candidate, XMT-1592, and any other current or future product candidates in the United States and certain foreign jurisdictions, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities.

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

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

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

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

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

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

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

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

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

Adverse pricing limitations may hinder our ability to recoup our investment in UpRi, our lead product candidate, XMT-1592, or any other current or future product candidates, even if such product candidates obtain marketing approval.

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

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

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

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

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

Within the United States, there have been ongoing government efforts at the federal and state levels to reform the provision or control the cost of health care. There have been a number of legislative and regulatory changes to the healthcare system, such as the enactment and subsequent modification of the Health Care Reform Act, that could affect our future results of operations or the commercial success of our products, if approved. See “Business-Government regulation - Healthcare reform” in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on February 26, 2021. We continue to evaluate the effect that healthcare reform efforts may have on our business, but expect that healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to successfully commercialize our product candidates, if approved. Healthcare reform efforts to contain or reduce costs of health care may adversely affect:

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

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

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

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

The biotechnology and biopharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. Many third parties compete with us in developing various approaches to cancer therapy. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations. Any treatments developed by our competitors could be superior to our product candidates. It is possible that these competitors will succeed in developing technologies that are more effective than our platforms or product candidates or that would render our platforms obsolete or noncompetitive. We anticipate that we will face increased competition in the future as additional companies enter our market and scientific developments surrounding other cancer therapies continue to accelerate.

We are also aware of multiple companies with ADC technologies that may be competitive to our platforms, including ADC Therapeutics, Astellas, AstraZeneca, Bolt, Daiichi Sankyo, Gilead, GSK, ImmunoGen, Pfizer, SeaGen, Silverback, and Sutro. These companies or their partners, including AbbVie, Genentech and Takeda, may develop product candidates which compete in the same indications as our current and future product candidates. We expect to compete on improved efficacy, safety and tolerability compared to other product candidates and if our products are not demonstrably superior in these respects compared to other approved therapeutics, we may not be able to compete effectively.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical studies, obtaining regulatory approval and marketing than we do. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Smaller or early-stage companies may also prove to be significant competitors, particularly through strategic partnerships with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to our programs.

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

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

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

- advance our technology platforms;
- obtain and maintain intellectual property protection for our technologies and products;
- obtain required government and other public and private approvals on a timely basis;
- attract and retain key personnel;
- commercialize effectively;
- obtain reimbursement for our products in approved indications;
- comply with applicable laws, regulations and regulatory requirements and restrictions with respect to the commercialization of our products, including with respect to any changed or increased regulatory restrictions; and
- enter into additional strategic partnerships to advance the development and commercialization of our product candidates.

Risks related to our intellectual property

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

Our success depends in large part on our ability to obtain and maintain protection with respect to our intellectual property and proprietary technology. We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our platforms and our product candidates, including UpRi and XMT-1592. The patent position of biopharmaceutical companies is generally uncertain because it involves complex legal and factual considerations and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights is highly uncertain. The standards applied by the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in patents. In addition, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The patent prosecution process is expensive, complex and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that we fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents.

The patent applications that we own or in-license may fail to result in issued patents, and even if they do issue as patents, such patents may not cover our platforms and product candidates in the United States or in other countries. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. For example, even if patent applications we license or own do successfully issue as patents and even if such patents cover our platforms and product candidates, third

parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not provide adequate protection or exclusivity for our ADC platform or product candidates, prevent others from designing around our claims or otherwise provide us with a competitive advantage. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If patent applications we own or have in-licensed with respect to our platforms or our product candidates fail to issue as patents, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity, it could dissuade companies from collaborating with us. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patents or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful development and commercialization of any product candidate. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by the USPTO or a third-party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent and the protection it affords is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, our owned or in-licensed patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a drug under patent protection could be further reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from similar or generic products. The launch of a generic version of one of our products in particular would be likely to result in an immediate and substantial reduction in the demand for our product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

Issued patents covering UpRi, our lead product candidate, XMT-1592, and any other current or future ADC product candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign authority.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering UpRi, our lead product candidate, XMT-1592, or any other current or future product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our licensors, our patent counsel and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our product candidates. Any such loss of patent protection could have a material adverse impact on our business, financial condition, results of operations and prospects.

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

We rely, in part, on license, collaboration and other agreements. We may need to obtain additional licenses from others to advance our research or allow commercialization of our product candidates and it is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to use. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

In addition, our existing licenses and collaboration agreements, including our license with Recepta Biopharma S.A., or Recepta, for intellectual property covering the NaPi2b antibody in UpRi and XMT-1592, and our license with Synaffix B.V, or Synaffix, for intellectual property covering components included in the Dolasynthen platform, impose, and any future licenses, collaborations or other agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, including, in the case of our agreement with Recepta, the license for the rights covering the NaPi2b antibody in UpRi and XMT-1592, and in the case of our agreement with Synaffix, the license for the rights covering components in the Dolasynthen platform. Any of the foregoing could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to

the licensed technology. Disputes may arise regarding intellectual property subject to a licensing, collaboration or other agreements, including:

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

In addition, the agreements under which we currently license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

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

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

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

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

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

In addition, in a litigation or other proceeding, a court or administrative judge may decide that a patent owned by or licensed to us is invalid or unenforceable, or a court may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. During the course of any patent or other intellectual property litigation or other proceeding, there could be public announcements of the results of hearings, rulings on motions and other interim proceedings or developments and if securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, programs or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations and prospects.

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

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

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

18 months after the earliest filing, and sometimes not at all. Therefore, patent applications covering our platforms or our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platforms, our product candidates or the use or manufacture of our product candidates.

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

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

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

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

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

Additionally, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our licensed and owned patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

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

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

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

Many of our and our licensors' employees, including our senior management, consultants or advisors are currently, or previously were, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of

any such individual's current or former employer. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

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

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

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

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make ADC products that are similar to any product candidates we may develop or utilize similar ADC-related technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our license partners or current or future strategic partners, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our license partners or current or future strategic partners, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks related to our business and industry

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

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

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

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

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

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

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

- federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;

- the federal anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving or providing any remuneration, directly or indirectly, to induce, either the referral of an individual for, or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid;

- the federal anti-kickback prohibition known as Eliminating Kickbacks in Recovery Act or EKRA, enacted in 2018, which prohibits certain payments related to referrals of patients to certain providers (recovery homes, clinical treatment facilities and laboratories) and applies to services reimbursed by private health plans as well as government health care programs;

- the federal law known as HIPAA, which, in addition to privacy protections to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program (which may include private health plans) or making false statements relating to healthcare matters;

- the FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;

- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;

- the so-called "federal sunshine" law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with teaching hospitals, physicians and certain non-physician practitioners to the federal government for re-disclosure to the public;

- the privacy, security and breach provisions of HIPAA, which impose obligations on certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) and certain of their "business associate" contractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal and state laws and regulations, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure and protection of health-related and other personal information.

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

- the Foreign Corrupt Practices Act, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and

- state law analogues of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including private health plans, state privacy laws, state consumer protection laws, and state laws regulating interactions between pharmaceutical manufacturers and healthcare providers, requiring disclosure of such financial interactions or mandating adoption of certain compliance standards, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

In addition, the regulatory approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the health care laws mentioned above, among other foreign laws.

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and

regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

- injury to our reputation;
- decreased demand for our product candidates or products that we may develop;
- withdrawal of clinical study participants;
- costs to defend the related litigations;
- a diversion of management’s time and our resources;
- substantial monetary awards to study participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical studies in the amount of $10 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for

which we have no coverage. In such instance, we might have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could adversely affect our business, financial condition, results of operations and prospects.

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

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

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

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

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

We may acquire additional technologies and assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are unable to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot be assured that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Our internal computer systems, or those of our strategic partners, third-party collaborators or other contractors or consultants, may fail or suffer security breaches, which could adversely affect our business, including through material disruptions of our programs or business operations.

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

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

Risks related to our common stock

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

Our stock price has been and may continue to be volatile. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this “Risk Factors” section, and others beyond our control, including:

- results and timing of preclinical studies and clinical studies of our current or future product candidates, including UpRi and XMT-1592;
- results of clinical studies of our competitors’ products;
- failure to adequately protect our trade secrets;
- the terms on which we raise additional capital or our ability to raise it;
- commencement or termination of any strategic partnership or licensing arrangement;
- regulatory developments, including actions with respect to our products or our competitors’ products;
- actual or anticipated fluctuations in our financial condition and operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;

- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us (including pursuant to the pre-funded warrants described below), our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- changes in market conditions for biopharmaceutical stocks; and
- changes in general market and economic conditions.

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

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

As of June 30, 2021, our executive officers, directors and stockholders who own more than 5% of our outstanding common stock, together with their respective affiliates, beneficially owned a significant amount of our common stock, including shares subject to outstanding options and warrants that are exercisable within 60 days after such date. Accordingly, these stockholders are able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management or board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

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

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

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

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

- authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to have discretion to modify, alter or repeal our amended and restated by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated by-laws.

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

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

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

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

For the years ended December 31, 2020, 2019 and 2018, the Company recorded no income tax benefit for the net operating losses incurred in each year, due to the uncertainty of realizing a benefit from those items. The Company has incurred net operating losses (NOLs) since its inception. As of December 31, 2020, the Company had federal NOLs of approximately $250.4 million and state NOLs of approximately $184.8 million. Of the $250.4 million of federal NOLs, $34.2 million expire at various dates through 2037. The remaining $216.2 million of federal NOLs do not expire. The state NOLs will expire at various dates through 2040. As of December 31, 2020, the Company had Federal and State research and development tax credit carryforwards of approximately $4.6 million and $1.5 million, respectively, which expire at various dates through 2040. Under the 2017 Tax Act, federal NOLs incurred in 2019 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the 2017 Tax Act. In addition, under Section 382 of the Internal Revenue Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change income or taxes may be limited. Our past issuances of stock and other changes in our stock ownership may have resulted in ownership changes within the meaning of Section 382 of the Code; accordingly, our pre-change NOLs may be subject to limitation under Section 382. If we determine that we have not undergone an ownership change, the Internal Revenue Service could challenge our analysis, and our ability to use our NOLs to offset taxable income could be limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in ownership changes under Section 382 of the Code further limiting our ability to utilize our NOLs. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. The Company has determined that ownership changes have occurred since our inception and that certain NOLs and research and development tax credit carryforwards will be subject to limitation. We may also have incurred subsequent ownership changes. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. federal taxable income. We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our NOLs. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

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

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the state or federal courts within the State of Delaware will be exclusive forums for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated by-laws or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity that purchases or otherwise acquires any interest in shares of our capital stock shall be deemed to have notice

of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

General risk factors

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

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

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

- Our clinical studies may be adversely affected, delayed or interrupted, including, for example, site initiation, patient recruitment and enrollment, availability of clinical study materials, and data analysis. Some patients and clinical investigators may not be able to comply with clinical study protocols and patients may choose to withdraw from our studies or we may have to pause enrollment or we may choose to or be required to pause enrollment and or patient dosing in our ongoing clinical studies in order to preserve health resources and protect study participants, which could delay our clinical studies or impact the strength or validity of our clinical study data. It is unknown how long these pauses or disruptions could continue.

- We currently rely on third parties to, among other things, manufacture raw materials, manufacture our product candidates for our clinical studies, shipping of investigation drugs and clinical study samples, perform quality testing and supply other goods and services to run our business. If any such third party in our supply chain for materials are adversely impacted by restrictions resulting from the coronavirus pandemic, including staffing shortages, raw material supplies, production slowdowns or disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical studies and conduct our research and development operations.

- Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical study sites and other important agencies and contractors.

- Our employees and contractors conducting research and development activities may not be able to access our laboratory for an extended period of time as a result of the closure of our offices and the possibility that governmental authorities further modify current restrictions. As a result, this could delay timely completion of preclinical activities, including completing Investigational New Drug (IND)-enabling studies or our ability to select future development candidates, and initiation of additional clinical studies for other of our development programs

- Health regulatory agencies globally may experience disruptions in their operations as a result of the coronavirus pandemic. The U.S. Food and Drug Administration, or FDA, and comparable foreign

regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical studies and, as a result, review, inspection, and other timelines may be materially delayed. It is unknown how long these disruptions could continue, were they to occur. Any prolongation or de-prioritization of our clinical studies or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates. For example, regulatory authorities may require that we not distribute a product candidate lot until the relevant agency authorizes its release. Such release authorization may be delayed as a result of the coronavirus pandemic and could result in delays to our clinical studies.

- The trading prices for our common shares and other biopharmaceutical companies have been highly volatile as a result of the coronavirus pandemic. As a result, we may face difficulties raising capital through sales of our common shares or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common shares.

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

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

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

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

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

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

Item 5. Other Information.

At the Annual Meeting of Stockholders held on June 11, 2021, the Company's stockholders voted, on an advisory basis, in favor of holding an annual advisory vote on the compensation of our named executive officers, or Say-on-Pay Vote, as previously reported in the Current Report on Form 8-K filed by the Company on June 17, 2021. Based on these results, and consistent with its recommendation, the Board has determined that the Company will hold an annual Say-on-Pay Vote unless changed as a result of a subsequent vote on the frequency of future Say-on-Pay votes.

Item 6. Exhibits.

EXHIBIT 3.1	- Fifth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on July 10, 2017).
EXHIBIT 3.2	- Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed on July 10, 2017).
EXHIBIT 10.1	- Form of Restricted Stock Unit under the 2017 Stock Incentive Plan.
EXHIBIT 31.1	- Rule 13a—14(a) / 15d—14(a) Certifications — Chief Executive Officer.
EXHIBIT 31.2	- Rule 13a—14(a) / 15d—14(a) Certifications — Principal Financial Officer.
EXHIBIT 32.1	- Section 1350 Certifications.
EXHIBIT 101	- The following financial and related information from Mersana Therapeutics, Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, formatted in Inline eXtensible Business Reportable Language (iXBRL) includes: (i) the Condensed Consolidated Balance Sheet; (ii) the Condensed Consolidated Statement of Operations and Comprehensive Income (Loss); (iii) the Condensed Consolidated Statement of Changes in Stockholders' Equity; (iv) the Condensed Consolidated Statement of Cash Flows; and, (v) Notes to Condensed Consolidated Financial Statements.
EXHIBIT 104	- The cover page from the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, formatted in Inline XBRL (contained in Exhibit 101).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Mersana Therapeutics, Inc.

Dated: August 6, 2021

By: /s/ Anna Protopapas
Anna Protopapas
President and Chief Executive Officer

Dated: August 6, 2021

By: /s/ Brian DeSchuytner
Brian DeSchuytner
Senior Vice President, Finance & Product Strategy

MERSANA THERAPEUTICS, INC. 2017 STOCK INCENTIVE PLAN

RESTRICTED STOCK UNIT AGREEMENT

This agreement (this "**Agreement**") evidences a grant of restricted stock units ("**RSUs**") by Mersana Therapeutics, Inc. (the "**Company**") to the individual named above (the "**Grantee**"), an employee of the Company, pursuant to and subject to the terms of the Mersana Therapeutics, Inc. 2017 Stock Incentive Plan (as from time to time amended and in effect, the "**Plan**"). Except as otherwise defined herein, all capitalized terms used herein have the same meanings as in the Plan.

1. Grant of RSUs. The Company grants to the Grantee on the date set forth above (the "**Date of Grant**") the number of RSUs set forth above, giving the Grantee the conditional right to receive, with respect to each RSU granted hereunder, without payment and pursuant to and subject to the terms and conditions set forth in this Agreement and in the Plan, one share of Stock (a "**Share**"), subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof.

The RSUs are granted to the Grantee in connection with the Grantee's ongoing Employment with the Company.

2. Vesting; Cessation of Employment.

(a) Vesting. Unless earlier terminated, forfeited, relinquished or expired, the RSUs will vest as to 25% of the shares on each of the first four anniversaries of the Date of Grant (each, a "Vesting Date"), subject to Grantee's continued Employment through such Vesting Date.

(b) Cessation of Employment. If the Grantee's Employment ceases for any reason, except as expressly provided for in any agreement between the Grantee and the Company or its Affiliate, the RSUs, to the extent not then vested, will be immediately forfeited.

3. Delivery of Shares. Subject to Section 4 below, the Company shall, as soon as practicable upon the vesting of any RSUs subject to this Agreement (but in no event later than 30 days following a Vesting Date), effect delivery of the Shares with respect to such vested RSUs to the Grantee (or, in the event of the Grantee's death, to the person to whom the Award has passed by will or the laws of descent and distribution). No Shares will be issued pursuant to this Agreement unless and until all legal requirements applicable to the issuance or transfer of such Shares have been complied with to the satisfaction of the Administrator.

4. Forfeiture; Recovery of Compensation.

(a) The RSUs, and the proceeds from the exercise or disposition of the Shares, will be subject to forfeiture and disgorgement to the Company, with interest and related earnings, if at any time the Grantee is not in compliance with all applicable provisions of this Agreement and the Plan.

(b) By accepting, or being deemed to have accepted, the RSUs, the Grantee expressly acknowledges and agrees that his or her rights, and those of any permitted transferee of the RSUs, including the right to any Shares or proceeds from the disposition thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). Nothing in the preceding sentence may be construed as limiting the general application of Section 7 of this Agreement.

5. Nontransferability. The RSUs may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

6. Withholding.

(a) The Grantee expressly acknowledges and agrees that the Grantee's rights hereunder, including the right to be issued Shares in settlement of the RSUs subject to this Agreement, are subject to the Grantee's satisfaction of all taxes required to be withheld, if any.

(b) By accepting the RSUs, the Grantee hereby acknowledges and agrees that he or she elects to sell Shares having a Fair Market Value sufficient to satisfy the minimum statutory withholding tax obligations with respect to the RSUs ("Sell to Cover") and to allow E*Trade, or such other registered broker-dealer that is a member of the Financial Industry Regulatory Authority as the Company may select, as the Grantee's agent (the "Agent"), to remit the cash proceeds of such sale to the Company to satisfy such withholding obligations, unless the Company chooses to satisfy such withholding obligations by other means, in which case it shall notify the Grantee of the other means by which the Grantee shall satisfy such obligations.

(c) If such withholding obligations are satisfied through a Sell to Cover, the Grantee hereby irrevocably appoints the Agent as the Grantee's agent, and hereby authorizes and directs the Agent to: (i) sell on the open market at the then prevailing market price(s), on the Grantee's behalf, on or as soon as practicable after the date on which the Shares are delivered to the Grantee pursuant to Section 3 of this Agreement, the number (rounded up to the next whole number) of Shares sufficient to generate proceeds to cover (A) the satisfaction of the minimum statutory withholding tax obligations arising from the vesting of the RSUs and the related issuance and delivery of Shares to the Grantee and (B) all applicable fees and commissions due to, or required to be collected by, the Agent with respect thereto; (ii) remit directly to the Company the proceeds from the sale of such Shares; (iii) retain the amount required to cover all applicable fees and commissions due to, or required to be collected by, the Agent, relating directly to the sale of such Shares; and (iv) maintain any remaining funds from the sale of such Shares in the Grantee's account with the Agent.

(d) The Grantee hereby authorizes the Company and the Agent to cooperate and communicate with one another to determine the number of Shares that must be sold to satisfy the Grantee's obligations hereunder and to otherwise effect the purpose and intent of this Section 6 and satisfy the rights and obligations hereunder. The Grantee acknowledges that the Agent is under no obligation to arrange for the sale of Shares at any particular price under a Sell to Cover and that the Agent may affect sales under any Sell to Cover in one or more sales and that the average price for executions resulting from bunched orders may be assigned to the Grantee's account. The Grantee further acknowledges that he or she will be responsible for all brokerage fees and other costs of sale associated with any Sell to Cover or transaction contemplated by this Section 6 and agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale. In addition, the Grantee acknowledges that it may not be possible to sell Shares as provided for in this Section 6 due to various circumstances. If it is not possible to sell shares of Common Stock in a Sell to Cover, the Company will inform the Grantee of the other methods for the Grantee to satisfy his or her obligations hereunder, including by payment of an amount in cash or by check. The Grantee will continue to be responsible for the timely

payment to the Company of all taxes that are required to be paid or withheld with respect to the RSUs. In such event, or in the event that the Company determines that the cash proceeds from a Sell to Cover are insufficient to satisfy the minimum statutory withholding tax obligations with respect to the RSUs, the Grantee hereby authorizes the Company and its subsidiaries to withhold such amounts from any payments owed to the Grantee, but nothing in this sentence shall be construed as relieving the Grantee of any liability for satisfying his or her obligations under the preceding provisions of this Section 6.

(e) The Grantee hereby agrees to execute and deliver to the Agent or the Company any other agreements or documents, or to take any other actions, as the Agent or the Company reasonably deem necessary or appropriate to carry out the purposes and intent of this Agreement, including without limitation, any agreement intended to ensure the Sell to Cover and the corresponding authorization and instruction to the Agent set forth in this Section 6 to sell Shares to satisfy the minimum statutory withholding tax obligations with respect to the RSUs comply with the requirements of Rule 10b5-1(c) under the Securities Exchange Act of 1934, as amended. The Agent is a third-party beneficiary of this Section 6.

(f) The Grantee's election to Sell to Cover to satisfy is irrevocable. Upon acceptance of the Award, the Grantee has elected to Sell to Cover to satisfy the minimum statutory withholding tax obligations with respect to the RSUs, and the Grantee acknowledges that he or she may not change this election at any time in the future.

7. Effect on Employment. This grant of the RSUs will not give the Grantee any right to be retained in the Employment or service of the Company or any of its subsidiaries, affect the right of the Company or any of its subsidiaries to terminate the Grantee's Employment or service at any time, or affect any right of the Grantee to terminate his or her Employment or service with the Company at any time.

8. Provisions of the Plan. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been furnished or made available to the Grantee. By accepting, or being deemed to have accepted, all or any part of the RSUs, the Grantee agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan will control.

Exhibit 31.1

Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002

I, Anna Protopapas, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Mersana Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report), that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Mersana Therapeutics, Inc.

/s/ Anna Protopapas

Anna Protopapas

President and Chief Executive Officer

(Principal Executive Officer)

Dated: August 6, 2021

Exhibit 31.2

Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002

I, Brian DeSchuytner, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Mersana Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report), that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Mersana Therapeutics, Inc.

/s/ Brian DeSchuytner

Brian DeSchuytner

Senior Vice President, Finance & Product Strategy

(Principal Financial Officer)

Dated: August 6, 2021

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Mersana Therapeutics, Inc. (the "Company") for the quarter ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the company, hereby certifies, pursuant to Section 1350 of Chapter 63 of Title 18, United States Code, that to the best of her or his knowledge:

1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 6, 2021

/s/ Anna Protopapas

Anna Protopapas

President and Chief Executive Officer
(Principal Executive Officer)

Dated: August 6, 2021

/s/ Brian DeSchuytner

Brian DeSchuytner

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