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, 2023

OR

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

For the transition period from to

Commission file number 001-38129

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

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

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

(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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

There were 120,507,291 shares of Common Stock ($0.0001 par value per share) outstanding as of August 4, 2023.

REFERENCES TO MERSANA

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

FORWARD LOOKING STATEMENTS AND INDUSTRY DATA

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

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

- the initiation, cost, timing, progress and results of our current and future research and development activities, preclinical studies and clinical trials;
- our efforts and ability to successfully resolve the continuing clinical hold imposed by the U.S. Food and Drug Administration on our Phase 1 trial of XMT-2056;
- the adequacy of our inventory of XMT-1660 and our other product candidates to support our ongoing and planned clinical trials, as well as the outcome of planned manufacturing runs;
- the timing of, and our ability to obtain and maintain, regulatory approvals for our product candidates;
- our ability to quickly and efficiently identify and develop additional product candidates;
- our ability to advance any product candidate into, and successfully complete, clinical trials;
- unmet needs of patients with cancer indications;
- the timing of, and our ability to obtain and maintain, regulatory approvals for our product candidates;
- our intellectual property position, including with respect to our trade secrets;
- the potential benefits of strategic collaborations and our ability to enter into selective strategic collaborations;
- our strategic priorities and our restructuring plan announced on July 27, 2023; and
- our estimates regarding expenses, future revenues, capital requirements, the sufficiency of our current and expected cash resources and our need for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023, particularly in the "Risk Factors" section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

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

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

RISK FACTORS SUMMARY

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

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

- We have incurred net losses since our inception, we have no products approved for commercial sale and we anticipate that we will continue to incur substantial operating losses for the foreseeable future.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- We have a credit facility that requires us to meet certain affirmative and negative covenants and places restrictions on our operating and financial flexibility.
- We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.
- We only have a limited number of product candidates being evaluated in clinical trials. A failure of any of our current or future product candidates in clinical development could adversely affect our business and may require us to discontinue development of other product candidates based on the same technology.
- We can provide no assurance that our product candidates will obtain regulatory approval or that the results of clinical trials will be favorable.
- Drug discovery and development is a complex, time-consuming and expensive process that is fraught with risk and a high rate of failure. We can provide no assurance of the successful and timely development of new antibody-drug conjugate, or ADC, products.
- If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates.
- Our restructuring and workforce reduction announced on July 27, 2023 may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

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

- We rely upon patents and other intellectual property rights to protect our technology. We may be unable to protect our intellectual property rights, and we may be liable for infringing the intellectual property rights of others.

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

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 128,732	$ 128,885
Short-term marketable securities	157,856	151,827
Accounts receivable	—	30,000
Prepaid expenses and other current assets	10,499	8,507
Total current assets	297,087	319,219
Property and equipment, net	4,266	3,985
Operating lease right-of-use assets	9,130	10,475
Other assets, noncurrent	517	661
Total assets	$ 311,000	$ 334,340
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 16,918	$ 13,951
Accrued expenses	33,468	43,184
Deferred revenue	20,500	30,610
Operating lease liabilities	3,025	2,798
Other current liabilities	1,009	990
Total current liabilities	74,920	91,533
Operating lease liabilities, noncurrent	6,927	8,575
Long-term debt, net	25,080	24,929
Deferred revenue, noncurrent	114,197	117,043
Other liabilities, noncurrent	76	203
Total liabilities	221,200	242,283
Commitments (Note 11)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 25,000,000 shares authorized; 0 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.0001 par value; 350,000,000 shares authorized; 120,459,232 and 105,144,864 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	12	11
Additional paid-in capital	854,998	746,889
Accumulated other comprehensive income (loss)	(49)	(152)
Accumulated deficit	(765,161)	(654,691)
Total stockholders' equity	89,800	92,057
Total liabilities and stockholders' equity	$ 311,000	$ 334,340

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Collaboration revenue	$ 10,654	$ 4,284	$ 18,456	$ 6,320
Operating expenses:				
Research and development	48,968	41,231	96,243	77,037
General and administrative	18,187	14,803	36,515	27,585
Total operating expenses	67,155	56,034	132,758	104,622
Other income (expense):				
Interest income	3,219	291	5,840	309
Interest expense	(1,025)	(760)	(2,008)	(1,484)
Total other income (expense), net	2,194	(469)	3,832	(1,175)
Net loss	(54,307)	(52,219)	(110,470)	(99,477)
Other comprehensive loss				
Unrealized (loss) gain on marketable securities	(61)	(126)	103	(126)
Comprehensive loss	$ (54,368)	$ (52,345)	$ (110,367)	$ (99,603)
Net loss attributable to common stockholders — basic and diluted	$ (54,307)	$ (52,219)	$ (110,470)	$ (99,477)
Net loss per share attributable to common stockholders — basic and diluted	$ (0.47)	$ (0.55)	$ (0.99)	$ (1.13)
Weighted-average number of shares of common stock used in net loss per share attributable to common stockholders — basic and diluted	115,608,156	95,756,782	111,583,765	87,886,411

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, 2021	73,709,056	$ 7	$ 572,213	$ —	$ (450,479)	$ 121,741
Issuance of common stock from at-the-market transactions, net of issuance costs of $1,322	13,169,903	2	60,460	—	—	60,462
Exercise of stock options	26,951	—	96	—	—	96
Vesting of restricted stock units	167,174	—	—	—	—	—
Stock-based compensation expense	—	—	5,485	—	—	5,485
Net loss	—	—	—	—	(47,258)	(47,258)
Balance at March 31, 2022	87,073,084	$ 9	$ 638,254	$ —	$ (497,737)	$ 140,526
Issuance of common stock from at-the-market transactions, net of issuance costs of $941	9,904,964	1	39,898	—	—	39,899
Exercise of common stock warrant	16,654	—	—	—	—	—
Vesting of restricted stock units	17,417	—	—	—	—	—
Purchase of common stock under ESPP	154,235	—	606	—	—	606
Stock-based compensation expense	—	—	5,348	—	—	5,348
Other comprehensive loss	—	—	—	(126)	—	(126)
Net loss	—	—	—	—	(52,219)	(52,219)
Balance at June 30, 2022	97,166,354	$ 10	$ 684,106	$ (126)	$ (549,956)	$ 134,034
Balance at December 31, 2022	105,144,864	$ 11	$ 746,889	$ (152)	$ (654,691)	$ 92,057
Issuance of common stock from at-the-market transactions, net of issuance costs of $558	3,535,093	—	21,795	—	—	21,795
Exercise of stock options	8,826	—	34	—	—	34
Vesting of restricted stock units	372,291	—	—	—	—	—
Stock-based compensation expense	—	—	6,407	—	—	6,407
Other comprehensive gain	—	—	—	164	—	164
Net loss	—	—	—	—	(56,163)	(56,163)
Balance at March 31, 2023	109,061,074	$ 11	$ 775,125	$ 12	$ (710,854)	$ 64,294
Issuance of common stock from at-the-market transactions, net of issuance costs of $1,524	10,929,438	1	71,874	—	—	71,875
Exercise of stock options	88,770	—	393	—	—	393
Vesting of restricted stock units	88,690	—	—	—	—	—
Purchase of common stock under ESPP	291,260	—	963	—	—	963
Stock-based compensation expense	—	—	6,643	—	—	6,643
Other comprehensive loss	—	—	—	(61)	—	(61)
Net loss	—	—	—	—	(54,307)	(54,307)
Balance at June 30, 2023	120,459,232	$ 12	$ 854,998	$ (49)	$ (765,161)	$ 89,800

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,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (110,470)	$ (99,477)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	643	432
Net amortization of premiums and discounts on marketable securities	(3,191)	(104)
Stock-based compensation	13,050	10,833
Other non-cash items	319	381
Changes in operating assets and liabilities:		
Accounts receivable	30,000	—
Prepaid expenses and other current assets	(1,992)	419
Accounts payable	3,337	(4,383)
Accrued expenses	(9,502)	4,904
Operating lease right-of-use assets	1,344	1,493
Operating lease liabilities	(1,421)	(1,199)
Deferred revenue	(12,956)	33,970
Net cash used in operating activities	(90,839)	(52,731)
Cash flows from investing activities		
Maturities of marketable securities	119,000	—
Purchase of marketable securities	(121,733)	(89,813)
Purchase of property and equipment	(1,310)	(986)
Net cash used in investing activities	(4,043)	(90,799)
Cash flows from financing activities		
Net proceeds from at-the-market facilities	93,620	100,361
Proceeds from exercise of stock options	427	96
Proceeds from purchases of common stock under ESPP	963	606
Payment of debt issuance costs	(150)	—
Payments under finance lease obligations	(131)	(142)
Net cash provided by financing activities	94,729	100,921
Decrease in cash, cash equivalents and restricted cash	(153)	(42,609)
Cash, cash equivalents and restricted cash, beginning of period	129,363	178,425
Cash, cash equivalents and restricted cash, end of period	$ 129,210	$ 135,816
Supplemental disclosures of non-cash activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ 367	$ 333
Common stock issuance costs in accounts payable and accrued expenses	$ 81	$ —
Cash paid for interest	$ 1,637	$ 1,100
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 298

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

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements
(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 platforms that enable it to develop ADCs that are designed to have improved efficacy, safety and tolerability relative to existing ADCs and other approved therapies. The Company's next-generation platforms include Dolasynthen, which delivers a proprietary auristatin payload, and Immunosynthen, which delivers a proprietary stimulator of interferon genes ("STING") agonist payload.

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

In July 2023, the Company announced top-line data from its Phase 2 UPLIFT clinical trial of upifitamab rilsodotin ("UpRi"), which did not meet its primary endpoint. In connection with this announcement, on July 27, 2023, the Company further announced that its primary focus moving forward would be on advancing product candidates and collaborations utilizing its next-generation ADC platforms, Dolasynthen and Immunosynthen. As a result, the Company is winding down its UpRi-related development activities, including its Phase 3 clinical UP-NEXT and UPGRADE-A clinical trials of UpRi, on which the FDA had placed a partial clinical hold in June 2023, and its regulatory and commercial readiness efforts.

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

The Company has incurred cumulative net losses since inception. For the three months ended June 30, 2023, the net loss was $54.3 million, compared to $52.2 million in the three months ended June 30, 2022. For the six months ended June 30, 2023, the net loss was $110.5 million, compared to $99.5 million in the six months ended June 30, 2022. The Company expects to continue to incur operating losses for at least the next several years. As of June 30, 2023, the Company had an accumulated deficit of $765.2 million. The future success of the Company is dependent on, among other factors, its ability to identify and develop its product candidates and ultimately upon its ability to attain profitable operations. The Company has devoted substantially all of its financial resources and efforts to research and development and general and administrative expense to support such research and development. Net losses and negative operating cash flows have had, and will continue to have, an adverse effect on the Company's stockholders' equity and working capital.

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

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

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

Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2022 and the notes thereto, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 28, 2023.

The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company's management, the accompanying unaudited condensed consolidated financial statements contain all adjustments that are necessary to present fairly the Company's financial position as of June 30, 2023, the results of its operations for the three and six months ended June 30, 2023 and 2022, the statements of stockholders' equity for the three and six months ended June 30, 2023 and 2022 and statements of cash flows for the six months ended June 30, 2023 and 2022. Such adjustments are of a normal and recurring nature. The results for the three and six months ended June 30, 2023 are not necessarily indicative of the results for the year ending December 31, 2023, or for any future period.

2. Summary of significant accounting policies

Principles of Consolidation

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

Use of Estimates

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

Segment Information

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

Summary of Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements for the three and six months ended June 30, 2023 are consistent with those discussed in Note 2, *Summary of Significant Accounting Policies*, in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
(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 820, *Fair Value Measurement*, establishes a three-level valuation hierarchy for instruments measured at fair value. The hierarchy is based on the transparency of inputs to the valuation of an asset or liability as of the measurement date. The three levels are defined as follows:

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

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

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

Concentration of Credit Risk and Off-balance Sheet Risk

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

Cash and Cash Equivalents

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

Recently Issued Accounting Pronouncements

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

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

3. Collaboration agreements

GSK

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

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

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

Accounting Analysis

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

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

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

During the three and six months ended June 30, 2023, the Company recorded collaboration revenue of $0.6 million and $1.3 million, respectively, related to its efforts under the GSK Agreement. As of June 30, 2023 and December 31, 2022 the Company had recorded $96.7 million and $98.0 million, respectively, in deferred revenue related to the unsatisfied performance obligations under the GSK Agreement. This deferred revenue will be recognized over the remaining performance period and classified as current or noncurrent on the consolidated balance sheets based upon the expected timing of satisfaction of the performance obligations.

Janssen

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

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

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

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

Accounting Analysis

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

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

As of June 30, 2023, the revised total transaction price for the Janssen Agreement was $44.0 million. During 2023, the Company revised the estimated transaction price by $2.0 million based on the reassessment of the constraint of certain development milestones and the remaining risks associated with the development required to achieve the milestones.

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

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

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
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During the three months ended June 30, 2023 and 2022 and the six months ended June 30, 2023 and 2022 the Company recorded collaboration revenue of $7.5 million, $4.3 million, $9.1 million, and $6.0 million, respectively, related to its performance obligations under the Janssen Agreement. As of June 30, 2023 and December 31, 2022, the Company had recorded $8.7 million and $15.8 million, respectively, in deferred revenue related to the Janssen Agreement that will be recognized over the remaining performance period and classified as current or noncurrent on the consolidated balance sheets based upon the expected timing of satisfaction of respective performance obligations.

Merck KGaA and affiliates

Immunosynthen Platform Agreement

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

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

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

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

Accounting Analysis

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

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

During the three and six months ended June 30, 2023, the Company recorded collaboration revenue of $2.5 million and $5.6 million, respectively, related to its efforts under the 2022 Merck KGaA Agreement. As of June 30, 2023 and December 31, 2022, the Company had recorded $25.4 million and $30.0 million, respectively, in deferred revenue related to the unsatisfied performance obligations under the 2022 Merck KGaA Agreement. This deferred revenue will be recognized over the remaining performance period and classified as current or noncurrent on the consolidated balance sheets based upon the expected timing of satisfaction of respective performance obligations.

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
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Dolaflexin Platform Agreement

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

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

All six targets were designated prior to 2018. The Company has previously received $3.0 million related to development milestones under the 2014 Merck KGaA Agreement. There have been no additional milestone payments during the six months ended June 30, 2023 or 2022.

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

Accounting Analysis

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

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

As of June 30, 2023, the Company has completed its research service obligations associated with four of the six designated targets and the joint research committee services. Collaboration revenue recognized during the three months ended June 30, 2023 and 2022 was immaterial. There was no collaboration revenue or corresponding research and development expense recognized during the three and six months ended June 30, 2023 and 2022 related to the 2018 Merck KGaA Supply Agreement.

As of June 30, 2023 and December 31, 2022, the Company had recorded $3.9 million in deferred revenue related to the 2014 Merck KGaA Agreement and 2018 Merck KGaA Supply Agreement, in the aggregate, that will be recognized over the remaining performance period.

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
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Summary of Contract Assets and Liabilities

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

	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Six months ended June 30, 2023				
Contract liabilities:				
Total deferred revenue	$ 147,653	$ 808	$ 13,764	$ 134,697
Six months ended June 30, 2022				
Contract liabilities:				
Total deferred revenue	$ 3,944	$ 40,000	$ 6,030	$ 37,914

The Company had no contract assets associated with its collaboration agreements as of June 30, 2023 and June 30, 2022.

During the three and six months ended June 30, 2023 and 2022, the Company recognized the following revenues as a result of changes in the contract liability balances in the respective periods:

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Revenue recognized in the period from:				
Amounts included in the contract liability at the beginning of the period	$ 8,497	$ 4,284	$ 13,607	$ 21

Other Revenue

The Company has provided limited services for a collaborator, Asana BioSciences, LLC ("Asana Biosciences"). The Company did not recognize revenue related to these services during the three and six months ended June 30, 2023 and the three months ended June 30, 2022. During the six months ended June 30, 2022 the Company recognized revenue of $0.3 million related to these services. During the six months ended June 30, 2023 the Company recognized revenue of $2.5 million related to achievement of a development milestone under the research, development and license agreement for which performance obligations were previously completed.

4. Fair value measurements

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

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
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(in thousands)	June 30, 2023 Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents				
Money market funds	$ 52,105	$ 52,105	$ —	$ —
U.S. treasury securities	4,990	4,990	—	—
	$ 57,095	$ 57,095	$ —	$ —
Marketable securities				
U.S. treasury securities	$ 83,362	$ 83,362	$ —	$ —
U.S. government agency securities	74,494	—	74,494	—
	$ 157,856	$ 83,362	$ 74,494	$ —

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

There were no changes in valuation techniques or transfers between fair value measurement levels during the six months ended June 30, 2023 or during the year ended December 31, 2022.

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

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

As of June 30, 2023 and December 31, 2022, the carrying value of the Company's outstanding borrowing under the New Credit Facility (as defined in Note 7, *Debt*) approximated fair value (a Level 2 fair value measurement), reflecting interest rates currently available to the Company. The New Credit Facility is discussed in more detail in Note 7, *Debt*.

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

Cash and cash equivalents

The following table summarizes the Company's cash, cash equivalents, and restricted cash as of June 30, 2023 and 2022.

(in thousands)	Six Months Ended June 30, 2023		Six Months Ended June 30, 2022	
	Beginning of period	End of period	Beginning of period	End of period
Cash and cash equivalents	$ 128,885	$ 128,732	$ 177,947	$ 135,338
Restricted cash included in other assets, noncurrent	478	478	478	478
Total cash, cash equivalents and restricted cash per statement of cash flows	$ 129,363	$ 129,210	$ 178,425	$ 135,816

Marketable securities

The following tables summarize the Company's marketable securities held at June 30, 2023 and December 31, 2022.

(in thousands)	June 30, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities				
U.S. treasury securities	$ 83,391	$ 8	$ (37)	$ 83,362
U.S. government agency securities	74,514	9	(29)	74,494
Total	$ 157,905	$ 17	$ (66)	$ 157,856

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

All of the Company's marketable securities are due within one year or less. The Company did not realize any gains or losses recognized on the sale of marketable securities during the six months ended June 30, 2023, and, as a result, the Company did not reclassify any amounts out of accumulated comprehensive loss.

As of June 30, 2023, the Company's debt security portfolio consisted of 13 securities that were in an unrealized loss position and had an aggregate fair value of $84.2 million. There were no securities in an unrealized loss position for greater than 12 months as of June 30, 2023. The unrealized losses on the Company's marketable securities were caused by market interest rate increases. The Company has the intent and ability to hold such securities until recovery. As a result, the Company did not record any charges for credit-related impairments for its marketable debt securities for the three months ended June 30, 2023.

Mersana Therapeutics, Inc.
Notes to condensed consolidated financial statements (continued)
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6. Accrued expenses

Accrued expenses consisted of the following as of June 30, 2023 and December 31, 2022:

(in thousands)	June 30, 2023	December 31, 2022
Accrued clinical expenses	$ 10,741	$ 14,822
Accrued manufacturing expenses	8,378	11,536
Accrued payroll and related expenses	7,591	11,558
Accrued research and non-clinical expenses	4,589	2,767
Accrued professional fees	1,649	1,865
Accrued other	520	636
	$ 33,468	$ 43,184

7. Debt

On October 29, 2021, the Company entered into a loan and security agreement (the "New Credit Facility") with Silicon Valley Bank ("former SVB") and Oxford Finance LLC ("Oxford" and, together with former SVB and the other lenders from time to time a party thereto, the "Lenders"). In March 2023, Silicon Valley Bridge Bank, N.A ("SVBB"), as successor in interest to former SVB, replaced former SVB as a Lender, and then Silicon Valley Bank, a division of First-Citizens Bank & Trust Company ("SVB"), which assumed all deposits and loans of SVBB, subsequently replaced SVBB as a Lender. The New Credit Facility as amended on February 17, 2022, October 17, 2022, December 27, 2022, and March 23, 2023, is secured by substantially all of the Company's personal property owned or later acquired, excluding intellectual property (but including the rights to payments and proceeds from intellectual property), and a negative pledge on intellectual property. The Company has drawn $25.0 million under the New Credit Facility as of June 30, 2023. Following the Company's July 2023 announcement of top-line data from the Company's UPLIFT clinical trial, the Company does not consider any additional borrowing amounts to be available to it under the New Credit Facility, as amended.

Refer to Note 8, *Debt*, in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022 for more information regarding the New Credit Facility. As of June 30, 2023, the Company was in compliance with all covenants under the New Credit Facility. There are no events of default under the New Credit Facility as of June 30, 2023.

The following is a summary of obligations under the New Credit Facility as of June 30, 2023:

(in thousands)	June 30, 2023
Total debt	$ 25,000
Less: Current portion of long-term debt	—
Total debt, net of current portion	25,000
Debt financing costs, net of accretion	(280)
Accretion related to final payment	360
Long-term debt, net	$ 25,080

Interest expense related to the New Credit Facility for the three months ended June 30, 2023 and 2022 and six months ended June 30, 2023 and 2022 was $1.0 million, $0.8 million, $1.9 million, and $1.5 million, respectively.

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8. Stockholders' equity

Preferred stock

As of June 30, 2023, the Company had 25,000,000 shares of authorized preferred stock. No shares of preferred stock have been issued.

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

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

In February 2022, the Company established a new ATM equity offering program (the "February 2022 ATM"), pursuant to which it was able to offer and sell up to $100.0 million of its common stock from time to time at prevailing market prices. During the six months ended June 30, 2022, the Company sold 11,334,657 shares of common stock under the February 2022 ATM, resulting in net proceeds of $45.8 million. During the first quarter of 2023, the Company sold 256,386 shares of common stock under the February 2022 ATM, resulting in net proceeds of $1.6 million. As of March 31, 2023, the February 2022 ATM had been fully utilized.

In November 2022, the Company established an additional ATM equity offering program (the "November 2022 ATM"), pursuant to which it is able to offer and sell up to $150.0 million of its common stock from time to time at prevailing market prices. During the six months ended June 30, 2023, the Company sold 14,208,145 shares of common stock under the November 2022 ATM, resulting in net proceeds of $92.2 million. As of June 30, 2023, approximately $55.9 million remained unsold and available for sale under the November 2022 ATM.

Warrants

In connection with a 2013 Series A-1 Preferred Stock issuance, the Company granted to certain investors warrants to purchase 129,491 shares of common stock. The warrants have a $0.05 per share exercise price and a contractual life of 10 years. The fair value of these warrants was recorded as a component of equity at the time of issuance. As of June 30, 2023, there were warrants to purchase 22,590 shares of common stock outstanding. During the six months ended June 30, 2023, there were no exercises of warrants in exchange for common stock.

Common stock

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

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

As of June 30, 2023 and December 31, 2022, there were 16,052,928 and 11,944,664, respectively, shares of common stock reserved for the exercise of outstanding stock options, restricted stock units ("RSUs") and warrants.

	June 30, 2023	December 31, 2022
Stock options	12,359,185	10,051,283
Restricted stock units	3,671,153	1,870,791
Warrants	22,590	22,590
	16,052,928	11,944,664

9. Stock-based compensation

Stock incentive plans

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

In June 2017, the Company's stockholders approved the 2017 Plan. Under the 2017 Plan, shares of common stock could be granted to the Company's employees, officers, directors, consultants and advisors in the form of options, RSUs or other stock-based awards. The number of shares of common stock issuable under the 2017 Plan will be cumulatively increased annually on January 1 by the lesser of (a) 4% of the outstanding shares on the immediately preceding December 31 or (b) such other amount specified by the Board. The terms of the awards are determined by the Board, subject to the provisions of the 2017 Plan. Any cancellations or forfeitures of options granted under the 2007 Plan, which expired in June 2017, would increase the number of shares that could be granted under the 2017 Plan. On January 1, 2023, the number of shares of common stock issuable under the 2017 Plan was increased by 4,205,794 shares. During the six months ended June 30, 2023, the Company granted 4,566,682 RSUs and options to purchase shares of common stock to employees under the 2017 Plan. As of June 30, 2023, there were 1,718,690 shares available for future issuance under the 2017 Plan.

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

Inducement awards

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

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In February 2022, the Board adopted the Company's 2022 Inducement Stock Incentive Plan (the "Inducement Plan"), which provides for the grant of nonstatutory options, stock appreciation rights, restricted stock, RSUs and other stock-based awards, with respect to an aggregate of 2,000,000 shares of the Company's common stock (subject to adjustment as provided in the Inducement Plan). During the six months ended June 30, 2023, the Company granted 677,905 RSUs and options to purchase shares of common stock to newly hired employees under the Inducement Plan. As of June 30, 2023, there were 664,270 shares available for future issuance under the Inducement Plan.

As of June 30, 2023, there were options to purchase 757,500 shares of common stock outstanding which were granted as inducement awards prior to the establishment of the Inducement Plan.

Stock option activity

A summary of stock option activity is as follows:

	Number of Shares		Weighted-Average Exercise Price
Outstanding at January 1, 2023	10,051,283	$	9.84
Granted	2,864,451	$	6.11
Exercised	(97,596)	$	4.37
Cancelled	(458,953)	$	11.15
Outstanding at June 30, 2023	12,359,185	$	8.97
Exercisable at June 30, 2023	6,591,352	$	9.21

The weighted-average grant date fair value of options granted during the six months ended June 30, 2023 and 2022 was $4.88 and $3.95 per share, respectively. The total intrinsic value of options exercised during the six months ended June 30, 2023 and 2022 was $0.3 million and immaterial, respectively. The aggregate intrinsic value represents the difference between the exercise price and the selling price received by option holders upon the exercise of stock options during the period.

Cash received from the exercise of stock options was $0.4 million and immaterial, respectively, for the six months ended June 30, 2023 and 2022.

Mersana Therapeutics, Inc.
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Restricted stock units

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

A summary of the RSU activity is as follows:

	Number of Shares
Unvested at January 1, 2023	1,870,791
Granted	2,380,136
Vested	(460,981)
Forfeited	(118,793)
Unvested at June 30, 2023	3,671,153

Employee stock purchase plan

During the year ended December 31, 2017, the Board adopted, and the Company's stockholders approved the 2017 employee stock purchase plan (the "2017 ESPP"). The number of shares of common stock issuable under the 2017 ESPP was increased by 450,000 on January 1, 2023. The Company issued 291,260 and 154,235 shares, respectively, under the 2017 ESPP during the six months ended June 30, 2023 and 2022. As of June 30, 2023, there were 454,531 shares available for issuance under the 2017 ESPP.

Stock-based compensation expense

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

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Stock options	$ 4,288	$ 3,933	$ 8,507	$ 8,051
Restricted stock units	2,060	1,258	3,953	2,467
Employee stock purchase plan	295	157	590	315
Stock-based compensation expense included in total operating expenses	$ 6,643	$ 5,348	$ 13,050	$ 10,833

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,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Research and development	$ 3,396	$ 2,746	$ 6,728	$ 5,679
General and administrative	3,247	2,602	6,322	5,154
Stock-based compensation expense included in total operating expenses	$ 6,643	$ 5,348	$ 13,050	$ 10,833

Mersana Therapeutics, Inc.
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As of June 30, 2023, there was $33.9 million and $21.2 million of unrecognized stock-based compensation expense related to unvested stock options and unvested RSUs, respectively, that is expected to be recognized over a weighted-average period of 2.0 years and 2.9 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,	
	2023	2022	2023	2022
Risk-free interest rate	3.7 %	2.9 %	3.6 %	2.0 %
Expected dividend yield	— %	— %	— %	— %
Expected term (years)	5.84	5.84	6.04	5.99
Expected stock price volatility	100 %	90 %	99 %	87 %

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

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

10. Net loss per share

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

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

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

	Three and six months ended June 30, 2023	Three and six months ended June 30, 2022
Stock options	12,359,185	10,511,694
Unvested restricted stock units	3,671,153	1,706,904
Warrants	22,590	22,590
	16,052,928	12,241,188

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

11. Commitments

License agreements

During the three and six months ended June 30, 2023 and the three months ended June 30, 2022, the Company did not record research and development expense related to non-refundable license payments. During the six months ended June 30, 2022, the Company recorded research and development expense related to non-refundable license payments of $1.5 million.

During the three and six months ended June 30, 2023 and 2022, the Company did not record research and development expense related to development milestones.

12. Subsequent Events

On July 27, 2023, the Company announced decisions to reprioritize its areas of focus and to discontinue its clinical development of UpRi following an evaluation of top-line data from the Company's UPLIFT Phase 2 clinical trial of UpRi in patients with platinum-resistant ovarian cancer, which did not meet its primary endpoint. In connection with these decisions, on July 26, 2023, the Company's board of directors approved certain expense reduction measures, including a reduction of approximately 50% of the Company's current employee base (the "Restructuring").

In connection with the Restructuring, the Company estimated that it will incur approximately $7-8 million in costs resulting from cash expenditures consisting of severance and benefit payments, notice pay, outplacement services and related expenses. The estimate of costs that the Company expects to incur are subject to a number of assumptions, and actual results may differ. The Company may also incur other cash or non-cash charges or cash expenditures not currently contemplated due to events that may occur as a result of, or in association with, the Restructuring.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited financial statements and the accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission, or SEC, on February 28, 2023.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any 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 Part II, Item 1A. Risk Factors.

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

Overview

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

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

On July 27, 2023, we reported top-line data from our Phase 2 UPLIFT clinical trial of upifitamab rilsodotin, or UpRi, and announced that UPLIFT did not meet its primary endpoint. UPLIFT was a single-arm clinical trial that enrolled platinum-resistant ovarian cancer patients with one to four prior treatment regimens. The primary endpoint for UPLIFT was the investigator-assessed objective response rate, or ORR, in the NaPi2b-positive population. NaPi2b-positive status was defined by a tumor proportion score, or TPS, of ≥75%. The lower bound of the confidence interval for the primary endpoint did not meet our goal of excluding a 12% ORR seen with standard-of-care single-agent chemotherapy. We are in the process of conducting an in-depth analysis of various factors to better understand the results, as well as the characteristics of patients who responded to UpRi therapy, particularly those whose responses were deep and durable.

In connection with our announcement of top-line data from UPLIFT, on July 27, 2023, we further announced that our primary focus moving forward would be on advancing product candidates and collaborations utilizing our next-generation ADC platforms, Dolasynthen and Immunosynthen. As a result, we are winding down UpRi-related development activities, including our UP-NEXT and UPGRADE-A clinical trials of UpRi, on which the U.S. Food and Drug Administration, or FDA, had placed a partial clinical hold in June 2023 following our submission of a recent aggregate safety report of all patients dosed with UpRi evaluating bleeding events, and our regulatory and commercial readiness efforts. UP-NEXT was our Phase 3 clinical trial of UpRi as monotherapy maintenance treatment following treatment with platinum doublets in recurring platinum sensitive ovarian cancer. UPGRADE-A was a Phase 1 combination trial in which we explored combining UpRi with carboplatin, a standard platinum chemotherapy broadly used in the treatment of platinum sensitive ovarian cancer. If further analyses of data enable the identification of a path forward for UpRi, we will consider strategic alternatives for the asset, including partnering. We also announced that on July 26, 2023, our board of directors approved certain expense reduction measures, including a reduction of approximately 50% of the our then-current employee base, or the Restructuring. The Restructuring is expected to be complete by the end of 2023.

We continue to develop two ADCs, XMT-1660 and XMT-2056, leveraging our Dolasynthen and Immunosynthen platforms respectively. XMT-1660 is a B7-H4-directed Dolasynthen ADC designed with a precise, target-optimized drug-to-antibody ratio, or DAR, of 6 and our proprietary auristatin payload. We are currently enrolling patients in our multicenter Phase 1 trial investigating the safety, tolerability and anti-tumor activity of XMT-1660 in patients with breast, endometrial and ovarian cancers. We began dosing patients in August 2022, plan to the complete the dose escalation portion of the trial in 2023 and plan to initiate the dose expansion portion of the trial in 2024. The FDA has granted Fast Track designation to XMT-1660 for the treatment of adult patients with advanced or metastatic triple-negative breast cancer.

XMT-2056 is a systemically administered Immunosynthen STING agonist ADC (DAR 8) that is designed to target a novel epitope of human epidermal growth factor receptor 2, or HER2, distinct from that targeted by either trastuzumab or pertuzumab, and to locally activate STING signaling in both tumor-resident immune cells and in tumor cells, providing the potential to treat patients with HER2-high or -low tumors as monotherapy and in combination with standard-of-care agents. We initiated a multicenter Phase 1 open-label trial of XMT-2056 in previously treated patients with advanced/recurrent solid tumors expressing HER2, including breast, gastric, colorectal and non-small cell lung cancers, in January 2023. In March 2023, we announced that this Phase 1 trial of XMT-2056 had been placed on clinical hold by the FDA following our communication to FDA that we were voluntarily suspending the trial due to a Grade 5 (fatal) serious adverse event, or SAE, that was deemed to be related to XMT-2056. The SAE occurred in the second patient who had been enrolled at the initial dose level in the dose escalation portion of the Phase 1 trial in previously treated patients with HER2+ recurrent or metastatic solid tumors. We have received additional laboratory data from this patient, but the SAE and its cause remain under investigation. We are diligently working to address the clinical hold and are preparing a response to the FDA's clinical hold letter.

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

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

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

Since inception, we have incurred significant cumulative operating losses. For the six months ended June 30, 2023, our net loss was $110.5 million, compared to $99.5 million in the six months ended June 30, 2022. As of June 30, 2023, we had an accumulated deficit of $765.2 million. We expect to continue to incur significant expenses and operating losses over the next several years as we:

- continue clinical development and manufacturing activities for XMT-1660;
- continue to work to address the clinical hold on our Phase 1 clinical trial of XMT-2056;
- continue activities to discover, validate and develop additional product candidates, including XMT-2068 and XMT-2175; and
- maintain, expand and protect our intellectual property portfolio.

Financial Operations Overview

Revenue

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

In December 2022, we entered into a collaboration and commercial license agreement, or the 2022 Merck KGaA Agreement, with Ares Trading S.A., or MRKDG, a wholly-owned subsidiary of Merck KGaA, for the development and commercialization of ADC product candidates utilizing our Immunosynthen platform for up to two target antigens. MRKDG is responsible for generating antibodies against the target antigens, and we are responsible for performing bioconjugation activities to create ADCs as well as certain chemistry, manufacturing and controls development and early-stage manufacturing activities at their cost. MRKDG has the exclusive right to and is responsible for the further development and commercialization of these ADC product candidates. During the three and six months ended June 30, 2023, we recognized $2.5 million and $5.6 million, respectively, of collaboration revenue related to the 2022 Merck KGaA Agreement.

In August 2022, we entered into a collaboration, option and license agreement, or the GSK Agreement, with GSK to provide GSK with an exclusive option to obtain an exclusive license to co-develop and to commercialize products containing XMT-2056, or Licensed Products. We are responsible for manufacturing, research and early clinical development related to our XMT-2056 program prior to GSK's exercise, if any, of its option. If GSK exercises its option, GSK will have the exclusive right to and will be responsible for the further co-development and commercialization of Licensed Products. During the three and six months ended June 30, 2023, we recognized $0.6 million and $1.3 million, respectively, of collaboration revenue related to the GSK Agreement.

In February 2022, we entered into a research collaboration and license agreement, or the Janssen Agreement, with Janssen for the development and commercialization of ADC product candidates utilizing our Dolasynthen platform for up to three target antigens. Janssen is responsible for generating antibodies against the target antigens, and we are responsible for performing bioconjugation activities to create ADCs as well as certain chemistry, manufacturing and controls development and early-stage manufacturing activities at Janssen's cost. Janssen has the exclusive right to and is responsible for the further development and commercialization of these ADC product candidates. During the three months ended June 30, 2023 and 2022 and six months ended June 30, 2023 and 2022 we recognized $7.5 million, $4.3 million, $9.1 million, and $6.0 million respectively, of collaboration revenue related to performance under the Janssen Agreement.

In June 2014, we entered into a collaboration and commercial license agreement, or the 2014 Merck KGaA Agreement, with Merck KGaA for the development and commercialization of ADC product candidates utilizing our Dolaflexin platform for up to six target antigens. Merck KGaA is responsible for generating antibodies against the target antigens, and we are responsible for generating Dolaflexin and conjugating this to such antibodies to create the ADC product candidates. Merck KGaA has the exclusive right to and is responsible for the further development and commercialization of these ADC product candidates. In May 2018, we entered into a supply agreement, or the Merck KGaA Supply Agreement, with Merck KGaA for the supply of materials that could be used for investigational new drug, or IND, -enabling studies and clinical trials. For each of the three and six months ended June 30, 2023 and 2022, we recognized an immaterial amount of revenue related to the 2014 Merck KGaA Agreement and Merck KGaA Supply Agreement.

During the six months ended June 30, 2023 and 2022 we recognized $2.5 million and $0.3 million, respectively, of revenue related to achievement of a development milestone and services provided, respectively, related to Asana BioSciences, LLC, or Asana Biosciences.

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

Expenses

Research and development expenses

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

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

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

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

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

We incur significant external costs for manufacturing our product candidates and platforms and for clinical research organizations that conduct clinical trials on our behalf. We capture these external expenses for each product candidate in clinical development. Costs for our platforms with an associated product candidate in clinical development are typically allocated to our most clinically advanced product candidate based on that platform. In light of our decision to discontinue further clinical development of XMT-1592, a Dolasynthen ADC that had been in a Phase 1 dose exploration trial in patients with ovarian cancer and non-small cell lung cancer, in the second quarter of 2022, all costs associated with our Dolasynthen platform were prospectively re-allocated to XMT-1660, which is now our lead Dolasynthen-based product candidate, following such decision. All external research and development expenses not attributable to our product candidates in clinical development are captured within preclinical and discovery costs. These costs relate to our product candidates XMT-2068 and XMT-2175 and additional earlier discovery stage programs and certain unallocated costs. The following table summarizes our external research and development expenses, presented by program as described above, for each of the three and six month periods ended June 30, 2023 and 2022.

(in thousands)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
UpRi external costs	$ 19,246	$ 13,881	$ 36,101	$ 24,024
XMT-1592 external costs	68	363	400	2,789
XMT-1660 external costs	3,392	6,721	6,900	6,721
XMT-2056 external costs	1,040	—	3,978	—
Preclinical and discovery costs	1,916	3,730	3,453	11,225
Internal research and development costs	23,306	16,536	45,411	32,278
Total research and development costs	$ 48,968	$ 41,231	$ 96,243	$ 77,037

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

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

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

For example, on July 27, 2023 we announced our decision to discontinue the clinical development of UpRi. Consequently, we will allocate resources previously dedicated to this program into our next-generation ADCs and platforms, Dolasynthen and Immunosynthen. We expect to incur significant research and development expenses over the next several years as we continue our clinical development and manufacturing of XMT-1660, continue to work to address the clinical hold on our Phase 1 clinical trial of XMT-2056, advance our preclinical pipeline and invest in improvements in our ADC technologies.

General and administrative expenses

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

We expect to incur significant general and administrative expenses over the next several years to support continued research and development activities, including increased costs related to fees to outside consultants and patent costs, among other expenses.

Other income (expense)

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

Results of Operations

Comparison of the three months ended June 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended June 30, 2023 and 2022, together with the changes in those items:

	Three Months Ended June 30,		
(in thousands)	**2023**	**2022**	**Dollar Change**
Collaboration revenue	$ 10,654	$ 4,284	$ 6,370
Operating expenses:			
Research and development	48,968	41,231	7,737
General and administrative	18,187	14,803	3,384
Total operating expenses	67,155	56,034	11,121
Other income (expense):			
Interest income	3,219	291	2,928
Interest expense	(1,025)	(760)	(265)
Total other income (expense), net	2,194	(469)	2,663
Net loss	$ (54,307)	$ (52,219)	$ (2,088)

Collaboration Revenue

Collaboration revenue increased by $6.4 million, from $4.3 million during the three months ended June 30, 2022 to $10.7 million during the three months ended June 30, 2023, primarily due to an increase of $3.2 million and $2.5 million in collaboration revenue recognized under the Janssen Agreement and 2022 Merck KGaA Agreement, respectively.

Research and Development Expense

Research and development expense increased by $7.7 million, from $41.2 million for the three months ended June 30, 2022 to $49.0 million for the three months ended June 30, 2023.

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

- an increase of $5.4 million related to manufacturing and clinical development activities for UpRi;
- an increase of $3.0 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; and
- an increase of $2.1 million related to consulting and professional fees.

These increased costs were partially offset by a decrease of $3.5 million primarily related to manufacturing activities for XMT-1660 and the Dolasynthen platform.

Stock-based compensation expense included in research and development expenses increased by $0.7 million, primarily as a result of increased headcount.

General and Administrative Expense

General and administrative expense increased by $3.4 million from $14.8 million during the three months ended June 30, 2022 to $18.2 million during the three months ended June 30, 2023. The increase in general and administrative expense was primarily attributable to an increase of $2.1 million related to employee compensation (excluding stock-based compensation) related to an increase in headcount and an increase of $0.8 million related to UpRi-related consulting and professional services. Stock-based compensation expense included in general and administrative expense increased $0.6 million, also primarily as a result of increased headcount.

Total Other Income (Expense), net

Total other income (expense), net increased by $2.7 million from $(0.5) million during the three months ended June 30, 2022 to $2.2 million during the three months ended June 30, 2023. The increase to the net balance was primarily due to an increase in interest income earned on marketable securities.

Comparison of the six months ended June 30, 2023 and 2022

The following table summarizes our results of operations for the six months ended June 30, 2023 and 2022:

(in thousands)	Six Months Ended June 30, 2023	2022	Dollar Change
Collaboration revenue	$ 18,456	$ 6,320	$ 12,136
Operating expenses:			
Research and development	96,243	77,037	19,206
General and administrative	36,515	27,585	8,930
Total operating expenses	132,758	104,622	28,136
Other income (expense):			
Interest income	5,840	309	5,531
Interest expense	(2,008)	(1,484)	(524)
Total other income (expense), net	3,832	(1,175)	5,007
Net loss	$ (110,470)	$ (99,477)	$ (10,993)

Collaboration Revenue

Collaboration revenue increased by $12.1 million from $6.3 million during the six months ended June 30, 2022 to $18.5 million during the six months ended June 30, 2023, primarily due to an increase of $5.6 million and $3.1 million in collaboration revenue recognized under the 2022 Merck KGaA Agreement and the Janssen Agreement, respectively.

Research and Development Expense

Research and development expense increased by $19.2 million, from $77.0 million for the six months ended June 30, 2022 to $96.2 million for the six months ended June 30, 2023.

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

- an increase of $12.0 million related to manufacturing and clinical development activities for UpRi;
- an increase of $7.5 million related to employee compensation (excluding stock-based compensation), primarily due to an increase in headcount supporting the growth of our research and development activities; and
- an increase of $3.4 million related to consulting and professional fees.

These increased costs were partially offset by a decrease of $3.4 million primarily related to manufacturing activities for XMT-1660 and the Dolasynthen platform and a decrease of $1.3 million related to non-refundable license payments under our third-party licensing agreements.

Stock-based compensation expense included in research and development expenses increased by $1.0 million, primarily as a result of increased headcount.

General and Administrative Expense

General and administrative expense increased by $8.9 million from $27.6 million during the six months ended June 30, 2022 to $36.5 million during the six months ended June 30, 2023. The increase in general and administrative expense was primarily attributable to an increase of $4.1 million related to employee compensation (excluding stock-based compensation) related to an increase in headcount and an increase of $3.6 million related to UpRi-related consulting and professional services. Stock-based compensation increased $1.2 million also primarily as a result of increased headcount.

Total Other Income (Expense), net

Total other income (expense), net increased by $5.0 million from $(1.2) million during the six months ended June 30, 2022 to $3.8 million during the six months ended June 30, 2023. The increase to the net balance was primarily due to an increase in interest income earned on marketable securities.

Liquidity and Capital Resources

Sources of Liquidity

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

In May 2020, we established an ATM equity offering program, the 2020 ATM, pursuant to which we were able to offer and sell to the public through Cowen and Company, LLC, or Cowen, as sales agent, up to $100.0 million of our common stock from time to time at prevailing market prices. During the six months ended June 30, 2022, we sold approximately 11.7 million shares of common stock under the 2020 ATM, resulting in gross and net proceeds of $55.9 million and $54.8 million, respectively. As of June 30, 2022, there were no amounts remaining unsold and available for sale under the 2020 ATM.

In February 2022, we entered into a new sales agreement, or the February 2022 ATM, with Cowen, as sales agent, under which we are able to offer and sell to the public through Cowen up to $100.0 million of our common stock from time to time at prevailing market prices. During the six months ended June 30, 2022, we sold approximately 11.3 million shares of common stock under the February 2022 ATM, resulting in gross and net proceeds of $46.7 million and $45.8 million, respectively. During the six months ended June 30, 2023, we sold approximately 0.3 million shares of common stock under the February 2022 ATM, resulting in gross and net proceeds of $1.6 million. As of June 30, 2023, there were no amounts remaining unsold and available for sale under the February 2022 ATM.

In November 2022, we entered into an additional sales agreement, or the November 2022 ATM, with Cowen, as sales agent, under which we are able to offer and sell to the public through Cowen up to $150.0 million of our common stock from time to time at prevailing market prices. During the six months ended June 30, 2023, we sold approximately 14.2 million shares of common stock under the November 2022 ATM, resulting in gross and net proceeds of $94.1 million and $92.2 million, respectively. Approximately $55.9 million remained unsold and available for sale under the November 2022 ATM as of June 30, 2023.

On May 8, 2019, we entered into a loan and security agreement, or the Prior Credit Facility, with Silicon Valley Bank, or former SVB, which was subsequently amended on June 29, 2019, August 28, 2020 and August 27, 2021. On October 29, 2021, we entered into a loan and security agreement, or the New Credit Facility, with Oxford Finance LLC as the collateral agent and a lender, former SVB as a lender, and the other lenders from time to time a party thereto, or together the Lenders. In March 2023, Silicon Valley Bridge Bank, N.A., or SVBB, as successor in interest to former SVB, replaced former SVB as a Lender, and then Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, or SVB, which assumed all deposits and loans of SVBB, subsequently replaced SVBB as a lender. As of June 30, 2023, we have borrowed $25.0 million under the New Credit Facility, as amended on February 17, 2022, October 17, 2022, December 27, 2022 and March 23, 2023, and, following the top-line data from our UPLIFT clinical trial that we disclosed in July 2023, we do not believe that additional borrowing amounts will be available to us under the New Credit Facility, as amended to date. The New Credit Facility is secured by substantially all of our personal property owned or later acquired, excluding intellectual property (but including the right to payments and proceeds of intellectual property), and a negative pledge on intellectual property, which ensures that the Lenders' rights to repayment would be senior to the rights of the holders of our common stock in the event of liquidation. Upon entering into the New Credit Facility, we terminated all commitments by former SVB to extend further credit under the Prior Credit Facility and all guarantees and security interests granted by us to former SVB under the Prior Credit Facility.

As of June 30, 2023, we had cash, cash equivalents and marketable securities of $286.6 million. In addition to our existing cash, cash equivalents and marketable securities, we are eligible to earn milestone and other payments under our collaboration agreements with GSK, Janssen, Merck KGaA and its affiliate MRKDG and Asana Biosciences. Our ability to earn the milestone payments and the timing of earning these amounts are dependent upon the timing and outcome of our development, regulatory and commercial activities and, as such, are uncertain at this time.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2023 and 2022:

	Six Months Ended June 30,	
(in thousands)	**2023**	**2022**
Net cash used in operating activities	$ (90,839)	$ (52,731)
Net cash used in investing activities	(4,043)	(90,799)
Net cash provided by financing activities	94,729	100,921
Decrease in cash, cash equivalents and restricted cash	$ (153)	$ (42,609)

Net Cash Used in Operating Activities

Net cash used in operating activities was $90.8 million during the six months ended June 30, 2023 and primarily consisted of a net loss of $110.5 million adjusted for changes in our net working capital, deferred revenue related to our collaboration agreements, and other non-cash items including stock-based compensation of $13.1 million and net amortization of premiums and discounts on marketable securities of $3.2 million. Net cash used in operating activities was $52.7 million for the six months ended June 30, 2022 and primarily consisted of a net loss of $99.5 million adjusted for changes in our net working capital and $34.0 million in deferred revenue related to the Janssen Agreement, and other non-cash items including stock-based compensation of $10.8 million and depreciation of $0.4 million.

Net Cash Used in Investing Activities

Net cash used in investing activities was $4.0 million during the six months ended June 30, 2023 as compared to net cash used in investing activities of $90.8 million during the six months ended June 30, 2022. During the six months ended June 30, 2023, net cash used in investing activities consisted primarily of purchases of marketable securities, partially offset by maturities of marketable securities. During the six months ended June 30, 2022, net cash used in investing activities consisted primarily of purchases of marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $94.7 million during the six months ended June 30, 2023 as compared to $100.9 million during the six months ended June 30, 2022. During the six months ended June 30, 2023, net cash provided by financing activities consisted primarily of proceeds from sales of common stock under our February 2022 ATM and November 2022 ATM of $93.6 million. During the six months ended June 30, 2022, net cash provided by financing activities consisted primarily of proceeds from the use of our 2020 ATM and 2022 ATM of $100.4 million.

Funding Requirements

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

As of June 30, 2023, we had cash, cash equivalents and marketable securities of $286.6 million. We believe our currently available funds will be sufficient to fund our current operating plan commitments into 2026. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

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

- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our product candidates.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of strategic collaborations, licensing arrangements, equity offerings and debt financings. We have the potential to earn cash milestone payments in connection with our agreements with GSK, Janssen, Merck KGaA and its affiliate MRKDG and Asana BioSciences, if research and development activities are successful under our collaborations with those parties. If we raise funds through additional strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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. 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.

Contractual Obligations

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

Critical Accounting Estimates

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risks

We are exposed to market risk related to changes in interest rates. As of June 30, 2023, we had cash, cash equivalents and marketable securities of $286.6 million. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments, including cash equivalents and marketable securities are invested in U.S. Treasury obligations, commercial paper, corporate bonds and U.S. government agency securities. However, we believe that due to the short-term duration of our investment portfolio and low-risk profile of our investments, an immediate 100 basis points change in the prime rate would not have a material effect on the fair market value of our investments portfolio.

The interest rate on our New Credit Facility is sensitive to changes in interest rates. Interest accrues on borrowings under the credit facility at a floating rate equal to the greater of (i) 8.50% and (ii) the prime rate plus 5.25%. We do not currently engage in any hedging activities against changes in interest rates. As of June 30, 2023, there was $25.0 million outstanding under the New Credit Facility, and a potential change in the associated interest rates would be immaterial to the results of our operations.

Foreign Currency Exchange Rate Risks

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

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

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

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2023, the end of the period covered by this Quarterly Report on Form 10-Q. Based upon such evaluation, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended June 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

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

Risks Related to Development and Approval of Our ADC Product Candidates

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

UpRi, XMT-1660 and XMT-2056 are currently our only product candidates in clinical trials. In July 2023, following our announcement that the data in our UPLIFT clinical trial of UpRi did not meet its primary endpoint, we announced our plans to wind-down UpRi-related development activities, including our UPGRADE-A and UP-NEXT clinical trials of UpRi, each of which were placed on partial clinical hold by the FDA in June 2023. Additionally, our clinical trial of XMT-2056 has been placed on clinical hold by the U.S. Food and Drug Administration, or FDA. While we have certain other preclinical programs in development, it will take additional investment and time, and regulatory clearance, for such programs to reach the clinical stage of development. In addition, we have other product candidates in our current pipeline that are based on the same platforms as XMT-1660 and XMT-2056. If a product candidate fails in development as a result of any underlying problem with our platforms, then we may be required to discontinue development of the product candidates that are based on the same technologies. If we were required to discontinue development of XMT-1660 or XMT-2056 or of any other current or future product candidate, or if XMT-1660 or XMT-2056 or any other current or future product candidate were to fail to receive regulatory approval or were to fail to achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability.

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

The results from our preclinical studies of XMT-1660 and XMT-2056 and the early results from preclinical studies or clinical trials of any other current or future product candidates are not necessarily predictive of the results from our ongoing or future discovery programs, preclinical studies or clinical trials. Promising results in preclinical studies and early encouraging clinical results of a drug candidate may not be predictive of similar results in later-stage preclinical studies or in humans during clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in earlier stages of clinical development, and we have faced and may again face similar setbacks. For instance, in July 2023, we announced that our UPLIFT Phase 2 clinical trial of UpRi did not meet its primary efficacy endpoint, despite promising efficacy data from our Phase 1b clinical trial of UpRi. Other companies' setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy events in preclinical or clinical trials, including previously unreported adverse events. We similarly have identified new safety signals as our clinical trials have advanced, such as our assessment that serious bleeding events appear to occur in patients who received UpRi at a higher rate than background, which assessment led us to submit an aggregate data safety report to the FDA in June 2023.

Similarly, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. In March 2023, we announced that the FDA had issued a clinical hold on our Phase 1 trial of XMT-2056 following our communication to the FDA that we were voluntarily suspending the trial due to a Grade 5 (fatal) serious adverse event, or SAE, that was deemed to be related to XMT-2056. The SAE occurred in the second patient who had been enrolled at the initial dose level in the dose escalation portion of the Phase 1 clinical trial. We are continuing to investigate this SAE and its cause, and we are working diligently to address the clinical hold on our trial of XMT-2056, which may include clinical trial protocol changes.

Any clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In addition, clinical trial results for one of our product candidates, or for competitor products utilizing similar technology, may raise concerns about the safety or efficacy of other product candidates in our pipeline. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented from or delayed in obtaining marketing approval for our product candidates. For example, patients in our clinical trials of UpRi experienced SAEs, including, without limitation, death, pneumonitis, renal impairment, abdominal pain, fatigue, vomiting, sepsis, pyrexia and serious bleeding events. In June 2023, following our submission to the FDA of an aggregate safety analysis across all of our clinical trials of UpRi reporting our assessment that serious bleeding events appear to occur at a higher rate than background, the FDA placed a partial clinical hold on our UPGRADE-A and UP-NEXT clinical trials. Additionally, a patient in our Phase 1 clinical trial of XMT-2056 suffered a Grade 5 SAE, resulting in the clinical hold currently placed on the trial by the FDA. We expect that certain patients in our ongoing clinical trial of XMT-1660 and in future clinical trials will experience additional SAEs, including those that may result in death, as our product candidates progress through clinical development.

There can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain FDA approval. Even if we or our collaborators believe that the results of clinical trials of our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

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

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

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

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

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

- delays in reaching a consensus with regulatory agencies on trial design;
- delays in reaching, or failing to reach, agreement on acceptable terms with prospective clinical research organizations, or CROs, site management organizations, or SMOs, and clinical trial sites;
- difficulties in obtaining required Institutional Review Board, or IRB, or Ethics Committee, or EC, approval at each clinical trial site;
- challenges in recruiting and enrolling suitable patients to participate in clinical trials that meet the criteria of the protocol for the clinical trial;
- imposition of a clinical hold by regulatory agencies, IRBs or ECs for any reason, including safety concerns or after an inspection of clinical operations or trial sites;
- delays in necessary screenings caused by third parties with which we or any of our vendors or suppliers contract;

- failure by CROs, SMOs, other third parties or us to adhere to clinical trial requirements;
- failure to perform in accordance with the FDA's good clinical practices, or GCP, or applicable regulatory guidelines in other countries;
- inadequate quantity or quality of a product candidate or other materials necessary to conduct clinical trials, including, for example, delays in the testing, validation, manufacturing or delivery of the product candidates to the clinical sites;
- patients not completing participation in a trial or not returning for post-treatment follow-up, including as a result of the ongoing COVID-19 pandemic;
- expected or unexpected safety issues, including occurrence of SAEs, associated with any product candidate in clinical trials that are viewed as outweighing the product candidate's potential benefits or reports that may arise from preclinical or clinical testing of other similar cancer therapies that raise safety or efficacy concerns about our product candidates;
- changes in regulatory requirements or guidance that require amending or submitting new clinical protocols or submitting additional data;
- lack of adequate funding to continue one or more clinical trials; or
- geopolitical or other events, including the ongoing COVID-19 pandemic and the current conflict between Russia and Ukraine, that unexpectedly disrupt, delay or generally interfere in regional or worldwide operations of our clinical trial sites, CROs, SMOs or other operations applicable to the conduct of relevant development activities.

Delays, including delays caused by the above factors, can be costly and could negatively affect our ability to commence, enroll or complete our current and anticipated clinical trials. In June 2023, we announced that our UP-NEXT and UPGRADE-A clinical trials of UpRi had been placed on partial clinical hold by the FDA following submission to the FDA of an aggregate safety analysis across all of our clinical trials of UpRi reporting our assessment that serious bleeding events appear to occur at a higher rate than background. In July 2023, following our announcement that the data in our UPLIFT clinical trial of UpRi did not meet its primary endpoint, we announced our plans to wind-down UpRi-related development activities, including our UPGRADE-A and UP-NEXT clinical trials of UpRi. Additionally, in March 2023, we announced that our Phase 1 clinical trial of XMT-2056 had been placed on clinical hold by the FDA following a Grade 5 SAE. We are continuing to investigate this SAE and its cause, and we are working diligently to address the clinical hold on our trial of XMT-2056, which may include clinical trial protocol changes. If we or our collaborators are not able to successfully complete clinical trials, we or they will not be able to obtain regulatory approval and will not be able to commercialize our product candidates or our collaborators' product candidates based on our technology.

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

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

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the nature and complexity of the trial protocol, including eligibility criteria for the trial;
- the design of the trial;

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

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

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

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

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

Patients in our clinical trials experienced SAEs, including, without limitation, death, pneumonitis, renal impairment, abdominal pain, fatigue, vomiting, sepsis, pyrexia and serious bleeding events. For instance, in June 2023, following our submission to the FDA of an aggregate safety analysis across all of our clinical trials of UpRi reporting our assessment that serious bleeding events appear to occur at a higher rate than background, the FDA placed a partial clinical hold on our UPGRADE-A and UP-NEXT clinical trials of UpRi. Additionally, in March 2023, we announced that our Phase 1 clinical trial of XMT-2056 had been placed on clinical hold by the FDA following a Grade 5 SAE. We expect that certain patients in ongoing and future trials will experience additional SAEs, including those that may result in death, as our product candidates progress through clinical development. These or additional undesirable side effects caused by our product candidates or those of our competitors, either before or after receipt of marketing approval, could result in a number of potentially significant negative consequences, including:

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

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

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

At any time and for any reason, we may determine that one or more of our discovery programs, preclinical programs or product candidates does not have sufficient potential to warrant the allocation of resources toward such program or product candidate. Furthermore, because we have limited financial and personnel resources, we have placed significant focus on the development of a limited number of product candidates, including XMT-1660 and XMT-2056 and historically including UpRi and XMT-1592. Accordingly, we may choose not to develop a product candidate or elect to suspend or terminate one or more of our discovery or preclinical programs. If we suspend or terminate a program or product candidate in which we have invested significant resources, we will have expended resources on a program or product candidate that will not provide a full return on our investment. For example, in July 2023, we announced our decision to discontinue further development of UpRi based on the failure of our Phase 2 UPLIFT clinical trial to meet its primary endpoint. Additionally, in May 2022, we decided to discontinue development of XMT-1592 based in part on the lower prevalence of the NaPi2b biomarker in non-small cell lung cancer, or NSCLC, and the increasingly competitive nature of such indication. We may also cease developing a product candidate for a particular indication. For example, in November 2021, we determined to cease developing UpRi as a single agent in patients with NSCLC and determined to focus development on patients with ovarian cancer. As a result, we may have missed an opportunity to have allocated the resources originally used to develop UpRi and XMT-1592 to potentially more productive uses, including existing or future programs or product candidates. If we do not accurately evaluate the commercial potential or target market for a particular future product candidate, we may relinquish valuable rights to future product candidates through collaboration, licensing or other royalty arrangements.

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

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

Risks Related to our Financial Position and Need for Additional Capital

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

We have incurred net losses since our inception. Our net loss was $54.3 million for the three months ended June 30, 2023. As of June 30, 2023, we had an accumulated deficit of $765.2 million. Our losses have resulted principally from costs incurred in our discovery and development activities. Our net losses may fluctuate significantly from quarter to quarter and year to year. To date, we have not commercialized any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues for the foreseeable future. Absent the realization of sufficient revenues from product sales, we may never achieve profitability in the future.

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

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

- continue clinical development activities for XMT-1660;
- continue to work to address the clinical hold on our Phase 1 clinical trial of XMT-2056;
- continue activities to discover, validate and develop additional product candidates;
- obtain marketing approvals for our current and future product candidates for which we complete clinical trials;
- develop a sustainable and scalable manufacturing process for our product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- address any competing technological and market developments;
- maintain, expand and protect our intellectual property portfolio; and
- hire additional research, development and general and administrative personnel.

If we are required by the FDA or any equivalent foreign regulatory authority to perform clinical trials or preclinical trials in addition to those we currently expect to conduct, or if there are any delays in completing the clinical trials of XMT-1660 or any other current or future product candidates, our expenses could increase.

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

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

In October 2021, we entered into a Loan and Security Agreement, or the New Credit Facility, with Oxford Finance LLC as the collateral agent and a lender, Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, as a lender, and the other lenders party thereto, or together the Lenders. Pursuant to the New Credit Facility, as amended to date, we have borrowed $25 million. Following the top-line data from our UPLIFT clinical trial that we announced in July 2023, we do not believe that any additional borrowing amounts will be available to us under the New Credit Facility, as amended. The New Credit Facility is secured by substantially all of our personal property owned or later acquired, excluding intellectual property (but including the right to payments and proceeds from intellectual property), and a negative pledge on intellectual property.

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

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

Our cash, cash equivalents and marketable securities were $286.6 million as of June 30, 2023. We have utilized substantial amounts of cash since our inception and expect that we will continue to expend substantial resources for the foreseeable future developing XMT-1660, XMT-2056 and any other current or future product candidates. These expenditures may include costs associated with research and development, conducting preclinical studies and clinical trials, potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any, and potentially acquiring new technologies. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates. Our costs will increase if we experience any delays in our clinical trials for any current or future product candidates, including delays in enrollment of patients. We may also incur costs associated with operating as a public company, hiring additional personnel and expanding our facilities in the future.

Our future capital requirements depend on many factors, including:

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

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

We believe that our current cash, cash equivalents and marketable securities will be sufficient to fund our current operating plan commitments into 2026. However, we have based these estimates on assumptions that may prove to be wrong, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our future establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations.

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

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

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

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

Risks Related to Our Reliance on Third Parties

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

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

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

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

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

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

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

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

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

We designed the ongoing clinical trial of XMT-1660, the clinical trial of XMT-2056 that is currently on clinical hold, the trial for XMT-1592 that closed in September 2022, our Phase 1b and UPLIFT clinical trials of UpRi and the UPGRADE-A and UP-NEXT clinical trials of UpRi that we are winding-down, and we intend to design any future clinical trials for any future product candidates that we may develop if preclinical studies are successful and we do not have a strategic collaborator responsible for such trial design. However, we rely on CROs, SMOs, clinical sites, investigators and other third parties to assist in managing, monitoring and otherwise carrying out many of these trials. As a result, we have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. These CROs, SMOs, investigators and other third parties are not our employees, and we have limited control over the amount of time and resources that they dedicate to our programs. We compete with many other companies for the resources of these third parties. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with whom we contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, or complying with current good laboratory practices or current good clinical practices, as applicable, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

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

- have staffing difficulties;
- fail to comply with contractual obligations;

- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Commercialization of Our ADC Product Candidates

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

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

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

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

The incidence and prevalence for target patient populations of our drug candidates have not been established with precision. If the market opportunities for our drug candidates 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 B7-H4-expressing cancers and HER2-expressing cancers are uncertain. Our estimates of the number of people who have these diseases, as well as the subset of people who have the potential to benefit from treatment with our product candidates are based on estimates. The total addressable market opportunity for XMT-1660, XMT-2056 or any of our other current or future product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each such product candidate if our product 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 XMT-1660, XMT-2056 or any of our other current or future product candidates may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs or we may face increasing difficulties in identifying or gaining access to new patients, all of which would adversely affect our results of operations and our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approval and marketing than we do. In addition, many of these competitors are active in seeking patent protection and licensing arrangements in anticipation of collecting royalties for use of technology that they have developed. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, establishing clinical trial sites, recruiting patients and in manufacturing pharmaceutical products and may succeed in discovering, developing and commercializing products in our field before we do. Smaller or early-stage companies may also prove to be

significant competitors, particularly through strategic relationships with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, as well as in acquiring technologies complementary to our programs.

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

If patent applications we own or have in-licensed with respect to our platforms or our product candidates fail to issue as patents, if their breadth or strength of protection is threatened or inadequate, 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 inability to obtain relevant granted patents or 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, with respect to at least certain of our patents and patent applications, 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 being able to effectively prevent others from commercializing products competitive to our candidates. If we encounter delays in obtaining regulatory approvals, the period of time during which we could market a drug under patent protection could be further reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from similar or generic products. The launch of a generic version of one of our products in particular would be likely to result in an immediate and substantial reduction in the demand for our product, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a “first-to-invent” system to a “first-inventor-to-file” system. Under a first-inventor-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-inventor-to-file provisions, became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Potential further changes to the laws governing intellectual property in the United States or other countries, or in the continued interpretation and implementation of the provisions of the Leahy-Smith Act in the United States, create uncertainty in our ability to obtain, maintain and enforce our intellectual property rights and could have an adverse effect on our ability to do so in a way that protects our platforms and product candidates.

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

Issued patents covering UpRi, XMT-1660, XMT-2056 and any other current or future ADC product candidates could be found not infringed by a competitive product, invalid or unenforceable if challenged in court or before the USPTO or comparable foreign authority.

In some cases, it may be difficult to detect infringement of our intellectual property rights by third parties, and, even if detected, proving infringement may be difficult. If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering UpRi, XMT-1660, XMT-2056 or any other current or future product candidates, the defendant could counterclaim its product does not infringe the asserted patent or 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 infringement, invalidity and unenforceability is unpredictable. With respect to infringement, the court may interpret the claims in a way that establishes a third-party product does not infringe those claims, or we may be otherwise unsuccessful in establishing that a third-party product embodies or practices each element of the claim and therefore infringes the claim. 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 or a finding that a third party's competitive product does not infringe our patents could have a material adverse impact on our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition to patent and other intellectual property protection, we may seek market and data exclusivity for our biological product candidates subject to the biologics license application, or BLA, process at the FDA, which is currently 12 years in the United States, 10 years in Europe and other durations in other countries, where available. The term of the patents covering our product candidates may not extend beyond the data and market exclusivities. There is a risk that this data and market exclusivity could be shortened due to legislative action in the United States or other countries where such protection is currently available, potentially creating the risk that biosimilar competition could enter the market sooner than anticipated. In addition, the extent to which any biosimilar competitive product, once approved, may be substituted for our relevant reference product is not yet clear, and will depend on many market and regulatory factors which are uncertain.

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

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make ADC products that are similar to any product candidates we may develop or utilize similar ADC-related technology but that are not covered by the claims of the patents that we license or may own in the future;

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

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

Risks Related to Regulatory Approval and Other Legal Compliance Matters

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

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. We are not permitted to market our product candidates in the United States or in other countries until we receive approval of a BLA from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in development. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction. Additionally, we have no experience as a company in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process.

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

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Finally, our ability to develop and market new drug products may be threatened by ongoing litigation challenging the FDA's approval of mifepristone. Specifically, on April 7, 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and the distribution of which is governed by various measures adopted under a Risk Evaluation and Mitigation Strategy, or REMS. In reaching that decision, the district court made a number of findings that numerous representatives of the pharmaceutical and biotechnology industry believe will chill the development, approval and distribution of new drug products in the United States. Among other determinations, the district court substituted its scientific judgement for that of the FDA and it held that FDA must provide a special justification for any differences between an approved drug's labeling and the conditions that existed in the drug's clinical trials. Further, the district court read the jurisdictional requirements governing litigation in federal court so as to potentially allow virtually any party to bring a lawsuit against the FDA in connection with its decision to approve an NDA or BLA or establish requirements under a REMS. On April 13, 2023, the district court decision was stayed, in part, by the U.S. Court of Appeals for the Fifth Circuit. Thereafter, on April 21, 2023, the U.S. Supreme Court entered a stay pending disposition of the appeal of the district court decision in the Court of Appeals for the Fifth Circuit or the Supreme Court. The Court of Appeals for the Fifth Circuit held oral argument in the case on May 17, 2023. Depending on the outcome of this litigation and the regulatory uncertainty it has engendered, our abilities to develop new drug product candidates and to maintain an approval, if any, with respect to our existing drug product candidates and measures adopted under a REMS, if any, are at risk and could be delayed, undermined or subject to protracted litigation.

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

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

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

In addition, following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. After lapse of a transition period, the United Kingdom is no longer part of the European Single Market and European Union Customs Union as of January 1, 2021. A trade and cooperation agreement that outlined the future trading relationship between the United Kingdom and the European Union was agreed to in December 2020 and entered into force on May 1, 2021. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or the MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland will continue to be subject to EU rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law of the body of EU law instruments governing medicinal products that pre-existed prior to the United Kingdom's withdrawal from the European Union.

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

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

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

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

We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug or biologic. Moreover, with passage of the Pre-approval Information Exchange Act in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. Violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

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

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

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

Accordingly, in connection with our currently approved products and assuming we, or our collaborators, receive marketing approval for one or more of our product candidates, we, and our collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and our collaborators, are not able to comply with post-approval regulatory requirements, our or our collaborators' ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

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

We have in the past sought and may also in the future seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

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

We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

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

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

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

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

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

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

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

The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." The court concluded that orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA or Congress may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, we may lose any expected benefits of the orphan drug designation we have received for XMT-2056, and our business could be adversely impacted.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

Accordingly, if a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

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

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

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

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

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

In addition, the current conflict between Russia and Ukraine may also have an impact on our ability to successfully conduct trials outside of the United States. For example, we do business with a CRO that has had employees and operations in Ukraine that have been adversely impacted by Russian hostilities, though such employees and operations are not directly involved with our clinical trials. If we have difficulty conducting our clinical trials in jurisdictions outside the United States as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which could have a material adverse effect on our business.

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

We may seek approval of any of our current and future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA or other applicable regulatory agency makes the determination regarding whether a surrogate endpoint is reasonably likely to predict long-term clinical benefit.

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

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

The FDA may withdraw approval of a product candidate approved under the accelerated approval pathway if, for example, the trial required to verify the predicted clinical benefit of our product candidate fails to verify such benefit or does not demonstrate sufficient clinical benefit to justify the risks associated with the drug. The FDA may also

withdraw approval if other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use, we fail to conduct any required post approval trial of our product candidate with due diligence or we disseminate false or misleading promotional materials relating to our product candidate. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period for commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

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

More recently, in March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. While this guidance is currently only in draft form and will not be legally binding even when finalized, we will need to consider the FDA's guidance closely if we seek accelerated approval for any of our products.Accordingly, even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval.

Failure to successfully validate, develop and obtain regulatory approval for companion diagnostics could harm our drug development strategy.

We may employ companion diagnostics to help us more accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our product candidates that we are developing or may in the future develop. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and require separate regulatory approval or clearance prior to commercialization. Given our limited experience in developing diagnostics, we may rely on third-party collaborators in developing and obtaining approval or clearance for these companion diagnostics. There can be no guarantees that we will successfully find a suitable collaborator to develop companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval or clearance for the companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility, or clinical validation. Any delay or failure by us or our collaborators to develop or obtain regulatory approval or clearance of the companion diagnostics could delay or prevent approval of our product candidates. In addition, we or our 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, our ability to derive revenues from sales of any products, if approved, will be adversely affected. In addition, any diagnostic company with which 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. In such event, 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.

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

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

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

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

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

- the federal law known as Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program (which may include private health plans) or making false statements relating to healthcare matters;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

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

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

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. The final rule is currently the subject of ongoing litigation, but at least six states (Vermont, Colorado, Florida, Maine, New Mexico, and New Hampshire) have passed laws allowing for the importation of drugs from Canada with the intent of developing SIPs for review and approval by the FDA. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The final rule would also eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It was originally set to go into effect on January 1, 2022, but with passage of the IRA, has been delayed by Congress to January 1, 2032.

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

More recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Service, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

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

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

On June 6, 2023, Merck filed a lawsuit against HHS and CMS asserting that, among other things, the IRA’s Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, other parties, including the U.S. Chamber of Commerce, Bristol Myers Squibb Company, the Pharmaceutical Research and Manufacturers of America, Astellas and Johnson & Johnson also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. We expect that litigation involving the IRA will continue, with unpredictable and uncertain results.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted

price ceilings on specific products and therapies. In many countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our business could be materially harmed.

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

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

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

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

In addition to potential enforcement by HHS, we are also potentially subject to privacy enforcement from the Federal Trade Commission, or the FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be “unfair” under Section 5 of the FTC Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The agency is also in the process of developing rules related to commercial surveillance and data security that may impact our business. We will need to account for the FTC’s evolving rules and guidance for proper privacy and data security practices in order to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and (depending on the nature of the alleged violations). If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements.

States are also active in creating specific rules relating to the processing of personal information. In 2018, California passed into law the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the General Data Protection Regulation, or the GDPR, which is further described below, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act, or the CPRA, which went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – the sole responsibility of which is to enforce the CPRA, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, at least eleven other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data (which includes health data in some cases). Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2023 legislative sessions that will go into effect in 2024 and beyond, including New York and New Jersey. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

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

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

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-U.S. Privacy Shield. The European Union initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022 and the European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision will permit U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the EU to the U.S. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business internationally.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, which could adversely affect our business. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with federal, state and international laws regarding privacy and security of personal information could expose us to fines and penalties under such laws.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside the United States, we will need to dedicate additional resources to comply with U.S. laws regarding international operations and the laws and regulations in each jurisdiction in which we operate and plan to operate. The FCPA prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry because in many countries, hospitals are operated by the government and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Further, the provision of benefits or advantages to

physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of E.U. Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain E.U. Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual E.U. Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the E.U. Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

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

We and our third-party manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In the event of contamination or injury, or failure to comply with environmental, health and safety laws and regulations, we could be held liable for any resulting damages and any such liability could exceed our assets and resources. We could also incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In

particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal health care programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to our Business and Industry

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

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

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

Our restructuring and workforce reduction announced on July 27, 2023, may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

On July 27, 2023, following our discontinuance of the development of UpRi and the strategic reprioritization of our business activities, we announced that we were conducting a restructuring involving a headcount reduction of approximately 50% of our then-current employee base. We expect to complete the terminations by the end of 2023 and estimate that we will reduce our operating expenses going forward. However, these estimates are subject to several assumptions, and actual results may differ. We may not realize, in full or in part, the anticipated benefits and savings from this plan due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected cost savings from the announced plan, our operating results and financial condition could be adversely affected. The workforce reduction may be disruptive to our operations and could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale, as well as result in weaknesses in our infrastructure and operations, and may increase the risk that we become unable to comply with legal and regulatory requirements. Our workforce reductions could also harm our

ability to attract and retain qualified management, scientific, clinical, and/or manufacturing personnel. Any failure to attract or retain qualified personnel could prevent us from successfully developing XMT-1660, XMT-2056 or any other current or future product candidates.

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

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

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

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

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

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry

product liability insurance covering our clinical trials in the amount of $10 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. In such instance, we might have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product candidates, which could adversely affect our business, financial condition, results of operations and prospects.

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

We may acquire additional technologies and assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are unable to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot be assured that, following any such acquisition, we will achieve the expected synergies to justify the transaction. Our internal computer systems, or those of our strategic and other third-party collaborators or other contractors or consultants, may fail or suffer security breaches, which could adversely affect our business, including through material disruptions of our programs or business operations.

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

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

Risks Related to Our Common Stock

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

Our stock price has been and may continue to be volatile. During the period from August 4, 2020 to August 4, 2023, the closing price of our common stock ranged from a high of $27.59 per share to a low of $1.06 per share. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this "Risk Factors" section, and others beyond our control, including:

- results and timing of preclinical studies and clinical trials of our current or future product candidates, including XMT-1660 and XMT-2056, including, for example, the clinical hold placed by the FDA on our trial of XMT-2056 in March 2023;
- results of clinical trials of our competitors' products;
- failure to adequately protect our trade secrets;
- the terms on which we raise additional capital or our ability to raise it;
- commencement or termination of any strategic collaboration or licensing arrangement;
- regulatory developments, including actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy, including, for example, our strategic reprioritization announced in July 2023;
- the passage of legislation or other regulatory developments affecting us or our industry;
- changes in the structure of healthcare payment systems;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us (including pursuant to outstanding warrants or through our ATM offering programs), our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- changes in market conditions for biopharmaceutical stocks; and
- changes in general market and economic conditions.

In addition, the stock market has historically experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

This exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, which provides for exclusive jurisdiction of the federal courts. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act of 1933, as amended, or the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder, provided, that with respect to claims under the Securities Act, our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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

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

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

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

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

General Risk Factors

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

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

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

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

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

There can be no assurance that the amounts of insurance that we maintain will be sufficient to satisfy any damages and losses in the event a serious disaster or similar event occurs. If our facilities, or the manufacturing facilities of

our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs and commercialization efforts may be harmed.

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

None.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Fifth Amended and Restated Certificate of Incorporation, as amended, as of June 8, 2023 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on June 9, 2023).
3.2	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on March 31, 2023).
10.1*	Form of Restricted Stock Unit Agreement under the Mersana Therapeutics, Inc. 2022 Inducement Stock Incentive Plan
10.2*	Form of Restricted Stock Unit Agreement for Employees under the Mersana Therapeutics, Inc. 2017 Stock Incentive Plan
10.3*	Form of Restricted Stock Unit Agreement for Non-Employee Directors under the Mersana Therapeutics, Inc. 2017 Stock Incentive Plan
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document (included in Exhibit 101).

*Filed herewith.

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

SIGNATURES

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

Mersana Therapeutics, Inc.

Dated: August 8, 2023

By: /s/ Anna Protopapas

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

Dated: August 8, 2023

By: /s/ Brian DeSchuytner

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

Name: [●]
Number of RSUs: [●]
Date of Grant: [●]
Vesting Commencement Date [●]

MERSANA THERAPEUTICS, INC.

2022 INDUCEMENT 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**"), pursuant to and subject to the terms of the Mersana Therapeutics, Inc. 2022 Inducement 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. In consideration of the employment services to be rendered to the Company by the Grantee and as an inducement material for the Grantee to enter into employment with the Company, 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 pursuant to the inducement grant exception under Nasdaq Stock Market Rule 5635(c)(4), as an inducement that is material to the Grantee's entering into employment with the Company.

2. Vesting; Cessation of Service.

(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 Vesting Commencement Date (each, a "**Vesting Date**")][1], subject to Grantee's continued Service through such Vesting Date.

(b) Cessation of Service. If the Grantee's Service ceases for any reason, except as expressly provided for in any agreement between the Grantee and the Company or any of its subsidiaries, 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 issuance 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.

[1] Vesting to be specified based on grant terms.

(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)(4) 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)(2) of the Plan.

6. Withholding. 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. To the extent the Grantee has not previously executed and delivered to the Company effective durable sell-to-cover instructions that by their terms would cover any taxes required by law to be withheld with respect to the vesting of the RSUs, at such time as the Grantee is not aware of any material nonpublic information about the Company or the Stock, and the Grantee is not otherwise prevented from doing so under the Company's insider trading policy or otherwise, the Grantee shall execute the instruction set forth in Schedule A attached hereto (the "**Durable Automatic Sell-to-Cover Instruction**") as the means of satisfying such tax obligation. If the Grantee is required to but does not execute the Durable Automatic Sell-to-Cover Instruction prior to an applicable vesting date, then the Grantee agrees that if under applicable law the Grantee will owe taxes at such vesting date on the portion of the award of RSUs then vested, the Company shall be entitled to immediate payment from the Grantee of the amount of any tax required to be withheld by the Company. The Company shall not deliver any Shares to the Grantee until it is satisfied that all required withholdings have been made.

7. Effect on Service. This grant of the RSUs will not give the Grantee any right to be retained in the 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 Service at any time, or affect any right of the Grantee to terminate his or her 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.

Schedule A

Durable Automatic Sell-to-Cover Instruction

This Durable Automatic Sell-to-Cover Instruction (this "Instruction"), which is being delivered to Mersana Therapeutics, Inc. (the "Company") by the undersigned on the date set forth below (the "Adoption Date"), relates to any restricted stock units that may be granted to me from time to time by the Company under the Company's equity compensation programs, other than any restricted stock units which by the terms of the applicable award agreement require the Company to withhold shares for tax withholding obligations in connection with the vesting and settlement of such restricted stock units and therefore do not permit sell-to-cover transactions (the restricted stock units subject to this Instruction are referred to as "Covered RSUs"). This Instruction provides for "eligible sell-to-cover transactions" (as described in Rule 10b5-1(c)(1)(ii)(D)(3) under the Securities Exchange Act of 1934 (the "Exchange Act")) with respect to Covered RSUs and is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c)(1) under the Exchange Act.

I acknowledge that upon vesting and settlement of any Covered RSUs in accordance with the applicable RSU's terms, whether vesting is based on the passage of time or the achievement of performance goals, I will have compensation income equal to the fair market value of the shares of the Company's common stock subject to the RSUs that are settled on such settlement date and that the Company is required to withhold income and employment taxes in respect of that compensation income.

I desire to establish a plan and process to satisfy such withholding obligation in respect of all Covered RSUs through an automatic sale of the number of the shares of the Company's common stock that would otherwise be issuable to me on each applicable settlement date in an amount sufficient to satisfy the applicable withholding obligation, with the proceeds of the sale delivered to the Company in satisfaction of the applicable withholding obligation.

I understand that the Company has arranged for the administration and execution of its equity incentive programs and the sale of securities by participants thereunder pursuant to a platform administered by a third party (the "Administrator") and the Administrator's designated brokerage partner.

Upon the settlement of any of my Covered RSUs after the 30th day following the Adoption Date (or if I am an officer of the Company on the Adoption Date, after the later of: (i) the 90th day following the Adoption Date or (ii) two business days following the disclosure of the Company's financial results in Form 10-Q or Form 10-K for the completed fiscal quarter in which this Instruction was adopted (or, with respect to this clause (ii), if sooner, the 120th day after adoption of this Instruction)) (the "Cooling-Off Period"), I hereby appoint the Administrator (or any successor administrator) to automatically sell such number of shares of the Company's common stock issuable with respect to such RSUs that vested and settled as is sufficient to generate net proceeds sufficient to satisfy the Company's minimum statutory withholding obligations with respect to the income recognized by me in connection with the vesting and settlement of such RSUs (based on minimum statutory withholding rates for all tax purposes, including payroll and social security taxes, that are applicable to such income), and the Company shall receive such net proceeds in satisfaction of such tax withholding obligation.

I hereby appoint the Chief Executive Officer, the Chief Financial Officer, the Chief Legal Officer and the Treasurer, and any of them acting alone and with full power of substitution, to serve as my attorneys-in-fact to arrange for the sale of shares of the Company's common stock in accordance with this Instruction. I agree to execute and deliver such documents, instruments and certificates as may reasonably be required in connection with the sale of the shares of common stock pursuant to this Instruction.

I hereby certify that, as of the Adoption Date:

(i) I am not prohibited from entering into this Instruction by the Company's insider trading policy or otherwise;

(ii) I am not aware of any material nonpublic information about the Company or its common stock; and

(iii) I am adopting this Instruction in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b-5 under the Exchange Act.

_____

Print Name: _____

Date: _____

Name: [●]
Number of RSUs: [●]
Date of Grant: [●]
Vesting Commencement Date [●]

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. 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. To the extent the Grantee has not previously executed and delivered to the Company effective durable sell-to-cover instructions that by their terms would cover any taxes required by law to be withheld with respect to the vesting of the RSUs, at such time as the Grantee is not aware of any material nonpublic information about the Company or the Stock, and the Grantee is not otherwise prevented from doing so under the Company's insider trading policy or otherwise, the Grantee shall execute the instruction set forth in Schedule A attached hereto (the "**Durable Automatic Sell-to-Cover Instruction**") as the means of satisfying such tax obligation. If the Grantee is required to but does not execute the Durable Automatic Sell-to-Cover Instruction prior to an applicable vesting date, then the Grantee agrees that if under applicable law the Grantee will owe taxes at such vesting date on the portion of the award of RSUs then vested, the Company shall be entitled to immediate payment from the Grantee of the amount of any tax required to be withheld by the Company. The Company shall not deliver any Shares to the Grantee until it is satisfied that all required withholdings have been made.

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.

SCHEDULE A

DURABLE AUTOMATIC SELL-TO-COVER INSTRUCTION

This Durable Automatic Sell-to-Cover Instruction (this "Instruction"), which is being delivered to Mersana Therapeutics, Inc. (the "Company") by the undersigned on the date set forth below (the "Adoption Date"), relates to the Covered RSUs (as defined following my signature below). This Instruction provides for "eligible sell-to-cover transactions" (as described in Rule 10b5-1(c)(1)(ii)(D)(3) under the Securities Exchange Act of 1934 (the "Exchange Act")) and is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c)(1) under the Exchange Act.

I acknowledge that upon vesting and settlement of any Covered RSUs in accordance with the applicable RSU's terms, whether vesting is based on the passage of time or the achievement of performance goals, I will have compensation income equal to the fair market value of the shares of the Company's common stock subject to the RSUs that are settled on such settlement date and that the Company is required to withhold income and employment taxes in respect of that compensation income.

I desire to establish a plan and process to satisfy such withholding obligation in respect of all Covered RSUs through an automatic sale of the number of the shares of the Company's common stock that would otherwise be issuable to me on each applicable settlement date in an amount sufficient to satisfy the applicable withholding obligation, with the proceeds of the sale delivered to the Company in satisfaction of the applicable withholding obligation.

I understand that the Company has arranged for the administration and execution of its equity incentive programs and the sale of securities by participants thereunder pursuant to a platform administered by a third party (the "Administrator") and the Administrator's designated brokerage partner.

Upon the settlement of any of my Covered RSUs after the 30th day following the Adoption Date (or if I am an officer of the Company on the Adoption Date, after the later of: (i) the 90th day following the Adoption Date or (ii) two business days following the disclosure of the Company's financial results in Form 10-Q or Form 10-K for the completed fiscal quarter in which this Instruction was adopted (or, with respect to this clause (ii), if sooner, the 120th day after adoption of this Instruction)) (the "Cooling-Off Period"), I hereby appoint the Administrator (or any successor administrator) to automatically sell such number of shares of the Company's common stock issuable with respect to such RSUs that vested and settled as is sufficient to generate net proceeds sufficient to satisfy the Company's minimum statutory withholding obligations with respect to the income recognized by me in connection with the vesting and settlement of such RSUs (based on minimum statutory withholding rates for all tax purposes, including payroll and social security taxes, that are applicable to such income), and the Company shall receive such net proceeds in satisfaction of such tax withholding obligation.

I hereby appoint the Chief Executive Officer, the Chief Financial Officer, the Chief Legal Officer and the Treasurer, and any of them acting alone and with full power of substitution, to serve as my attorneys-in-fact to arrange for the sale of shares of the Company's common stock in accordance with this Instruction. I agree to execute and deliver such documents, instruments and certificates as may reasonably be required in connection with the sale of the shares of common stock pursuant to this Instruction.

Unless the third and final box in the definition of Covered RSUs below is checked, if I have previously adopted an automatic sale or sell-to-cover instruction relating to Covered RSUs, this Instruction shall be void *ab initio*.

I hereby certify that, as of the Adoption Date:

(i) I am not prohibited from entering into this Instruction by the Company's insider trading policy or otherwise;

(ii) I am not aware of any material nonpublic information about the Company or its common stock; and

(iii) I am adopting this Instruction in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b-5 under the Exchange Act.

_____

Print Name: _____

Date: _____

Covered RSUs:

The following restricted stock units ("RSUs") are covered by this Instruction.

Check all applicable boxes:

☐ The first award of RSUs granted to me on or after _____ [*insert date of grant of current RSUs the grant of which is triggering the execution of this Instruction; if instruction is being executed in advance of a grant of RSUs, insert the Adoption Date*] and any RSUs that may, from time to time following such date, be granted to me by the Company, other than any future granted RSUs which by the terms of the applicable award agreement require the Company to withhold shares for tax withholding obligations in connection with the vesting and settlement of such RSUs, and therefore do not permit sell-to-cover transactions.

☐ Any outstanding RSUs that were granted to me by the Company prior to the Adoption Date that (1) are <u>not</u> subject to any prior automatic sale or sell-to-cover instruction and (2) for which the next vesting date is after the Cooling-Off Period, other than any previously granted RSUs which by the terms of the applicable award agreement require the Company to withhold shares for tax withholding obligations in connection with the vesting and settlement of such RSUs, and therefore do not permit sell-to-cover transactions.

☐ With respect to any RSUs, whether or not granted to me by the Company prior to the Adoption Date, that already are subject to an automatic sale or sell-to-cover instruction (a "Prior Instruction"), I elect to have such sales effected pursuant to this Instruction and confirm that doing so does not modify or change the amount, price, or timing of such sales from those provided by the Prior Instruction (and, as a result the Cooling-Off Period is not applicable to sales pursuant to this Instruction that were previously subject to the Prior Instruction).

Name: [●]
Number of RSUs: [●]
Date of Grant: [●]
Vesting Commencement Date [●]

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**") in consideration of services rendered and to be rendered to the Company by the Grantee, 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 service as a director of the Company.

2. Vesting; Cessation of Service.

(a) Vesting. Unless earlier terminated, forfeited, relinquished or expired, the RSUs will vest as to [●]% of the Shares on [●] ([each,] a "Vesting Date"), subject to Grantee's continued service as a director of the Company through such Vesting Date.

(b) Cessation of Service. If the Grantee ceases to perform services as a director of the Company for any reason, except as expressly provided for in this Section 2(b) or in any other agreement between the Grantee and the Company or its Affiliate, the RSUs, to the extent not then vested, will be immediately forfeited. The RSUs will vest in full upon a termination of the Grantee's service as a director of the Company due to the Grantee's death or disability or immediately prior to a Corporate Transaction that constitutes a change in control event (within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(i)).

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. The Grantee acknowledges and agrees that, to the extent the Company is required to withhold any taxes in connection with the vesting of the RSUs, the Company has the right to deduct from payments of any kind otherwise due to the Grantee any federal, state, local or other taxes of any kind required by law to be withheld with respect to the vesting of the RSUs. The Company shall not deliver any Shares to the Grantee until it is satisfied that all required withholdings have been made.

7. Effect on Service. This grant of the RSUs will not give the Grantee any right to be retained in the 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 service at any time, or affect any right of the Grantee to terminate his or her 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.

Dated: August 8, 2023

By: /s/ Anna Protopapas

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

Exhibit 31.2

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

I, Brian DeSchuytner, certify that:

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

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

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

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

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

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

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

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

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

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

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

Mersana Therapeutics, Inc.

Dated: August 8, 2023

By: /s/ Brian DeSchuytner

Brian DeSchuytner
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Mersana Therapeutics, Inc. (the "Company") for the quarter ended June 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the company, hereby certifies, pursuant to Section 1350 of Chapter 63 of Title 18, United States Code, that to the best of her or his knowledge:

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

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

Dated: August 8, 2023

/s/ Anna Protopapas

Anna Protopapas

President and Chief Executive Officer
(Principal Executive Officer)

Dated: August 8, 2023

/s/ Brian DeSchuytner

Brian DeSchuytner

Chief Financial Officer
(Principal Financial Officer)