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 September 30, 2019

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: 001-32979

Molecular Templates, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**94-3409596**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
9301 Amberglen Blvd Suite 100 Austin, TX 78729 (Address of principal executive offices)	**78729 (Zip Code)**

(512) 869-1555
(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, $0.001 Par Value Per Share	MTEM	The Nasdaq Capital 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 ☒

On November 4, 2019, there were 36,968,510 shares of common stock, par value $0.001 per share, of Molecular Templates, Inc. outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements, other than statements of historical facts contained herein, regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, statements about:

- the implementation of our business strategies, including our ability to pursue development pathways and regulatory strategies for MT-3724 and other engineered toxin body, or ETB, product candidates;
- the timing and our ability to advance the development of our product candidates;
- our plans to pursue discussions with regulatory authorities, and the anticipated timing, scope and outcome of related regulatory actions or guidance;
- our ability to establish and maintain potential new partnering or collaboration arrangements for the development and commercialization of ETB product candidates;
- our financial condition, including our ability to obtain the funding necessary to advance the development of our product candidates;
- the anticipated progress of our product candidate development programs, including whether our ongoing and potential future clinical trials will achieve clinically relevant results;
- our ability to generate data and conduct analyses to support the regulatory approval of our product candidates;
- our ability to establish and maintain intellectual property rights for our product candidates;
- whether any product candidates that we are able to commercialize are safer or more effective than other marketed products, treatments or therapies;
- our ability to discover and develop additional product candidates suitable for clinical testing;
- our ability to identify, in-license or otherwise acquire additional product candidates and development programs;
- our anticipated research and development activities and projected expenditures;
- our ability to complete preclinical and clinical testing successfully for new product candidates that we may develop or license;
- our ability to have manufactured active pharmaceutical ingredient, or API, and drug product that meet required release and stability specifications;
- our ability to have manufactured sufficient supplies of drug product for clinical testing and commercialization;
- our ability to obtain licenses to any necessary third-party intellectual property;
- our ability to retain and hire necessary employees and appropriately staff our development programs; and
- the sufficiency of our cash resources; and other risks and uncertainties, including those listed under Part II, Item 1A, "Risk Factors".

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A, "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

Molecular Templates, Inc.

TABLE OF CONTENTS

		Page
PART I.	FINANCIAL INFORMATION	4
Item 1.	Financial Statements	4
	Condensed Consolidated Balance Sheets (Unaudited)	4
	Condensed Consolidated Statements of Operations (Unaudited)	5
	Condensed Consolidated Statements of Comprehensive Loss (Unaudited)	6
	Condensed Consolidated Statements of Stockholders' Equity (Deficit) (Unaudited)	7
	Condensed Consolidated Statements of Cash Flows (Unaudited)	8
	Notes to Condensed Consolidated Financial Statements (Unaudited)	9
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	24
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	37
Item 4.	Controls and Procedures	38
PART II.	OTHER INFORMATION	39
Item 1	Legal Proceedings	39
Item 1A.	Risk Factors	39
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	73
Item 3.	Defaults Upon Senior Securities	73
Item 4.	Mine Safety Disclosures	73
Item 5.	Other Information	74
Item 6.	Exhibits	75
SIGNATURES		76

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Molecular Templates, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	September 30, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,268	$ 87,721
Marketable securities, current	36,147	10,234
Prepaid expenses	2,340	2,244
Grants revenue receivable	5,591	4,329
Accounts receivable from related party	—	240
In-process research and development - held for sale	4,500	26,623
Other current assets	300	95
Total current assets	64,146	131,486
Operating lease right-of-use assets, non-current	10,397	—
Property and equipment, net	13,884	6,851
Other assets	4,735	1,821
Total assets	$ 93,162	$ 140,158
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,414	$ 780
Accrued liabilities	9,105	5,357
Deferred revenue, current	11,956	26,231
Other current liabilities	1,623	141
Total current liabilities	24,098	32,509
Deferred revenue, non-current	1,236	2,670
Long-term debt, non-current, net	3,001	3,254
Operating lease liabilities, non-current	10,573	—
Other liabilities	1,238	819
Total liabilities	40,146	39,252
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock, $0.001 par value:		
Authorized: 150,000,000 shares; issued and outstanding: 36,954,510 shares at September 30, 2019 and 36,736,012 shares at December 31, 2018	37	37
Additional paid-in capital	201,203	195,573
Accumulated other comprehensive income	20	—
Accumulated deficit	(148,244)	(94,704)
Total stockholders' equity	53,016	100,906
Total liabilities and stockholders' equity	$ 93,162	$ 140,158

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

Molecular Templates, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development revenue - from related party	$ 2,903	$ 1,914	$ 14,527	$ 3,009
Research and development revenue - other	284	117	284	197
Grant revenue	431	4,721	1,262	5,395
Total revenue	3,618	6,752	16,073	8,601
Operating expenses:				
Research and development	15,249	8,290	33,946	22,640
General and administrative	4,509	3,538	14,049	10,165
Loss on impairment of in-process research and development	22,123	—	22,123	—
Total operating expenses	41,881	11,828	70,118	32,805
Loss from operations	38,263	5,076	54,045	24,204
Interest and other income, net	396	107	1,449	307
Interest and other expense, net	(353)	(279)	(947)	(672)
Change in fair value of warrant liabilities	1	4	3	916
Net loss attributable to common shareholders	$ 38,219	$ 5,244	$ 53,540	$ 23,653
Net loss per share attributable to common shareholders:				
Basic and diluted	$ 1.03	$ 0.19	$ 1.45	$ 0.87
Weighted average number of shares used in net loss per share calculations:				
Basic and diluted	36,937,912	27,680,307	36,832,966	27,246,667

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

Molecular Templates, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	$ 38,219	$ 5,244	$ 53,540	$ 23,653
Other comprehensive income:				
Unrealized (loss) gain on available-for-sale securities	(5)	—	20	—
Comprehensive loss	$ 38,224	$ 5,244	$ 53,520	$ 23,653

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

MOLECULAR TEMPLATES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Total Stockholders' Equity (Deficit), beginning balances	$ 89,260	$ 62,177	$ 100,906	$ 77,289
Common Stock:				
Beginning balance	37	28	37	27
Issuance of common stock pursuant to stock plans	—	—	—	1
Issuance of common stock pursuant to Public offering	—	8	—	8
Ending balance	37	36	37	36
Additional Paid-In Capital				
Beginning balance	199,223	144,975	195,573	141,733
Issuance of common stock pursuant to stock plans	453	2	1,300	157
Issuance of warrant to purchase common stock in relation to term loan facility	—	—	—	1,522
Stock-based compensation	1,527	1,197	4,330	2,762
Issuance of common stock pursuant to Public offering	—	48,052	—	48,052
Ending balance	201,203	194,226	201,203	194,226
Accumulated Other Comprehensive Income (Loss):				
Beginning balance	25	—	—	—
Other comprehensive (loss) income	(5)	—	20	—
Ending balance	20	—	20	—
Accumulated deficit:				
Beginning balance	(110,025)	(82,826)	(94,704)	(64,471)
Net loss	(38,219)	(5,244)	(53,540)	(23,653)
Cumulative-effect adjustment upon adoption of new accounting standards	—	—	—	54
Ending balance	(148,244)	(88,070)	(148,244)	(88,070)
Total Stockholders' Equity	$ 53,016	$ 106,192	$ 53,016	$ 106,192

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

Molecular Templates, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ 53,540	$ 23,653
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and other	628	569
Stock-based compensation expense	4,330	2,762
Amortization of debt discount and accretion related to debt	347	219
Change in common stock warrant fair value	(3)	(916)
Accretion of asset retirement obligations	48	28
Capitalized interest	—	(125)
Loss on extinguishment of debt	—	115
Loss on impairment of long-lived assets	22,139	—
Changes in operating assets and liabilities:		
Prepaid expenses	(96)	(1,116)
Accounts receivable from related party	240	(31,163)
Grants revenue receivable	(1,262)	(4,100)
Other assets	(145)	(156)
Operating lease right-of-use assets, non-current	1,077	—
Accounts payable	524	(906)
Accrued liabilities	2,661	3,733
Operating lease liabilities	(511)	—
Other liabilities	—	215
Deferred revenue	(15,709)	30,635
Net cash used in operating activities	(39,272)	(23,859)
Cash flows from investing activities:		
Purchases of property and equipment	(6,329)	(5,421)
Purchase of marketable securities	(73,758)	—
Sales of marketable securities	48,583	—
Net cash used in investing activities	(31,504)	(5,421)
Cash flows from financing activities:		
Payments of capital and finance lease obligations	23	(36)
Proceeds from issuance of long-term debt and warrants, net	—	4,537
Repayment of long-term debt	—	(3,605)
Proceeds from stock option exercises	1,300	157
Proceeds from issuance of common stock and warrants, net of offering expenses	—	48,061
Net cash provided by financing activities	1,323	49,114
Net (decrease) increase in cash, cash equivalents, and restricted cash	(69,453)	19,834
Cash, cash equivalents and restricted cash, beginning of period	87,721	58,910
Cash, cash equivalents and restricted cash, end of period	$ 18,268	$ 78,744
Supplemental Cash Flow Information		
Cash paid for interest	$ 514	$ 286
Non-Cash Investing and Financing Activities		
Fixed asset additions in accounts payable and accrued expenses	$ 1,197	$ 192

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

NOTE 1 — ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of the Business

Molecular Templates, Inc. (the "Company") is a clinical stage biopharmaceutical company formed in 2001, with a biologic therapeutic platform for the development of novel targeted therapeutics for cancer and other diseases, headquartered in Austin, Texas. The Company's focus is on the research and development of therapeutic compounds for a variety of cancers. The Company operates its business as a single segment, as defined by U.S. generally accepted accounting principles ("U.S. GAAP").

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. GAAP pursuant to the requirements of the Securities and Exchange Commission ("SEC") for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for the fair presentation of results for the periods presented, have been included. The results of operations of any interim period are not necessarily indicative of the results of operations for the full year or any other interim period.

The condensed consolidated balance sheet at December 31, 2018 included herein was derived from the audited financial statements at that date, but includes a reclassification of $4.3 million from Other current assets to Grants revenue receivable in order to conform to current period presentation. Additionally, the condensed balance sheet also includes a reclassification of $26.6 million from In-process research and development to In-process research and development - held for sale in order to conform to current period presentation.

The preparation of condensed consolidated financial statements requires management to make estimates and assumptions that affect the recorded amounts reported therein. A change in facts or circumstances surrounding the estimates could result in a change to estimates and impact future operating results.

The unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the interim unaudited condensed consolidated financial statements have read or have access to the audited consolidated financial statements for the preceding fiscal year. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2018 included in the Company's Annual Report on Form 10-K filed with the SEC on March 29, 2019.

The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, and reflect the elimination of intercompany accounts and transactions.

Liquidity

At September 30, 2019, we had cash, cash equivalents, and marketable securities of $51.4 million. We have devoted substantially all of our resources to developing our ETB candidates and platform technology, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing for general and administrative support for these operations. Based on our current research and development plans, we expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements through 2020.

Recently Adopted Accounting Pronouncements

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") established Topic 842, Leases, by issuing Accounting Standards Update (ASU) No. 2016-02, which supersedes ASC 840, Leases, and requires lessees to recognize leases on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU No. 2018-01, Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements. Topic 842, as amended, (the "new lease standard") establishes a right-of-use model (ROU) that requires a lessee to recognize a ROU asset and lease liability on the consolidated balance sheets for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the consolidated statements of operation.

The Company adopted the new lease standard on January 1, 2019 and used the effective date asthe date of initial adoption. Consequently, financial information will not be updated, and the disclosures required under the new standard will not be provided for earlier periods.

The Company has completed a qualitative and quantitative assessment of its lease portfolio, in which the standard had a material impact on the condensed consolidated balance sheets but did not have an impact on the condensed consolidated statement of operations. Upon adoption, the Company recognized lease liabilities of approximately $4.7 million based on the present value of the remaining minimum rental payments under current leasing standards for our existing operating leases. The corresponding ROU assets of $4.2 million recognized upon adoption are net of deferred rent.

The new standard provides a number of optional practical expedients in transition. The Company elected the practical expedients, which permits lessees not to reassess under the new standard prior conclusions about lease identification, lease classification and initial direct costs. The Company did not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable to the Company. The new standard also provides practical expedients for an entity's ongoing accounting. The Company elected the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, ROU assets or lease liabilities will not be recognized, and this includes not recognizing ROU assets or lease liabilities for existing short-term leases of those assets in transition. The Company also elected the practical expedient to not separate lease and non-lease components for office leases.

Significant Accounting Policies

There have been no material changes to the Company’s significant accounting policies during the nine months ended September 30, 2019, as compared to the significant accounting policies disclosed in Note 1, Summary of significant accounting policies, to the consolidated financial statements in the Company’s Annual Report on Form 10-K for the year ended December 31, 2018, other than lease accounting as noted below.

Lease Accounting

At inception of a contract, the Company determines whether an arrangement is or contains a lease. For all leases, the Company determines the classification as either operating leases or finance leases. Operating leases are included in Operating lease right-of-use assets and Operating lease liabilities in our condensed consolidated balance sheets.

Lease recognition occurs at the commencement date and lease liability amounts are based on the present value of lease payments over the lease term. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. If a lease does not provide information to determine an implicit interest rate, the Company uses our incremental borrowing rate in determining the present value of lease payments. ROU assets represent the right to use an underlying asset for the lease term, and lease liabilities represent the obligation to make lease payments under the lease. ROU assets also include any lease payments made prior to the commencement date and exclude lease incentives received. Operating lease expense is recognized on a straight-line basis over the lease term. The depreciable life of assets and leasehold improvements are limited by the expected lease term, unless there is a transfer of title or purchase option reasonably certain of exercise. Lease agreements with both lease and non-lease components, are generally accounted for together as a single lease component.

Cash and Cash Equivalents

The Company considers temporary investments with original maturities of three months or less from date of purchase to be cash equivalents. Restricted cash is recorded in other assets, based on when the restrictions expire. Other assets include $3.0 million of restricted cash at September 30, 2019.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash and cash equivalents, investments, long term debt and accounts receivable.

The Company’s cash and cash equivalents are with two major financial institutions in the United States.

The Company performs an ongoing credit evaluation of its strategic partners’ financial conditions and generally does not require collateral to secure accounts receivable from its strategic partners. The Company’s exposure to credit risk associated with non-payment will be affected principally by conditions or occurrences within Takeda Pharmaceutical Company Ltd. (“Takeda”). Takeda accounted for approximately 80% and 28% of total revenues for the three months ended September 30, 2019 and 2018, respectively. Takeda accounted for approximately 90% and 35% of total revenues for the nine months ended September 30, 2019 and 2018,

respectively. There were no accounts receivable due from Takeda at September 30, 2019. There were $0.2 million in accounts receivable due from Takeda at December 31, 2018.

The Cancer Prevention Research Institute of Texas ("CPRIT") accounted for approximately 12% and 70% of total revenues for the three months ended September 30, 2019 and 2018, respectively. CPRIT accounted for approximately 8% and 63% of total revenues for the nine months ended September 30, 2019 and 2018, respectively. There were $5.6 million in accounts receivable due from CPRIT at September 30, 2019. There were $4.3 million in accounts receivable due from CPRIT at December 31, 2018. See also Note 3, Research and Development Agreements, regarding the collaboration and grant agreements.

Drug candidates developed by the Company may require approvals or clearances from the U.S. Food and Drug Administration ("FDA") or international regulatory agencies prior to commercial sales. There can be no assurance that the Company's drug candidates will receive any of the required approvals or clearances. If the Company were to be denied approval or clearance or any such approval or clearance were to be delayed, it would have a material adverse impact on the Company.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses, which amends the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the incurred-loss model with an expected-loss model. Accordingly, these financial assets will be presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than by reducing the carrying amount under the current, other-than-temporary-impairment model. The new standard is effective for interim and annual periods beginning on January 1, 2020, but may be adopted earlier. With certain exceptions, adjustments are to be applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings at the beginning of the fiscal year of adoption. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606, which clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC Topic 606 when the counterparty is a customer. In addition, Topic 808 precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. This guidance will be effective for the Company beginning January 1, 2020. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

NOTE 2 — NET LOSS PER COMMON SHARE

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by giving effect to all potential dilutive common shares, including outstanding options and warrants. More specifically, at September 30, 2019 and September 30, 2018, stock options, and warrants totaling approximately 8,121,000 and 7,723,000 shares, respectively, were excluded from the computation of diluted net loss per share as their effect would have been anti-dilutive.

NOTE 3 — RESEARCH AND DEVELOPMENT AGREEMENTS

Disaggregated Research and Development Revenue

Research and development revenue is attributable to regions based on the location of our collaboration partner's parent company headquarters. Research and development revenues disaggregated by location were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Japan	$ 2,903	$ 1,914	$ 14,527	$ 3,009
United States	284	117	284	197
Total research and development revenue	$ 3,187	$ 2,031	$ 14,811	$ 3,206

Related Party Collaboration Agreement - Takeda Pharmaceuticals, Inc.

Research and development revenue from related party relates to revenue from research and development agreements with Takeda Pharmaceuticals, Inc ("Takeda") and were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Takeda Collaboration Agreement	$ —	$ —	$ —	$ 92
Takeda Individual Project Agreement	—	1,246	54	1,909
Takeda Development and License Agreement	2,581	253	13,707	253
Takeda Multi-Target Agreement	322	415	766	755
Total research and development revenue	$ 2,903	$ 1,914	$ 14,527	$ 3,009

Deferred revenue and accounts receivable balances from the research and development agreements with Takeda were as follows (in thousands):

	September 30, 2019	December 31, 2018
Assets		
Unbilled revenue	$ —	$ 240
Liabilities		
Deferred revenue, current	$ 11,735	$ 26,231
Deferred revenue, non-current	1,236	2,670
Total deferred revenue	$ 12,971	$ 28,901

Takeda Development and License Agreement

On September 18, 2018, the Company entered into a Development and License Agreement with Takeda ("Takeda Development and License Agreement") for the development and commercialization of products incorporating or comprised of one or more CD38 SLT-A fusion proteins ("Licensed Products") for the treatment of patients with diseases such as multiple myeloma.

The Company, at its discretion, may choose to exercise its co-development option, which requires the Company to fund its share of development costs. If exercised, the Company is eligible to receive pre-clinical and clinical development milestone payments of up to $307.5 million upon the achievement of certain development milestones and regulatory approvals, and sales milestone payments of up to $325.0 million upon the achievement of certain sales milestone events.

If the Company does not exercise its co-development option, it is eligible to receive development milestone payments of up to $162.5 million upon the achievement of certain development milestones and regulatory approvals, and sales milestone payments of up to $175.0 million upon the achievement of certain sales milestone events.

The Company exercised the co-development option in July 2019 and may elect to end its co-development by providing Takeda with written notice of termination of the co-development. In the event the Company elects to end the co-development, the Company will be subject to reduced payments and royalty rates as set forth more specifically in the Takeda Development and License Agreement.

The Company will also be entitled to receive tiered royalties, subject to certain reductions, as percentages of annual aggregate net sales, if any, of Licensed Products. The royalty percentages would range from low double-digits to low twenties if the Company exercises its option to co-develop, and from high-single digits to low teens if the Company does not exercise its option to co-develop.

The Company identified one performance obligation at the inception of the Takeda Development and License Agreement, the research and development services for the CD38 ETBs, including manufacturing. The Company determined that research, development and commercialization license and the participation in the committee meetings are not distinct from the research and development services and therefore those promised services were combined into one combined performance obligation.

The total transaction price of $29.3 million consists of (1) the $30.0 million upfront payment, (2) a $10.0 million development milestone payment that is deemed probable of being achieved, (3) minus $10.7 million in expected co-share payment payable to Takeda during Early Stage Development, as defined in the Takeda Development and License Agreement. The expected co-share payment is considered variable consideration, and the Company applied a constraint using the expected value method. Significant

judgement was involved in determining transaction consideration, including the determination of the variable consideration, including the constraint on consideration.

At September 30, 2019, the other potential development milestones and sales milestones are not currently deemed probable of being achieved, as they are dependent on factors outside the Company's control. Therefore, these future development milestones and sales-based milestone payments have been fully constrained and are not included in the transaction price at September 30, 2019.

The Company recognizes revenue using a cost-based input measure. In applying the cost-based input method of revenue recognition, the Company used actual costs incurred relative to budgeted costs expected to be incurred for the combined performance obligation. These costs consist primarily of internal employee efforts and third-party contract costs. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligation over the estimated service period.

Concurrent with the exercise of the Company's co-development option in July 2019, the agreed upon collaboration budget was increased to cover additional research and development activities whereby both parties will continue to cost share. The Company evaluated the additional research and development services and concluded these services were distinct from services currently being provided and represented a cost sharing arrangement between the Company and Takeda. As such, research and development expenses for this performance obligation will be expensed as incurred. Any cost sharing reimbursements received from Takeda will be recorded as collaboration revenue, consistent with the Company's accounting policy for collaboration agreements.

For the three months ended September 30, 2019 and 2018, the Company recognized research and development revenue under the Takeda Development and License Agreement of $2.6 million and $0.3 million, respectively. For the nine months ended September 30, 2019 and 2018, the Company recognized research and development revenue under the Takeda Development and License Agreement of $13.7 million and $0.3 million, respectively. This revenue is deemed to be revenue from a related party (as discussed further in Note 4, Related Party Transactions). At September 30, 2019 and December 31, 2018, total deferred revenue related to the performance obligation was $9.7 million and $24.8 million, respectively.

Takeda Multi-Target Agreement

In June 2017, The Company entered into a Multi-Target Collaboration and License Agreement with Takeda (the "Takeda Multi-Target Agreement") in which the Company agreed to collaborate with Takeda to identify and generate ETBs, against two targets designated by Takeda. Takeda designated certain targets of interest as the focus of the research. Each party granted to the other nonexclusive rights in its intellectual property for purposes of the conduct of the research, and the Company agreed to work exclusively with Takeda with respect to the designated targets.

Under the Takeda Multi-Target Agreement, Takeda has an option during an option period to obtain an exclusive license under the Company's intellectual property to develop, manufacture, commercialize and otherwise exploit ETBs against the designated targets. The option period for each target ends three months after the completion of the evaluation of such designated target.

At April 2018, the Company received cumulative payments of $5.0 million from Takeda pursuant to the Takeda Multi-Target Agreement. The Company may receive additional payments from the following:

- $25.0 million in aggregate through the exercise of the option to license ETBs.
- Clinical development milestone payments of up to approximately $397.0 million, for achievement of development milestones and regulatory approval of collaboration products under the Takeda Multi-Target Agreement.
- Commercial milestone payments of up to $150.0 million, for achievement of pre-specified sales milestones related to net sales of all collaboration products under the Takeda Multi-Target Agreement.
- Tiered royalty payments of a mid-single to low-double digit percentage of net sales of any licensed ETBs, subject to certain reductions.
- Up to $10.0 million in certain contingency fees.

The Takeda Multi-Target Agreement will expire on the expiration of the option period (within three months after the completion of the evaluation of each designated target) for the designated targets if Takeda does not exercise its options, or, following exercise of the option, on the later of the expiration of patent rights claiming the licensed ETB or ten years from first commercial sale of a licensed ETB. The Takeda Multi-Target Agreement may be terminated sooner by Takeda for convenience or upon a material change of control, or by either party for an uncured material breach of the agreement. Under the Takeda Multi-Target Agreement, both parties have the right to terminate the agreement, with a specified notice period.

The Company evaluated the contract termination clause and concluded that it was a non-substantive termination provision. As such, an initial contract term was defined as the length of the termination notice period, with a deemed renewal option to continue the research and development services over the remainder of the contract term as a material right.

The Company determined that the promised goods and services under the Takeda Multi-TargetAgreement were the background IP license, the research and development services, manufacturing during the initial contract period, and a renewal option to continue the research and development services. The Company determined that there were two performance obligations: research and development services, and the renewal options. Since the background IP and manufacturing were not distinct from the research and development services, they were deemed to be one performance obligation. Transaction consideration was allocated to each of the performance obligations using an estimate of the standalone selling price, and revenues are recognized over the period that the research and development services occur. The Company also concluded that, since the option for the exclusive license is deemed to be at fair value, the option does not provide the customer with a material right and should be accounted for if and when the option is exercised.

During the three months ended September 30, 2019 and 2018, the Company recognized $0.3 million and $0.4 million, respectively, in research and development revenue under the Takeda Multi-Target Agreement. During the nine months ended September 30, 2019 and 2018, the Company recognized $0.8 million, for both periods, in research and development revenue under the Takeda Multi-Target Agreement. This revenue is deemed to be revenue from a related party (as discussed further in Note 4, Related Party Transactions). At September 30, 2019 and December 31, 2018, deferred revenue related to the performance obligation was $3.3 million and $4.1 million, respectively.

Takeda Collaboration Agreement

In October 2016, the Company entered into a collaboration and option agreement (the "Takeda Collaboration Agreement") with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda, to discover and develop CD38-targeting engineered toxin bodies ("ETBs"), which includes TAK-169 for evaluation by Takeda. All research and development services under the Takeda Collaboration Agreement were performed at December 31, 2018.

The Company recognized no research and development revenue under the Takeda Collaboration Agreement for the three and nine months ended September 30, 2019. The Company recognized no revenue for the three months ended September 30, 2018. The Company recognized revenue of $0.1 million for the nine months ended September 30, 2018. This revenue is deemed to be revenue from a related party (as discussed further in Note 4, Related Party Transactions).

Takeda Individual Project Agreement

In connection with the Takeda Collaboration Agreement, the Company entered into an Individual Project Agreement (the "Takeda Individual Project Agreement") with Takeda in June 2018, that was subsequently amended in July 2018. Under the Takeda Individual Project Agreement, the Company is responsible to perform certain research and development services relating to Chemistry, Manufacturing, and Controls ("CMC") work for three potential lead ETBs targeting CD38. In consideration of these services, the Company will receive up to $2.2 million in compensation that includes an increase in transaction consideration of $1.1 million as a result of the amendment to the Takeda Individual Project Agreement in July 2018.

All research and development services under the Takeda Collaboration Agreement were performed at March 31, 2019, as such, no associated research and development revenue was recognized for the three months ended September 30, 2019. The Company recognized $1.2 million of research and development revenue for the three months ended September 30, 2018. The Company recognized $0.1 million and $1.9 million of research and development revenue for the nine months ended September 30, 2019 and 2018, respectively.

Other Collaboration Agreements

In September 2016, the Company entered into a collaboration agreement with an undisclosed pharmaceutical company ("Other Collaboration Agreement") to generate ETBs and provide the customer (i) new ETBs generated using the customer's materials and (ii) ETB study molecules for testing and evaluation. The customer exercised an option under the Other Collaboration Agreement for the manufacture of additional quantities of ETB molecules in November 2017.

Under the Other Collaboration Agreement, the Company recognized $0.3 million and $0.1 million of research and development revenue for the three months ended September 30, 2019 and 2018, respectively. Under the Other Collaboration Agreement, the Company recognized $0.3 million and $0.2 million of research and development revenue for the nine months ended September 30, 2019 and 2018, respectively. All research and development services under the Other Collaboration Agreement were performed at December 31, 2018.

Grant Agreements

In September 2018, the Company entered into a cancer research agreement ("CD38 CPRIT Agreement") withCPRIT, under which CPRIT awarded a $15.2 million product development grant to fund research of a cancer therapy involving a CD38 targeting ETB. Pursuant to the CD38 CPRIT Agreement, the Company may also use such funds to develop a replacement CD38 targeting ETB, with or without a partner.

In November 2011, the Company entered into a cancer research agreement ("CPRIT Agreement") with CPRIT under which CPRIT awarded a $10.6 million product development grant for the CD20-targeting ETB MT-3724.

During the three months ended September 30, 2019 and 2018, the Company recognized $0.4 million and $4.7 million, respectively, in grant revenue under these awards. During the nine months ended September 30, 2019 and 2018, the Company recognized $1.3 million and $5.4 million, respectively, in grant revenue under these awards. Qualified expenditures submitted for reimbursement in excess of amounts received are recorded as receivables in Grant revenue receivable. At September 30, 2019 and December 31, 2018, the Company had $5.6 million and $4.3 million, respectively, recorded in Grants revenue receivable.

NOTE 4 — RELATED PARTY TRANSACTIONS

Takeda Collaboration and Stock Purchase

The Company has multiple agreements with Takeda. Takeda's Vice President and Global Head of Oncology and Neuroscience Business Development, Jonathan Lanfear, is a member of the Company's Board of Directors. Refer to Note 3, Research and Development Collaboration Agreements, for more details about the agreements between the Company and Takeda.

NOTE 5 —MARKETABLE SECURITIES AND FAIR VALUE MEASUREMENTS

The Company accounts for its marketable securities in accordance with ASC 820*"Fair Value Measurements and Disclosures."* ASC 820 defines fair value, establishes a framework for measuring fair value in U.S. GAAP, and expands disclosures about fair value measurements. ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company utilizes the market approach to measure fair value for its financial assets and liabilities. The market approach uses prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities. For Level 2 securities that have market prices from multiples sources, a "consensus price" or a weighted average price for each of these securities can be derived from a distribution-curve-based algorithm which includes market prices obtained from a variety of industrial standard data providers (e.g. Bloomberg), security master files from large financial institutions, and other third-party sources. Level 2 securities with short maturities and infrequent secondary market trades are typically priced using mathematical calculations adjusted for observable inputs when available.

The following table sets forth the Company's financial assets (cash equivalents and marketable securities) at fair value on a recurring basis (in thousands):

		Basis of Fair Value Measurements		
	September 30, 2019	Level 1	Level 2	Level 3
Money market funds	$ 14,261	$ 14,261	$ —	$ —
Commercial paper	19,841	—	19,841	—
United States Treasury Bills	7,246	—	7,246	—
United States government-related debt securities	7,006		7,006	
Corporate bonds	2,951	—	2,951	
Total	$ 51,305	$ 14,261	$ 37,044	$ —
Amounts included in:				
Cash and cash equivalents	$ 15,158			
Marketable securities, current	36,147			
Total cash equivalents and marketable securities	$ 51,305			

		Basis of Fair Value Measurements		
	December 31, 2018	Level 1	Level 2	Level 3
Money market funds	$ 82,843	$ 82,843	$ —	$ —
Commercial paper	12,825	—	12,825	—
Total	$ 95,668	$ 82,843	$ 12,825	$ —
Amounts included in:				
Cash and cash equivalents	$ 85,434			
Marketable securities, current	10,234			
Total cash equivalents and marketable securities	$ 95,668			

The Company invests in highly-liquid, investment-grade securities. The following is a summary of the Company's available-for-sale securities (in thousands):

	September 30, 2019				
	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value	Maturity Dates
Cash equivalents - money market funds, commercial paper and corporate bonds	$ 15,158	$ —	$ —	$ 15,158	9/2019 - 11/2019
Marketable securities, current - commercial paper, Treasury bills and corporate bonds	$ 36,127	$ 20	$ —	$ 36,147	10/2019 - 7/2020

	December 31, 2018				
	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value	Maturity Dates
Cash equivalents - money market funds and commercial paper	$ 85,434	$ —	$ —	$ 85,434	
Marketable securities, current - commercial paper	$ 10,234	$ —	$ —	$ 10,234	1/2019 - 9/2019

The following table sets forth the Company's financial liabilities measured at fair value on a recurring basis at the date indicated below:

		Basis of Fair Value Measurements		
	September 30, 2019	Level 1	Level 2	Level 3
2017 Warrants	$ —	$ —	$ —	$ —

	December 31, 2018	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
2017 Warrants	$ 3	$ —	$ —	$ 3

The Company determined the fair value of the liability associated with its 2017 Warrants to purchase in aggregate 377,273 shares of outstanding common stock using a Black-Scholes Model. See detailed discussion in Note 12, Stockholders' Equity, of the Company's previously filed Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 29, 2019 .

At September 30, 2019 and December 31, 2018 the fair value of the long-term debt approximated its carrying value of $3.0 million and $3.3 million, respectively, because it is carried at a market observable interest rate, which are considered Level 2.

The Company received no proceeds and $1.3 million of proceeds from the sale of available-for-sale securities for the three and nine months ended September 30, 2019, respectively, with an immaterial realized gain. The basis on which the cost of the security sold was determined is specific identification.

NOTE 6 — BALANCE SHEET COMPONENTS

Accrued liabilities consisted of the following (in thousands):

	September 30, 2019	December 31, 2018
Accrued liabilities:		
General and administrative	$ 619	$ 297
Clinical trial related costs	1,696	598
Non-clinical research and manufacturing operations	4,796	2,644
Payroll related	1,950	1,787
Other accrued expenses	44	31
Total Accrued liabilities	$ 9,105	$ 5,357

At September 30, 2019 and December 31, 2018, the Company had $13.2 million and $28.9 million, respectively, of Deferred revenue related to research and development agreements.

NOTE 7 — BORROWING ARRANGEMENTS

Perceptive Credit Facility

On February 27, 2018, the Company entered into a term loan facility with Perceptive Credit Holdings II, LP (Perceptive) in the amount of $10.0 million (the "Perceptive Credit Facility"). The Perceptive Credit Facility consists of a $5.0 million term loan, which was drawn on the effective date of the Perceptive Credit Facility, and an additional $5.0 million term loan to be drawn down at a future date. The Company used a portion of the proceeds from the Perceptive Credit Facility to pay off the existing debt facility with Silicon Valley Bank. Payments for the first 24 months are interest only and are paid quarterly. After the second anniversary of the closing date of the Perceptive Credit Facility, principal payments of $0.2 million are due each calendar quarter, with a final payment of $3.4 million due on February 27, 2022. This term loan facility matures on February 27, 2022 and includes both financial and non-financial covenants, including a minimum cash balance requirement. The Company is required to pay an exit fee of $0.1 million on a pro rata basis on the maturity date or the earlier date of repayment of the term loans in full. The exit fee is being accreted to interest expense over the term of the Perceptive Credit Facility using the effective interest method.

Borrowings under the Perceptive Credit Facility are secured by all the property and assets of the Company. The principal on the facility accrues interest at an annual rate equal to three-month LIBOR plus the Applicable Margin. The Applicable Margin is 11.00%. Upon the occurrence, and during the continuance, of an event of default, the Applicable Margin, defined above, will be increased by 4.00% per annum. The interest rate at September 30, 2019 was 13.10%.

For the three months ended September 30, 2019 and 2018, the Company recorded interest expense of $0.2 million, for both periods. For the three months ended September 30, 2019 and 2018, the Company recorded $0.1 million of amortization of debt discount related to the Perceptive Credit Facility, for both periods. For the nine months ended September 30, 2019 and 2018, the Company recorded interest expense of $0.5 million and $0.4 million, respectively. For the nine months ended September 30, 2019 and

2018, the Company recorded $0.2 million and $0.1 million, respectively, of amortization of debt discount related to the Perceptive Credit Facility.

In connection with the Perceptive Credit Facility, on February 27, 2018 the Company issued Perceptive a warrant to purchase 190,000 shares of the Company's common stock. The warrant is exercisable for a period of seven years from the date of issuance at an exercise price per share of $9.58, subject to certain adjustments as specified in the Warrant. See Note 12, Stockholders' Equity, of the Company's previously filed Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 29, 2019 for further discussion of the warrant. The fair value of the warrant of $1.5 million was recorded as a debt discount, which is being amortized to interest expense over the term of the Perceptive Credit Facility using the effective interest method

At September 30, 2019 and December 31, 2018, the Perceptive Credit Facility principal balance was $5.0 million. At September 30, 2019, the Company was in compliance with the non-financial covenants of the Perceptive Credit Facility.

Future required principal and final payments on the Perceptive Credit Facility were as follows at September 30, 2019 (in thousands):

2019	$ —
2020	800
2021	800
2022	3,500
2023	—
Total	5,100
Debt discount and deferred finance costs	(1,498)
Total Debt, net	3,602
Short-term debt, current	(601)
Total Long-term debt, non-current, net	$ 3,001

NOTE 8 – LEASES

On January 1, 2019, the Company adopted a new accounting standard that amends the guidance for the accounting and reporting of leases. Required disclosures have been made on a modified retrospective basis in accordance with the guidance of the standard. See Note 1, Organization and Summary of Significant Accounting Policies under the heading *Significant accounting policies.*

The Company has operating leases for administrative offices and R&D facilities, and certain finance leases for equipment. The operating leases have remaining terms of three years to nine years, and the finance leases have remaining terms of less than one year to two years. Leases with an initial term of 12 months or less will not be recorded on the condensed consolidated balance sheets as operating leases or finance leases, and the Company will recognize lease expense for these leases on a straight-line basis over the lease term. For leases commencing in 2019 and later, the Company will account for lease components (e.g., fixed payments including rent, real estate taxes, and insurance costs) with non-lease components (e.g. common area maintenance costs). Certain leases include options to renew, with renewal terms that can extend the lease term from one to five years. The exercise of lease renewal options for our existing leases is at our sole discretion and not included in the measurement of lease liability and ROU asset as they are not reasonably certain to be exercised. Certain finance leases also include options to purchase the leased equipment. The depreciable life of assets and leasehold improvements are limited by the expected lease term, unless there is a transfer of title or purchase option reasonably certain of exercise. The leases do not contain any residual value guarantees or material restrictive covenants.

As a result of applying the modified retrospective method to adopt the lease guidance, the following adjustments were made to accounts on the condensed consolidated balance sheet at January 1, 2019 (in thousands):

Balance Sheet	December 31, 2018	Effect of adoption of ASC 842	January 1, 2019
Assets			
Operating lease right-of-use assets, non-current	$ —	$ 4,180	$ 4,180
Total assets	$ —	$ 4,180	$ 4,180
Liabilities			
Operating lease liabilities, current	$ —	$ 976	$ 976
Deferred rent[1]	525	(525)	—
Operating lease liabilities, non-current	—	3,729	3,729
Total liabilities	$ 525	$ 4,180	$ 4,705

1. Included in Other liabilities on the balance sheet.

In January 2019, the Company entered into a lease agreement for an additional 57,000 square feet of administrative office and R&D space in Austin, Texas. The lease commenced March 2019 and expires August 2028 and does not contain an option to renew. The tables below include the impact of this lease. Upon the commencement of the lease, the Company recorded an operating lease ROU asset and a lease liability of $7.2 million. In connection with entering into the lease and in lieu of a cash deposit, the Company obtained a letter of credit of $3.0 million. Additionally, the Company has recorded an asset retirement obligation as a result of this lease which has a balance of $0.4 million at September 30, 2019.

At September 30, 2019, the Company did not have any operating and finance leases that have not yet commenced.

The components of lease expense were as follows (in thousands):

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Operating leases		
Operating lease expense	$ 597	$ 1,595
Variable lease expense	124	$ 356
Total operating lease expense	$ 721	$ 1,951
Finance leases		
Amortization of right-of-use asset	$ 2	$ 6
Interest on lease liabilities	1	3
Total finance lease expense	$ 3	$ 9
Sublease rental income	$ (27)	$ (110)

Sublease rental income is recorded in Interest and other income, net, on the Company's Condensed Consolidated Statement of Operations.

The following table summarizes the balance sheet classification of leases at September 30, 2019 (in thousands):

Operating leases		
Operating lease right-of-use assets, non-current	$	10,397
Operating lease liabilities, current[1]	$	963
Operating lease liabilities, non-current		10,573
Total operating lease liabilities	$	11,536
Finance leases		
Property and equipment, at cost	$	77
Accumulated depreciation		39
Property and equipment, net	$	38
Finance lease liabilities, current[1]	$	25
Finance lease liabilities, non-current[2]		3
Total finance lease liabilities	$	28

1. Included in other current liabilities.
2. Included other liabilities.

The following table presents other information on leases as of September 30, 2019:

	Weighted Average Remaining Lease Term	Weighted Average Discount Rate
Operating leases	7.1	6.74 %
Finance leases	1.0	7.02 %

Maturities of lease liabilities were as follows as of September 30, 2019 (in thousands):

	Operating Leases	Finance Leases
2019, remainder [1]	$ —	$ 8
2020	2,517	21
2021	2,589	—
2022	2,650	—
2023	1,961	—
Thereafter	7,236	—
Total lease payments	16,953	29
Less:		
Imputed interest	(3,877)	(1)
Total lease liabilities	$ 13,076	$ 28

1. Maturities for operating lease liabilities in 2019 is less than tenant improvement allowances expected to be received.

Supplemental cash flow information related to the Company's leases were as follows for the nine months ended September 30, 2019 (in thousands):

Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$	979
Operating cash flows from finance leases	$	3
Financing cash flows from finance leases	$	23
Right-of-use asset obtained in exchange for lease obligations:		
Operating leases	$	7,296

NOTE 9 — CONTRACTUAL COMMITMENTS

The Company is obligated under operating lease agreements covering the Company's office facilities in Austin, Texas and Jersey City, New Jersey. Facilities expense under the operating leases was approximately $0.7 million and $0.4 million for the three months ended September 30, 2019 and 2018, respectively, and $2.0 million and $1.0 million for the nine months ended September 30, 2019 and 2018, respectively.

Future minimum payments due under the operating lease agreements at September 30, 2019 were as follows (in thousands):

2019, remainder	$ 406
2020	2,517
2021	2,589
2022	2,650
2023	1,961
Thereafter	7,236
Total	$ 17,359

The Company has entered into project work orders for each of its clinical trials with clinical research organizations ("CRO") and related laboratory vendors. Under the terms of these agreements, the Company is required to pay certain upfront fees for direct services costs. Based on the particular agreement some of the fees may be for services yet to be rendered and are reflected as a current prepaid asset and have an unamortized balance of approximately $1.0 million at September 30, 2019. In connection with the Company's clinical trials, it has entered into separate project work orders for each trial with its CRO. The Company has entered into agreements with CROs and other external service providers for services, primarily in connection with the clinical trials and development of the Company's product candidates. The Company was contractually obligated for up to approximately $41.0 million of future services under these agreements at September 30, 2019, for which amounts have not been accrued as services have not been performed. The Company's actual contractual obligations will vary depending upon several factors, including the progress and results of the underlying services.

We have entered into estimated purchase obligations ranging from $1.0 million to $1.9 million which include signed orders for capital equipment.

As a result of our collaboration agreement with Takeda, we exercised our right to cost-share approximately 50% of the development costs for Phase I. Future clinical trial expense related to this trial has not been included within the purchase commitments because they are contingent on enrollment in clinical trials and the activities required to be performed by the clinical sites.

NOTE 10 — STOCK-BASED COMPENSATION

The Company recognizes stock-based compensation in accordance with ASC 718, "Compensation—Stock Compensation." Stock-based compensation expense, which consists of the compensation cost for employee stock options granted under the 2009 Stock Plan, as amended (the "2009 Stock Plan"), the Company's 2014 Equity Incentive Plan, as amended (the "2014 Equity Incentive Plan"), the Company's 2018 Equity Incentive Plan (the "2018 Equity Incentive Plan") and the value of options issued to non-employees for services rendered, was allocated to research and development and general and administrative expenses in the unaudited condensed consolidated statements of operations.

The following table summarizes the total stock-based compensation expense included in the Company's Statement of Operations for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 655	$ 331	$ 1,690	$ 827
General and administrative	872	866	2,640	1,935
Total stock-based compensation	$ 1,527	$ 1,197	$ 4,330	$ 2,762

At September 30, 2019, the total unrecognized compensation cost related to unvested stock-based awards granted to employees under the Company's equity incentive plans was approximately $14.3 million. This cost will be recorded as compensation expense on a ratable basis over the remaining weighted average requisite service period of approximately 2.78 years.

Valuation Assumptions

The Company estimated the fair value of stock options granted using the Black-Scholes option-pricing formula and a single option award approach. This fair value is being amortized ratably over the requisite service periods of the awards, which is generally the vesting period.

The fair value of employee stock options was estimated using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Employee Stock Options:				
Risk-free interest rate	1.87%	3.01%	2.47%	2.79%
Expected term (in years)	6.08	6.07	6.08	6.03
Dividend yield	—	—	—	—
Volatility	107.21%	109.00%	108.67%	107.00%
Weighted-average fair value of stock options granted	$ 4.96	$ 4.50	4.36	$ 5.82

To determine the expected term of the Company's employee stock options granted, the Company utilized the simplified approach as defined by SEC Staff Accounting Bulletin No. 107, "Share-Based Payment" ("SAB 107"). To determine the risk-free interest rate, the Company utilized an average interest rate based on U.S. Treasury instruments with a term consistent with the expected term of the Company's stock-based awards. To determine the expected stock price volatility for the Company's stock-based awards, the Company utilized the historical volatility of the Company's common stock. The Company records forfeitures as they occur. The fair value of the Company's stock-based awards assumes no dividends as the Company does not anticipate paying cash dividends on its common stock.

Equity Incentive Plans

The Company's equity incentive plans include the 2009 Stock Plan, the 2014 Equity Incentive Plan and the 2018 Equity Incentive Plan. No additional shares will be issued under the 2009 Stock Plan and the 2014 Equity Incentive Plan.

The following table summarizes stock option activity under the Company's equity incentive plans:

Options	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (in millions)
Outstanding at December 31, 2018	4,002,999	$ 10.43	6.4	$ 1.5
Granted	1,756,650	$ 5.24	—	$ —
Exercised	(218,498)	$ 5.95	—	$ —
Forfeitures	(941,908)	$ 23.00	—	$ —
Outstanding at September 30, 2019	4,599,243	$ 6.09	8.3	$ 5.8
Exercisable at September 30, 2019	1,587,602	$ 5.79	7.0	$ 3.0

The total intrinsic value of stock options exercised during the nine months ended September 30, 2019 and 2018, was $0.3 million and $1.6 million, respectively, as determined at the date of the option exercise.

Cash received from stock option exercises was $1.3 million and $0.2 million for the nine months ended September 30, 2019 and 2018, respectively. The Company issues new shares of common stock upon exercise of options. In connection with these exercises, there was no tax benefit realized by the Company due to the Company's current loss position.

NOTE 11 – IN-PROCESS RESEARCH AND DEVELOPMENT

In-process research and development represent the fair value of the Company's legacy program, Evofosfamide, which was acquired as a part of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), dated as of March 16, 2017, by and among the Company (formerly known as Threshold Pharmaceuticals, Inc.), Merger Sub, Inc., our wholly owned subsidiary, and Molecular Templates OpCo, Inc. or what was then known as "Molecular Templates, Inc." For more information refer to Note 3 included in the Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 29, 2019.

Fair value of In-process research and development is estimated based upon internal evaluation of each asset that includes quantitative analyses of net revenue and cash flows, review of recent sales of similar assets and market responses based upon discussions in connection with offers received from potential buyers. Certain factors used for these types of nonrecurring fair value measurements are considered Level 3 inputs. During the three and nine months ended September 30, 2019, the Company's board and management classified this asset as held for sale. The Company obtained a fair value estimate, from a third party specialist as of August 1, 2019, and determined the asset was impaired and the value was not recoverable. During the three and nine months ended September 30, 2019, the Company recorded a related impairment of $22.1 million. Future write-downs of the asset are possible based upon the amount of proceeds from an eventual sale of the asset.

Additionally, the Company has reclassified the remaining $4.5 million to In-process research and development - held for sale as the Company plans to sell the asset within the next year.

See Part II, Item 5 (Other Information) for more information.

NOTE 12 – STOCKHOLDERS' EQUITY

Public offering

On September 25, 2018, the Company closed its underwritten public offering (the "Public Offering") of 9,430,000 shares of its common stock, which included the exercise in full by the underwriters of their option to purchase 1,230,000 additional shares of common stock, at a price to the public of $5.50 per share. The net proceeds to the Company from the offering, after deducting the underwriting discounts and commissions and offering expenses payable by the Company, were approximately $48.1 million.

NOTE 13 – PROPERTY AND EQUIPMENT

Property and equipment comprise the following (in thousands):

	September 30, 2019	December 31, 2018
Laboratory equipment	$ 7,256	$ 4,676
Leasehold improvements	8,857	3,274
Furniture and fixtures	142	89
Computer and equipment	282	145
	16,537	8,184
Less: Accumulated depreciation	(2,653)	(1,333)
Total property and equipment, net	$ 13,884	$ 6,851

Depreciation expense for the three months ended September 30, 2019 and 2018 was $0.5 million and $0.4 million, respectively.

Depreciation expense for the nine months ended September 30, 2019 and 2018 was $1.3 million and $0.6 million, respectively.

During Q3 2019 the Company completed the new R&D facility at its new location in Austin, Texas and continued construction on the expansion of its cGMP facility. In connection with the completion of its new R&D facility in September 2019 the Company recorded a related asset retirement obligation ("ARO") asset and liability of $0.4 million.

In connection with the continued construction of the expansion of the cGMP facility the Company recorded a related ARO asset and liability of $0.4 million at September 30, 2019. The expansion is expected to be completed during Q1 2020.

At September 30, 2019 and December 31, 2018, the Company had net ARO assets totaling $0.9 million and $0.1 million, respectively. The ARO assets are included in Leasehold improvements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in the Annual Report on Form 10-K for the year ended December 31, 2018 filed with the SEC on March 29, 2019.

Certain matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as "may," "will," "anticipate," "estimate," "expects," "projects," "intends," "plans," "believes" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

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 and under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018.

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.

You should read the following discussion and analysis of financial condition and results of operations together with Part I, Item 1, "Financial Statements," which includes our financial statements and related notes, elsewhere in this Quarterly Report on Form 10-Q.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery and development of engineered toxin bodies, or ETBs, which are differentiated, targeted, biologic therapeutics for cancer. We believe ETBs offer a differentiated mechanism of action that may address some of the limitations associated with currently available cancer therapeutics. ETBs utilize a genetically engineered form of Shiga-like Toxin A subunit, or SLTA, a ribosome inactivating bacterial protein that can be targeted to specifically destroy cancer cells.

Business

We are a clinical-stage biopharmaceutical company focused on the discovery and development of differentiated, targeted, biologic therapeutics for cancer. We utilize our proprietary biologic drug platform to design and generate ETBs, which we believe provides a differentiated mechanism of action that may be beneficial in patients resistant to currently available cancer therapeutics. ETBs use a genetically engineered version of the SLTA. In its wild-type form, SLT is thought to induce its own entry into a cell when proximal to the cell surface membrane, self-route to the cytosol, and enzymatically and irreversibly shut down protein synthesis via ribosome inactivation. SLTA is normally coupled to its cognate Shiga-like Toxin B subunit, or SLTB, to target the CD77 cell surface marker, a non-internalizing glycosphingolipid. In our scaffold, a genetically engineered SLTA subunit with no cognate SLTB component is genetically fused to antibody domains or fragments specific to a cancer target, resulting in a biologic therapeutic that can identify the particular target and specifically kill the cancer cell. The antibody domains may be substituted with other antibody domains having different specificities to allow for the rapid development of new drugs to selected targets in cancer.

ETBs combine the specificity of an antibody with SLTA's potent mechanism of cell destruction. Based on the disease setting, we have created ETBs that have reduced immunogenicity and are capable of delivering additional payloads into a target cell. Immunogenicity is the ability of a foreign substance to provoke an immune response in a host. ETBs have relatively predictable pharmacokinetic, or PK, and absorption, distribution, metabolism and excretion, or ADME, profiles and can be rapidly screened for desired activity in robust cell-based and animal-model assays. Because SLTA can induce internalization against non- and poorly-internalizing receptors, the universe of targets for ETBs should be substantially larger than that seen with antibody drug conjugates, or ADCs, which are not likely to be effective if the target does not readily internalize the ADC payload.

ETBs have a differentiated mechanism of cell-kill in cancer therapeutics (the inhibition of protein synthesis via ribosome destruction), and we have preclinical and clinical data demonstrating the utility of these molecules in chemotherapy-refractory cancers. ETBs have shown good safety data in multiple animal models as well as in our clinical studies to date. We believe the target specificity of ETBs, their ability to self-internalize, their potent and differentiated mechanism of cell kill and their safety profile provide opportunities for the clinical development of these agents to address multiple cancer types.

Our initial approach to drug development in oncology involves the selection of lead compounds to validated targets in cancer. We have developed ETBs for various targets, including CD20, CD38, HER2, and PD-L1. CD20 is central to B cell malignancies and is clinically validated as a target for the treatment of lymphomas and autoimmune disease. CD38 has been validated as a meaningful clinical target in the treatment of multiple myeloma. PD-L1 is central to immune checkpoint pathways and is a target expressed in a variety of solid tumor cancers.

Our lead compound, MT-3724, is an ETB that recognizes CD20, a B cell marker and is currently in multiple Phase II studies. The dose escalation portion of its first Phase I clinical trial has been completed for MT-3724 and was followed by the initiation of a Phase Ib expansion cohort, which was initiated in the fourth quarter of 2017. Results of the Phase I/Ib study are scheduled to be presented at the American Society of Hematology (ASH) Annual Meeting, December 7-10, 2019 in Orlando, FL.

In the first quarter of 2019, we initiated a Phase II monotherapy study with MT-3724, which has the potential to be a pivotal study. We have also initiated a Phase II combination study with MT-3724 and chemotherapy (gemcitabine and oxaliplatin) in earlier lines of DLBCL and a second Phase II combination study with MT-3724 and Revlimid® (lenalidomide) in earlier lines of DLBCL. We expect to provide an update on all three Phase II studies of MT-3724 in the fourth quarter of 2019.

We filed an IND for MT-5111, our ETB targeting HER2, in March 2019 and the IND was accepted in April 2019. We began dosing patients in a Phase I study of MT-5111 in the fourth quarter of 2019. We anticipate providing an update on this study in the fourth quarter of 2019. Takeda filed an IND for TAK-169, our jointly discovered ETB targeting CD38, in May 2019 and the IND was accepted in June 2019. Phase I dosing for TAK-169 is expected to start in the second half of 2019. We anticipate starting a Phase I study for our ETB targeting PD-L1 in 2020.

We have built up multiple core competencies around the creation and development of ETBs. We developed the ETB technology in-house and continue to make iterative improvements in the scaffold and identify new uses of the technology. We also developed the proprietary process for manufacturing ETBs under Good Manufacturing Process, or GMP standards and continue to make improvements to its manufacturing processes.

We have conducted multiple GMP manufacturing runs with our lead compound and believe this process is robust and could support commercial production with gross margins that are similar to those seen with antibodies.

We are a clinical-stage company and have not generated revenue from product sales. Our ability to generate revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our ETB candidates. Since inception, we have incurred significant operating losses. For the three months ended September 30, 2019 and 2018, we incurred net losses of $38.2 million and $5.2 million, respectively. For the nine months ended September 30, 2019 and 2018, we incurred net losses of $53.5 million and $23.7 million, respectively. At September 30, 2019, we had an accumulated deficit of $148.2 million.

In September 2018, we completed a public offering of 9,430,000 shares of common stock at an offering price of $5.50 per share, which included the exercise in full by the underwriters of their option to purchase up to 1,230,000 additional shares of common stock. We received net proceeds of approximately $48.1 million, after deducting underwriting discounts, commissions and estimated offering related transaction costs. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations.

On December 21, 2018, we filed a universal shelf registration statement on Form S-3 (Registration No. 333-228975) with the SEC, which was automatically declared effective on February 13, 2019. In December 2018 we entered into a controlled equity

offering sales agreement (the "Sales Agreement') with Cantor Fitzgerald & Co. ("Cantor"), pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $50,000,000 from time to time through Cantor acting as our agent. Under the Sales Agreement, Cantor may sell the shares by any method permitted by law and deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act. To date, we have not sold any shares under the Sales Agreement.

However, we expect to incur significant expenses and operating losses for the foreseeable future as we advance our lead ETB candidates through clinical trials, progress our pipeline ETB candidates from discovery through pre-clinical development, and seek regulatory approval and pursue commercialization of our ETB candidates. In addition, if we obtain regulatory approval for any of our ETB candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In addition, we may incur expenses in connection with the in-license or acquisition of additional technology to augment or enable development of future ETB candidates. Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

As a result, we will need additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity and debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

We expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through 2020.

Collaboration Agreements

Takeda Pharmaceuticals

We recognize collaboration revenue over time as a customer obtains control of promised goods or services. For more information about our collaboration revenue, please see Note 3, Research and Development Agreements to our unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2019, included in this Quarterly Report on Form 10-Q.

Takeda Collaboration and Individual Project Agreements

In October 2016, we entered into the Takeda Collaboration Agreement to discover and develop CD38-targeting ETBs, which includes TAK-169 for evaluation by Takeda. As of December 31, 2018, we had received $2.0 million under the Takeda Collaboration Agreement and all research and development services were performed at December 31, 2018.

In connection with the Takeda Collaboration Agreement, we entered into the Takeda Individual Project Agreement in June 2018 that was subsequently amended in July 2018. Under the Takeda Individual Project Agreement, we were responsible for performing certain research and development services relating to Chemistry, Manufacturing, and Controls ("CMC") work for three potential lead ETBs targeting CD38, where we could receive $2.2 million in compensation. As of June 30, 2019, we had received $2.2 million under the Takeda Individual Project Agreement. All services were performed at March 31,2019.

Takeda Development and License Agreement

On September 18, 2018, we entered into a Development Collaboration and Exclusive License Agreement with Takeda ("Takeda Development and License Agreement") for the development and commercialization of products incorporating or comprised of one or more CD38 SLT-A fusion proteins ("Licensed Products") for the treatment of patients with diseases such as multiple myeloma.

The agreement has a total transaction price of $29.3 million, consisting of(1) the $30.0 million upfront payment, (2) a $10.0 million development milestone payment that is deemed probable of being achieved, (3) minus $10.7 million in expected co-share payment payable to Takeda during Early Stage Development. We exercised our co-development option, which requires us to fund our share of development costs, to become eligible to receive up to an additional $307.5 million in milestone payments upon the achievement of certain development and regulatory milestone events and up to an additional $325 million in milestone payments upon the achievement of certain sales milestone events. If we do not continue to exercise our co-development option, we may receive up to an additional $162.5 million in milestone payments upon the achievement of certain development and regulatory milestone events and up to an additional $175 million in milestone payments upon the achievement of certain sales milestone events. We will also be entitled to receive tiered royalties, subject to certain reductions, as percentages of annual aggregate net sales, if any, of Licensed Products. The royalty percentages would range from low double-digits to low twenties if we exercise our option to co-develop, and from high-single digits to low teens if we do not exercise its option to co-develop.

The parties will share in co-development costs in accordance with the terms of the Takeda Development and License Agreement, and Takeda will be responsible for all costs incurred commercializing the Licensed Products.

Unless earlier terminated, the Takeda Development and License Agreement will expire upon the expiration of the last-to-expire co-development royalty term (or royalty term, if applicable) for a Licensed Product. Takeda has the right to terminate the Takeda Development and License Agreement at any time upon no less than ninety days' prior written notice to us. We or Takeda may, subject to specified cure periods, terminate the Takeda Development and License Agreement in the event of the other party's uncured material breach, and either party may terminate the Takeda Development and License Agreement under specified circumstances relating to the other party's insolvency.

Concurrent with the exercise of the Company's co-development option in July 2019, the agreed upon collaboration budget was increased to cover additional research and development activities whereby both parties will continue to cost share. The Company evaluated the additional research and development services and concluded these services were distinct from services currently being provided and represented a cost sharing arrangement between the Company and Takeda. As such, research and development expenses for this performance obligation will be expensed as incurred. Any cost sharing reimbursements received from Takeda will be recorded as collaboration revenue, consistent with the Company's accounting policy for collaboration agreements. Therefore, in July 2019 the Company did not adjust the percent complete as calculated from inception of the agreement resulting in revenue of $2.6 million recognized during the three months ended September 30, 2019.

Takeda Multi-Target Agreement

In June 2017, we entered into a multi-target collaboration and license agreement with Takeda (the "Takeda Multi-Target Agreement"), pursuant to which we will collaborate with Takeda to identify, generate and evaluate ETBs, against certain targets designated by Takeda. Pursuant to the Takeda Multi-Target Agreement, Takeda will designate certain targets of interest as the focus of the research. Takeda will provide to us targeting moieties against the designated targets and we will create and characterize ETBs against those targets and provide them to Takeda for further evaluation. We are entitled to receive up to $5.0 million in technology access fees and research and development fees associated with our performance and completion of our obligations under the agreement. In December 2017, Takeda nominated both targets under the Takeda Multi-Target Agreement. At September 30, 2019, we have received $5.0 million under the Takeda Multi-Target Agreement.

Under the Takeda Multi-Target Agreement, Takeda has an option to acquire an exclusive license under our intellectual property to develop, manufacture, commercialize and otherwise exploit ETBs against the designated targets. Upon exercise of the option, Takeda is obligated to use commercially reasonable efforts to develop and obtain regulatory approval of any licensed ETBs in major market countries, and thereafter to commercialize licensed ETBs in those countries. We are obligated to manufacture ETBs to support research and clinical development through Phase I clinical trials, provided that Takeda can assume manufacturing responsibility at any time.

Under the Multi-Target Agreement, license fees and research and early and late state development milestone payments which are based on various research and clinical milestones, including the initiation of certain clinical studies, the submission for approval of a drug candidate to certain regulatory authorities for marketing approval and the commercial launch of collaboration products could become due. We may receive additional net milestone payments of $25.0 million in aggregate through the exercise of the option to license ETBs under the Takeda Multi-Target Agreement. Additionally, we are entitled to receive up to approximately $547.0 million in additional milestone payments through preclinical and clinical development and commercialization. We are also entitled to tiered royalty payments of a mid-single to low-double digit percentage of net sales of any licensed ETBs, subject to certain reductions. Finally, we are entitled to receive up to $10.0 million in certain contingency fees.

The Takeda Multi-Target Agreement will expire on the expiration of the option period for the designated targets if Takeda does not exercise its options, or, following exercise of the option, on the later of the expiration of patent rights claiming the licensed ETB or ten years from first commercial sale of a licensed ETB. The Takeda Multi-Target Agreement may be sooner terminated by Takeda for convenience; or by us upon a change of control; or by either party for an uncured material breach of the agreement.

For more information about our collaboration agreements, please see Note 3, Research and Development Agreements to our unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2019, included in this Quarterly Report on Form 10-Q.

CPRIT Grant Contract

On September 18, 2018, we entered into a Cancer Research Grant Contract (the "CPRIT Agreement") with CPRIT, in connection with a grant of approximately $15.2 million awarded by CPRIT to us in November 2016 to fund research of a cancer therapy involving an ETB that is targeting CD38 (TAK-169) (the "Award"). Pursuant to the CPRIT Agreement, we may also use such funds to develop a replacement CD38 targeting ETB, with or without a partner. The Award is contingent upon funds being available during the term of the Agreement and subject to CPRIT's ability to perform its obligations under the Agreement as well as our progress towards achievement of specified milestones, among other contractual requirements.

In November 2011, we were awarded a $10.6 million product development grant from CPRIT for its CD20-targeting ETB MT-3724.

Subject to the terms of the Agreement, full ownership of any CPRIT funded technology and CPRIT funded intellectual property rights developed pursuant to the CPRIT Agreement will be retained by us, our Collaborators (as defined in the CPRIT Agreement) and, to the extent applicable, any participating third party (the "Project Results"). With respect to any Project Results, we agreed to grant to CPRIT a nonexclusive, irrevocable, royalty-free, perpetual, worldwide license, solely for academic, research and other non-commercial purposes, under the Project Results and to exploit any necessary additional intellectual property rights, subject to certain exclusions.

We will pay to CPRIT, during the term of the CPRIT Agreement, certain payments equal to a percentage of revenue ranging from the low- to mid-single digits. These payments will continue up to and until CPRIT receives an aggregate amount of 400% of the sum of all monies paid to us by CPRIT under the CPRIT Agreement. If we are required to obtain a license from a third party to sell any such product, the revenue sharing percentages may be reduced. In addition, once we pay CPRIT 400% of the monies we have received under the CPRIT Agreement, we will continue to pay CPRIT a revenue-sharing percentage of 0.5%.

The CPRIT Agreement will terminate, with certain obligations extending beyond termination, on the earlier of (a) November 30, 2019 or (b) the occurrence of any of the following events: (i) by mutual written consent of the parties, (ii) by CPRIT for an Event of Default (as defined in the CPRIT Agreement) by us, (iii) by CPRIT if allocated funds should become legally unavailable during the term of the CPRIT Agreement and CPRIT is unable to obtain additional funds or (iv) by us for convenience. CPRIT may approve a no cost extension for the CPRIT Agreement for a period not to exceed six months after the termination date if additional time is required to ensure adequate completion of the approved project, subject to the terms and conditions of the CPRIT Agreement. In October 2019, the Company submitted a no cost extension request for an additional six-month period.

Financial Operations Overview

Revenue

Our revenue has consisted principally of research and development revenue and grant revenue.

Research and Development revenue primarily relates to our collaboration agreements with Takeda which are accounted for using the percentage-of-completion cost-to-cost method. We have an ongoing research collaboration with Takeda related to the evaluation of our ETB technology that was initiated in the fourth quarter 2016. The Takeda Collaboration Agreement, Takeda License Agreement and Takeda Multi-Target Agreement provide for upfront technology access fees, milestone payments and reimbursement payments.

Grant revenue relates to our Cancer Prevention Research Institute of Texas, or CPRIT grants for a CD-20 ETB (MT-3724) and a CD-38 ETB (TAK-169). CPRIT grant funds for MT-3724 are provided to us in advance as conditional cost reimbursement where revenue is recognized as allowable costs are incurred. Amounts collected in excess of revenue recognized are recorded as deferred revenue. CPRIT grant funds for TAK-169 are provided to us in arrears as cost reimbursement where revenue is recognized as allowable costs are incurred. Revenue recognized in excess of amounts collected are recorded as unbilled revenue.

For more information about our revenue recognition policy, please see Note 1, Summary of Significant Accounting Policies to our audited consolidated financial statements for the year ended December 31, 2018, included in our Annual Report on Form 10-Kfor the year ended December 31, 2018 filed with the SEC on March 29, 2019

We have no products approved for sale. Other than the sources of revenue described above, we do not expect to receive any revenue from any ETB candidates that we develop, including MT-3724, TAK-169 and other pre-clinical ETB candidates, until we obtain regulatory approval and commercialize such products, or until we potentially enter into collaborative agreements with third parties for the development and commercialization of such candidates.

Research and Development Expenses

Research and development expenses consist principally of:

- salaries for research and development staff and related expenses, including stock-based compensation expenses;
- costs for current good manufacturing practices, or cGMP, manufacturing of drug substances and drug products by contract manufacturers;
- fees and other costs paid to clinical trials sites and clinical research organizations, ("CROs"), in connection with the performance of clinical trials and preclinical testing;
- costs for consultants and contract research;
- costs of laboratory supplies and small equipment, including maintenance; and
- depreciation of long-lived assets.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including the initiation and enrollment of patients in clinical trials and manufacture of drug materials for clinical trials. We expect research and development expenses to increase as we advance the clinical development of MT-3724 and further advance the research and development of our pre-clinical ETB candidates, and other earlier stage products. The successful development of our ETB candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from any of our ETB candidates. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- clinical trials and early-stage results;
- the terms and timing of regulatory approvals; and
- the ability to market, commercialize and achieve market acceptance for MT-3724, or any other ETB candidate that we may develop in the future.

Any of these variables with respect to the development of MT-3724, co-development of TAK-169, or any other ETB candidate that we may develop could result in a significant change in the costs and timing associated with the development of MT-3724, co-development of TAK-169, or such other ETB candidates. For example, if the U.S. Food and Drug Administration, or the FDA, the European Medical Association or the EMA, or other regulatory authority were to require us to conduct pre-clinical and clinical studies beyond those which we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of our clinical development programs.

General and Administrative Expenses

Our general and administrative expenses consist principally of:

- salaries for employees other than research and development staff, including stock-based compensation expenses;
- professional fees for auditors and other consulting expenses related to general and administrative activities;
- professional fees for legal services related to the protection and maintenance of our intellectual property and regulatory compliance;
- cost of facilities, communication and office expenses;

- information technology services; and
- depreciation of long-lived assets.

We expect that our general and administrative costs will increase in the future as our business expands and we increase our headcount to support the expected growth in our operating activities. Additionally, we expect these expenses will also increase in the future as we incur additional costs associated with operating as a public company. These increases will likely include additional legal fees, accounting and audit fees, management board and supervisory board liability insurance premiums and costs related to investor relations. In addition, we expect to grant stock-based compensation awards to key management personnel and other employees.

Other Income (Expense)

Other income (expense) mainly includes interest income earned on our cash and marketable securities balances held, and interest expense on our outstanding borrowings.

Change in fair value of warrant liability

Change in fair value of warrant liability relates to the change in fair value of our warrants categorized as liabilities.

Results of Operations

Revenues

The table below summarizes our revenues as follows (in thousands):

	Three Months Ended September 30,			
	2019	2018	Change ($)	Change (%)
Research and development revenue - from related party	$ 2,903	$ 1,914	$ 989	52 %
Research and development revenue - other	284	117	167	143 %
Grant revenue	431	4,721	(4,290)	-91 %
Total revenue	$ 3,618	$ 6,752	$ (3,134)	-46 %

	Nine Months Ended September 30,			
	2019	2018	Change ($)	Change (%)
Research and development revenue - from related party	$ 14,527	$ 3,009	$ 11,518	383 %
Research and development revenue - other	284	197	87	44 %
Grant revenue	1,262	5,395	(4,133)	-77 %
Total revenue	$ 16,073	$ 8,601	$ 7,472	87 %

Research and Development Revenue – from related party

Concurrent with the exercise of the Company's co-development option in July 2019, the agreed upon collaboration budget was increased to cover additional research and development activities whereby both parties will continue to cost share. The Company evaluated the additional research and development services and concluded these services were distinct from services currently being provided and represented a cost sharing arrangement between the Company and Takeda. As such, research and development expenses for this performance obligation will be expensed as incurred. Any cost sharing reimbursements received from Takeda will be recorded as collaboration revenue, consistent with the Company's accounting policy for collaboration agreements. Therefore, in July 2019 the Company did not adjust the percent complete as calculated from inception of the agreement resulting in $2.6 million of revenue recognized during the three months ended September 30, 2019 and as such contributed to the increase in research and development revenue of $1.0 million from 2018. As a result, the Company also recognized revenue of $13.7 million under this collaboration for the nine months ended September 30, 2019 and as such contributed to the increase in research and development revenue of $11.5 million from 2018.

The increase in research and development revenue – from related party for the nine months ended September 30, 2019 was primarily due to research and development revenues that were recognized from the services provided under the new Takeda

Development and License Agreement (TAK-169) prior to the contract modification in July 2019. The Company entered into the agreement September 2018.

For more information about our collaboration agreements, please see Note 3, Research and Development Agreements, to our unaudited condensed financial statements for the three and nine months ended September 30, 2019, included in this Quarterly Report on Form 10-Q.

Grant Revenue

The decrease in grant revenue for the three and nine months ended September 30, 2019 was primarily due to the Company incurring significantly less expenses that met the CPRIT reimbursement criteria for grant CD-38 targeting ETB. Additionally, the three months ended September 30, 2018 included a year-to-date true-up adjustment for grant CD-38 targeting ETB.

Operating expenses

The table below summarizes our operating expenses as follows (in thousands):

	Three Months Ended September 30,			
	2019	2018	Change ($)	Change (%)
Research and development expenses	$ 15,249	$ 8,290	$ 6,959	84 %
General and administrative expenses	4,509	3,538	971	27 %
Loss on impairment of long-lived assets	22,123	—	22,123	100 %
Total operating expenses	$ 41,881	$ 11,828	$ 30,053	254 %

	Nine Months Ended September 30,			
	2019	2018	Change ($)	Change (%)
Research and development expenses	$ 33,946	$ 22,640	$ 11,306	50 %
General and administrative expenses	14,049	10,165	3,884	38 %
Loss on impairment of long-lived assets	22,123	—	22,123	100 %
Total operating expenses	$ 70,118	$ 32,805	$ 37,313	114 %

Research and Development Expenses

The table below summarizes our research and development expenses as follows (in thousands):

	Three Months Ended September 30,			
	2019	2018	$ Change	% Change
Program costs	$ 8,001	$ 5,076	$ 2,925	58 %
Employee compensation	4,521	1,957	2,564	131 %
Laboratory costs	886	633	253	40 %
Other research and development costs	1,841	624	1,217	195 %
Total research and development expenses	$ 15,249	$ 8,290	$ 6,959	84 %

	Nine Months Ended September 30,			
	2019	2018	$ Change	% Change
Program costs	$ 17,089	$ 13,518	$ 3,571	26 %
Employee compensation	10,965	5,523	5,442	99 %
Laboratory costs	2,011	1,759	252	14 %
Other research and development costs	3,881	1,840	2,041	111 %
Total research and development expenses	$ 33,946	$ 22,640	$ 11,306	50 %

Research and development ("R&D") expenses increased during the three and nine months ended September 30, 2019 primarily due to research and development expenses related to the discovery and development of ETBs. The Company is party to multiple collaboration agreements with a related party which can also contribute to increased R&D expense, typically offset by revenue from the related party.

Headcount increased in R&D to 111 from 46 or 141% from September 30, 2019 and September 30, 2018, respectively, in support of increased clinical trials and ramp up of GMP manufacturing facilities and support staff. This staffing increase resulted in increased employee compensation costs for the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018, respectively. Program costs increased during the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018, respectively.

Program costs increased $3.0 million and $3.6 million during the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018, respectively. Clinical Trials were the main driver as costs increased $2.3 million and $5.1 million during the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018, respectively. In 2018 one clinical trial was underway, today there are four; MT-3724 DLBCL has two Phase 2 studies in process, MT-5111 (HER2) and TAK-169 (CD38) are both in Phase 1. Three other platforms are in the preclinical phase. Expenses as of the end of the quarter are being driven by MT-3724 and HER2 centric clinical trials.

Non-clinical Development and CMC Operations partially offset the increase in Clinical expense. The expense reductions in these areas reflect the progression of the programs listed above out into clinical trials. These areas are now in a support role. Efforts to increase and refine the Company's manufacturing capabilities for its GMP facilities contributed $0.1 million and $0.8 million during the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018, respectively. These facilities are being created to control quality, quantity and timeliness of supply for current and future clinical trials as well as control future costs of production.

Other R&D costs (mainly facilities allocations and depreciation expense) increased $1.2 million during the three months ended September 30, 2019 and increased by $2.0 million for the nine months ended September 30, 2019 compared to the same periods ended September 30, 2018, respectively. Facilities allocation increased by $0.7 million from the same quarter a year ago and $1.2 million for the nine months ended September 30, 2019 from the same period a year ago. Depreciation expense increased $0.3m from the same quarter a year ago and $0.7 million for the nine months ended September 30, 2019 from the same period a year ago. The increase was driven primarily by equipment and facilities expense as GMP facilities were constructed and equipped to support the Collaboration Agreements described above.

General and Administrative Expenses

General and administrative expenses increased $1.0 million during the three months ended September 30, 2019 as compared to the three months ended September 30, 2018 and increased by $3.9 million for the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018.

Professional services, legal and consulting costs increased $1.1 million during the three months ended September 30, 2019 and by $1.7 million for the nine months ended September 30, 2019 versus the same periods in 2018. Legal and consulting services were secured to advise on various funding and partnership matters. IP Legal services were in support of increased patent related filings and investigations. Payroll and related costs increased by $1.5 million for the nine months ended September 30, 2019 versus the same period in 2018, mostly driven by stock compensation expense and payroll related costs as headcount grew to 21 from 17 employees. New hires were in HR, Facilities and Administration, specifically to support R&D Research and GMP expansion in support of an increase in R&D hiring and new facilities. Facilities costs increased $0.4 million during the three months ended September 30, 2019 and by $1.1 million for the nine months ended September 30, 2019, mainly due to increased rent. IT related costs increased $0.1 million during the three months ended September 30, 2019 and by $0.3 million for the nine months ended September 30, 2019, versus the same period in 2018, primarily due SaaS applications and outsourced IT support.

Loss on impairment of In-process research and development related to legacy program, Evofosfamide

The loss on impairment of long-lived assets relates to the impairment of in-process research and development relating to the Company's legacy program, Evofosfamide, which was acquired from Threshold Pharmaceuticals in 2017. The loss on impairment of long-lived assets is primarily due to the decrease in future projected cashflows of the in-process research and development relating to this program. The Company obtained a fair value estimate, from a third party specialist as of August 1, 2019, and determined the asset was impaired and the value was not recoverable. During the three and nine months ended September 30, 2019, the Company recorded a related impairment of $22.1 million. Additionally, the asset group was reclassified as held for sale. Future write-downs of the asset are possible based upon the amount of proceeds from an eventual sale of the asset.

Specifically, the Audit Committee of the Board of Directors made this determination in connection with the review of the financial statements required to be included in this Current Report. There can be no assurances whether any transaction will result involving Evofosfamide or, if any such transaction were to occur, its timing or value, or whether there may be additional future impairments regarding this legacy program. See Part II, Item 5 (Other Information) and Note 11 to the Financial Statements.

Nonoperating activities

The table below summarizes our nonoperating activities as follows (in thousands):

	Three Months Ended September 30,			
	2019	2018	Change ($)	Change (%)
Interest and other income, net	$ 396	$ 107	$ 289	270 %
Interest expense	$ (353)	$ (279)	$ (74)	27 %
Change in fair value of warrant liabilities	$ 1	$ 4	$ (3)	-75 %

	Nine Months Ended September 30,			
	2019	2018	Change ($)	Change (%)
Interest and other income, net	$ 1,449	$ 307	$ 1,142	372 %
Interest expense	$ (947)	$ (672)	$ (275)	41 %
Change in fair value of warrant liabilities	$ 3	$ 916	$ (913)	-100 %

Interest and Other Income and Interest Expense

The increase in interest and other income for both the three and nine months ended September 30, 2019 versus the same period in 2018 was primarily due to the Company investing in marketable securities and cash equivalents starting at the end of Q4 2018.

The increase in interest expense for both the three and nine months ended September 30, 2019 versus the same period in 2018 was primarily due to the increase in debt holdings to support buildout of the GMP facility that was completed in June 2018. This long-term debt matures in February 2022.

Change in fair value of warrant liability

The change in fair value of warrant liabilities relates to the revised fair value of the warrants categorized as liabilities. The decrease in the change in fair value of the warrant liabilities is primarily due to the decrease in the underlying stock price of our common stock as well the decrease in the expected term of the warrants as they are nearing expiration, which is February 2020.

Liquidity and Capital Resources

Sources of Funds

We have devoted substantially all of our resources to developing our ETB candidates and platform technology, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing for general and administrative support for these operations. We plan to increase our research and development expenses for the foreseeable future as we continue to advance MT-3724, TAK-169 and our earlier-stage pre-clinical programs. At this time, due to the inherently unpredictable nature of preclinical and clinical development and given the early stage of our programs and product candidates, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval and commercialize our products, if and when approved. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations.

In addition, we cannot forecast which products, if and when approved, may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

To date, we have financed our operations through private placements of equity securities, a reverse merger, and upfront and milestone payments received from our collaborators under our research evaluation agreements, as well as funding from governmental bodies and bank and bridge loans. From April 2014 through February 2018, we borrowed an aggregate of $6.0 million from Silicon Valley Bank. In February 2018, we borrowed $5.0 million through the Perceptive Credit Facility which was used to pay off the principal balance and final fee on the borrowings from Silicon Valley. The Perceptive Credit Facility allows for aggregate borrowings of up to $10.0 million, subject to our achievement of certain milestones. In September 2018, we entered into the CPRIT Agreement

for a research grant related to CD-38 targeting ETB of approximately $15.2 million. In September 2018, weraised gross proceeds of $52.0 million in a public offering of our common stock.

We expect to incur substantial additional losses in the future as we expand our research and development cost-sharing activities with our collaboration partners, we believe such investment is strategically aligned with increasing the value of our technology. We have incurred an accumulated deficit of $148.2 million through September 30, 2019. Based on our current research and development plans, we expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements through 2020.

At September 30, 2019 and December 31, 2018, we had cash, cash equivalents, and marketable securities of $51.4 million and $98.0 million, respectively, and grants revenue receivable of $5.6 million and $4.3 million, respectively.

On December 21, 2018, we filed a universal shelf registration statement on Form S-3 (Registration No. 333-228975) with the SEC, which was automatically declared effective on February 13, 2019. In December 2018 we entered into the Sales Agreement with Cantor, pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million from time to time through Cantor acting as our agent. Under the Sales Agreement, Cantor may sell the shares by any method permitted by law and deemed to be an “at the market” offering as defined in Rule 415 of the Securities Act. To date, we have not sold any shares under the Sales Agreement.

We have invested a substantial portion of our available cash in money market funds and high quality, marketable debt instruments of corporations and government sponsored enterprises in accordance with our investment policy. Our investment policy defines allowable investments and establishes guidelines relating to credit quality, diversification, and maturities of our investments to preserve principal and maintain liquidity. All investment securities have a credit rating of at least AA/A2 or better, or P-2/A-2/F2 or better, as determined by Moody’s, Standard & Poor’s or Fitch. Our investment portfolio has not been adversely impacted by the disruptions in the credit markets that have occurred in the past. However, if there are future disruptions in the credit markets, there can be no assurance that our investment portfolio will not be adversely affected.

Cash Flows

The table below summarizes our cash flow activities as follows (in thousands):

	Nine Months Ended September 30,			
	2019	2018	$ Change	% Change
Net cash used in operating activities	$ (39,272)	$ (23,859)	$ (15,413)	65%
Net cash used in investing activities	(31,504)	(5,421)	(26,083)	481%
Net cash provided by financing activities	1,323	49,114	(47,791)	-97%
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (69,453)	$ 19,834	$ (89,287)	-450%

The increase in net cash used in operating activities for the nine months ended September 30, 2019 was primarily due to an increase in operating cash disbursements as result of an increase in operating activities.

The increase in net cash used in investing activities for the nine months ended September 30, 2019 was primarily due to increased purchases of marketable securitiesand the expansion of the GMP and new R&D facilities. The R&D facility was completed in September 2019 and the expansion facility is expected to be completed during Q1 2020.

The decrease in net cash provided by financing activities was primarily due to the proceeds from issuance of common stock of $48.1 million in September 2018, compared to proceeds from stock option exercises of $1.3 million during the nine months ended September 30, 2019.

Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and had an accumulated deficit of $148.2 million at September 30, 2019. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our ETB candidates.

We expect our expenses to increase substantially in connection with our ongoing development activities related to MT-3724,co-development activities related to TAK-169, our pre-clinical programs, and expanding our operating capabilities. In addition, we expect to incur additional costs associated with operating as a public company. We anticipate that our expenses will increase substantially if and as we:

- support the ongoing Phase II monotherapy study of MT-3724, our lead ETB candidate;
- support the ongoing Phase Ib and initiate Phase II clinical trials of MT-3724;
- co-develop TAK-169 with Takeda;
- continue the research and development of our other ETB candidates, including completing pre-clinical studies and commencing clinical trials;
- seek to enhance our technology platform using our antigen-seeding technology approach to immuno-oncology;
- seek regulatory approvals for any ETB candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our increased operations;
- experience any delays or encounter any issues resulting from any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges,
- service long-term debt; and
- complete the expansion of the Company's cGMP facility.

Payments on the Perceptive Credit Facility commenced April 2018 and are interest only, paid quarterly through December 31, 2019. After the second anniversary of the closing date of the Perceptive Credit Facility, principal payments of $0.2 million are due each calendar quarter, with a final payment of $3.4 million due on the maturity date of February 27, 2022. The loan matures on February 27, 2022 and is secured by substantially all assets.

The Company's expansion of its cGMP is expected to be completed during Q1 2020. The Company expects to incur an additional $1.2 million to complete the buildout of this expansion. Additional costs may be incurred as a result of delays and/or other issues that may arise during the course of construction.

Based on our current research and development plans, we expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements through 2020. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with the development of MT-3724, co-development of TAK-169, and our other pre-clinical programs, and because the extent to which we may enter into collaborations with third parties for development of these ETB candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our ETB candidates. Our future capital requirements for MT-3724, TAK-169 or our other pre-clinical programs will depend on many factors, including:

- the progress, timing and completion of pre-clinical testing and clinical trials for our current or any future ETB candidates;
- the number of potential new ETB candidates we identify and decide to develop;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or any future ETB candidates;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties;
- the time and costs involved in obtaining regulatory approval for our ETB candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these ETB candidates;
- any licensing or milestone fees we might have to pay during future development of our current or any future ETB candidates;

- selling and marketing activities undertaken in connection with the anticipated commercialization of our current or any future ETB candidates and costs involved in the creation of an effective sales and marketing organization; and
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our ETB candidates, if approved.

Identifying potential ETB candidates and conducting pre-clinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our ETB candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as stockholders. Additional debt financing and equity 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 and may require the issuance of warrants, which could potentially dilute stockholders' ownership interest.

If we raise additional funds through collaborations, governmental grants, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or ETB candidates or 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 product development programs or any future commercialization efforts or grant rights to develop and market ETB candidates that we would otherwise prefer to develop and market ourselves.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses based on historical experience and on various assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. For further information on our critical accounting policies, see the discussion of critical accounting policies in our Annual Report on Form 10-K for the year ended December 31, 2018, which we filed with the SEC on March 29, 2019.

Recently Adopted Accounting Pronouncements

On January 1, 2019, we adopted Accounting Standards Update No. 2016-02, Leases (Topic 842) (ASU 2016-02), as amended, which supersedes the lease accounting guidance under Topic 840, and generally requires lessees to recognize operating and financing lease liabilities and corresponding right-of-use (ROU) assets on the consolidated balance sheets and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leasing arrangements. We adopted the new guidance using the modified retrospective transition approach by applying the new standard to all leases existing at the date of initial application and not restating comparative periods. The most significant impact was the recognition of ROU assets and lease liabilities for operating leases, while our accounting for finance leases remained substantially unchanged.

The impact of the adoption of the standard to prior period amounts is discussed in Note 8, Leases.

Recent Accounting Pronouncements Not Yet Adopted

For a discussion of recently issued accounting pronouncements and interpretations not yet adopted by us, please see Note 1, Organization and Summary of Significant Accounting Policies, to our unaudited condensed financial statements for the three and nine months ended September 30, 2019, included in this Quarterly Report on Form 10-Q.

Contractual Commitments and Obligations

The Company has entered into project work orders for each of its clinical trials with clinical research organizations ("CRO") and related laboratory vendors. Under the terms of these agreements, the Company is required to pay certain upfront fees for direct

services costs. Based on the particular agreement some of the fees may be for services yet to be rendered and are reflected as a current prepaid asset and have an unamortized balance of approximately $1.0 million at September 30, 2019. In connection with the Company's clinical trials, it has entered into separate project work orders for each trial with its CRO. The Company has entered into agreements with CROs and other external service providers for services, primarily in connection with the clinical trials and development of the Company's product candidates. The Company was contractually obligated for up to approximately $41.0 million of future services under these agreements at September 30, 2019, for which amounts have not been accrued as services have not been performed. The Company's actual contractual obligations will vary depending upon several factors, including the progress and results of the underlying services.

We have entered into estimated purchase obligations ranging from $1.0 million to $1.9 million which include signed orders for capital equipment.

As a result of our collaboration agreement with Takeda, we exercised our right to cost-share approximately 50% of the development costs for Phase I. Future clinical trial expense related to this trial has not been included within the purchase commitments because they are contingent on enrollment in clinical trials and the activities required to be performed by the clinical sites.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company is exposed to a variety of financial risks. The Company's overall risk management program seeks to minimize potential adverse effects of these financial risks on its financial performance.

Credit Risk

The Company considers all of its material counterparties to be creditworthy. The Company considers the credit risk for each of its counterparties to be low and does not have a significant concentration of credit risk at any of its counterparties.

Liquidity Risk

The Company manages its liquidity risk by maintaining adequate cash reserves at banking facilities, and by continuously monitoring its cash forecasts, its actual cash flows and by matching the maturity profiles of financial assets and liabilities.

Market Risk

The Company is not subject to any significant foreign exchange risk and interest rate risk.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures at September 30, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to its management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures at September 30, 2019, our principal executive officer and principal financial officer concluded that, at such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal controls over financial reporting.

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended September 30, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are subject to various legal proceedings, claims and administrative proceedings that arise in the ordinary course of our business activities. Although the results of the litigation and claims cannot be predicated with certainty, as of the date of this report, we do not believe we are party to any claim, proceeding or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 1A. RISK FACTORS

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. The risks described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time may also significantly impair our business operations. Our business could be harmed by any of these risks. Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes, before making any decision to purchase our common stock. If any of the possible adverse events described below actually occurs, we may be unable to conduct our business as currently planned and our prospects, financial condition, operating results and cash flows could be materially harmed. In addition, the trading price of our common stock could decline due to the occurrence of any of the events described below, and you may lose all or part of your investment. In assessing these risks, you should refer to the other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and related notes.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred losses since inception, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future.

We are a clinical development-stage biopharmaceutical company with a limited operating history. We have incurred net losses in each year since 2009, including net losses attributable to common shareholders of $53.5 million for nine months ended September 30, 2019. At September 30, 2019, we had an accumulated deficit of $148.2 million.

At September 30, 2019, we had cash, cash equivalents, and marketable securities of $51.4 million. In August 2017, we raised approximately $60.0 million though private placements of our common stock and warrants to purchase our common stock. In September 2018, we completed a public offering of 9,430,000 shares of common stock at an offering price of $5.50 per share, which included the exercise in full by the underwriters of their option to purchase up to 1,230,000 additional shares of common stock. We received net proceeds of approximately $48.1 million, after deducting underwriting discounts, commissions and estimated offering related transaction costs. On December 21, 2018, we filed a universal shelf registration statement on Form S-3 (Registration No. 333-228975) with the U.S. Securities and Exchange Commission, or the SEC, which was automatically declared effective on February 13, 2019. In December 2018 we entered into the Sales Agreement with Cantor, pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $50,000,000 from time to time through Cantor acting as our agent. Under the Sales Agreement, Cantor may sell the shares by any method permitted by law and deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act. To date, we have not sold any shares under the Sales Agreement. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates.

We have devoted substantially all of our financial resources to identify, acquire, and develop our product candidates, including conducting clinical trials and providing general and administrative support for our operations. To date, we have financed our operations primarily through the sale of equity securities and convertible promissory notes. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or grants. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We expect losses to increase as we complete Phase I development and advance into Phase II development of our lead product candidates. We have not yet commenced pivotal clinical trials for any product candidate and it may be several years, if ever, before we complete pivotal clinical trials and have a product candidate approved for commercialization. We expect to invest significant funds into the research and development of our current product candidates to determine the potential to advance these product candidates to regulatory approval.

If we obtain regulatory approval to market one or more products, our future revenue will depend upon the size of any markets in which our product candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors and adequate market share for our product candidates in those markets. Even if we obtain adequate market share for one or more products, because the potential markets in which our product candidates may ultimately receive regulatory approval could be very small, we may never become profitable despite obtaining such market share and acceptance of our products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future and our expenses will increase substantially if and as we:

- continue the clinical development of our product candidates;
- continue efforts to discover new product candidates;
- undertake the manufacturing of our product candidates or increase volumes manufactured by third parties;
- advance our programs into larger, more expensive clinical trials;
- initiate additional preclinical, clinical, or other trials or studies for our product candidates;
- seek regulatory and marketing approvals and reimbursement for our product candidates;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market for ourselves;
- seek to identify, assess, acquire, and/or develop other product candidates;
- make milestone, royalty or other payments under third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- seek to attract and retain skilled personnel; and
- experience any delays or encounter issues with the development and potential for regulatory approval of our clinical candidates such as safety issues, clinical trial accrual delays, longer follow-up for planned studies, additional major studies or supportive studies necessary to support marketing approval.

Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

Our ability to use our net operating losses to offset future taxable income, if any, may be subject to certain limitations.

In general, under Section 382 of the Internal Revenue Code, or the Code, a corporation that undergoes an "ownership change" (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period) is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. If we undergo additional ownership changes (some of which changes may be outside our control), our ability to utilize our NOLs could be further limited by Section 382 of the Code. The merger with Private Molecular (the "Merger") resulted in an ownership change under Section 382 of the Code for us, and our pre-Merger NOL carryforwards and certain other tax attributes will be subject to limitation or elimination. The NOL carryforwards and certain other tax attributes of ours may also be subject to limitations as a result of ownership changes. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. federal taxable income. We have incurred net losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our NOLs.

We are obligated to develop and maintain proper and effective internal control over financial reporting. In the future, we may not complete our execution of our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may result in additional material misstatements in our condensed consolidated financial statements and may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. Complying with Section 404 requires a rigorous compliance program as well as adequate time and resources. We may not be able to complete our internal control evaluation, testing and any required remediation in a timely fashion. Additionally, if we identify one or more material weaknesses in our internal control over financial reporting, we will not be able to assert that our internal controls are effective. For example, our management concluded that our internal controls over financial reporting were not effective as of December 31, 2017, because a material weakness existed in our internal control over financial reporting related to not having adequate accounting personnel, which resulted in not timely and appropriately accounting for and disclosing the impact of complex, non-routine transactions in accordance with United States Generally Accepted Accounting Principles, or GAAP. Even though we remediated this material weakness as of December 31, 2018, if other material weaknesses are identified in the future or we are not able to comply with the requirements of Section 404 in a timely manner, our reported financial results could be materially misstated, which could result in investors losing confidence in our reported financial information and may lead to a decline in the stock price. Failure to comply with Section 404 of the Sarbanes-Oxley Act could potentially subject us to sanctions or investigations by the SEC the Financial Industry Regulatory Authority or other regulatory authorities, as well as increasing the risk of liability arising from litigation based on securities law.

As of December 31, 2019, we will be an "accelerated filer" and are therefore subject to the auditor attestation requirement in the assessment of our internal control over financial reporting.

Because the worldwide market value of our common stock held by non-affiliates exceeded $75 million (but was less than $700 million), as of the last business day of our fiscal quarter ended June 30, 2018, we are an "accelerated filer" as defined by SEC rule as of December 31, 2019. We are not an "emerging growth company". Therefore, we are now subject to the requirement that we include in our annual report on Form 10-K for the fiscal year ending December 31, 2019, the auditor's attestation report on its assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. If we do not have a sufficient history for us and our independent registered public accounting firm to test and evaluate our new processes and controls, we may be unable to obtain an unqualified attestation report from our independent registered public accounting firm required under Section 404 of the Sarbanes-Oxley Act. If our independent registered public accounting firm is not able to render an unqualified attestation, it could result in lost investor confidence in the accuracy, reliability, and completeness of our financial reports. We expect that our status as an accelerated filer and compliance with these increased requirements will require management to expend additional time while also condensing the time frame available to comply with certain requirements, which may further increase our legal and financial compliance costs.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our stock price.

Section 404 of the Sarbanes-Oxley Act and the related rules and regulations of the SEC require annual management assessments of the effectiveness of our internal control over financial reporting. If we fail to maintain the adequacy of our internal control over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act and the related rules and regulations of the SEC. If we cannot favorably assess, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on, the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

We have never generated any revenue from product sales and may never become profitable.

We have no products approved for commercialization and have never generated any revenue. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaborators, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize one or more of our product candidates. We do not anticipate generating revenue from product sales for the foreseeable future. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and development of one or more of our product candidates;
- obtaining regulatory and marketing approvals for one or more of our product candidates;

- manufacturing one or more product candidates and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible;
- marketing, launching and commercializing one or more product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- gaining market acceptance of one or more of our product candidates as treatment options;
- meeting our supply needs in sufficient quantities to meet market demand for our product candidates, if approved;
- addressing any competing products;
- protecting, maintaining and enforcing our intellectual property rights, including patents, trade secrets and know-how;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- obtaining reimbursement or pricing for one or more of our product candidates that supports profitability; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with launching and commercializing any approved product candidate. We also will have to develop or acquire manufacturing capabilities or continue to contract with contract manufacturing organizations, or CMOs, in order to continue development and potential commercialization of our product candidates. For instance, if our costs of manufacturing our drug products are not commercially feasible, then we will need to develop or procure our drug products in a commercially feasible manner to successfully commercialize any future approved product, if any. Additionally, if we are not able to generate revenue from the sale of any approved products, we may never become profitable.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Future debt obligations may expose us to risks that could adversely affect our business, operating results and financial condition and may result in further dilution to our stockholders.

Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings or collaborations, licensing arrangements and government funding arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. On December 21, 2018, we filed a universal shelf registration statement on Form S-3 (Registration No. 333-228975) with the SEC, which was automatically declared effective on February 13, 2019. In December 2018 we entered into the Sales Agreement with Cantor, pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $50,000,000 from time to time through Cantor acting as our agent. Under the Sales Agreement, Cantor may sell the shares by any method permitted by law and deemed to be an "at the market" offering as defined in Rule 415 of the Securities Act. To date, we have not sold any shares under the Sales Agreement.

To the extent that we raise additional capital through the sale of equity, convertible debt or other securities convertible into equity, the ownership interest of our stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect rights of our stockholders. Debt financing, if available at all, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, making additional product acquisitions or declaring or paying dividends. For instance, our term loan facility with Perceptive Credit Holdings II, LP limits additional indebtedness, liens, guaranties, mergers and consolidations, substantial asset sales, investments and loans, sale and leasebacks, transactions with affiliates and fundamental changes. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We cannot be assured that we will be able to obtain additional funding if and when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially harm our business, financial condition, and results of operations. In addition, securing additional financing would require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

We also have historically received funds from state and federal government grants for research and development. The grants have been, and any future government grants and contracts we may receive may be, subject to the risks and contingencies set forth below under this section titled "*—Risks Related to the Development of Our Product Candidates—Reliance on government funding for our programs may add uncertainty to our research and commercialization efforts with respect to those programs that are tied to such*

funding and may impose requirements that limit our ability to take certain actions, increase the costs of commercialization and production of product candidates developed under those programs and subject us to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations." Although we might apply for government contracts and grants in the future, we cannot assure that we will be successful in obtaining additional grants for any product candidates or programs.

Changes in interpretation or application of U.S. GAAP may adversely affect our operating results.

We prepare our condensed consolidated financial statements to conform to U.S. GAAP. These principles are subject to interpretation by the Financial Accounting Standards Board, or FASB, American Institute of Certified Public Accountants, the SEC and various other regulatory and accounting bodies. A change in interpretations of, or our application of, these principles can have a significant effect on our reported results and may even affect our reporting of transactions completed before a change is announced. In addition, when we are required to adopt new accounting standards, our methods of accounting for certain items may change, which could cause our results of operations to fluctuate from period to period and make it more difficult to compare our financial results to prior periods.

Risks Related to the Development of Our Product Candidates

Manufacturing difficulties, disruptions or delays could limit supply of our drug candidates and adversely affect our clinical trials.

We completed the construction of our current good manufacturing practices, or cGMP, manufacturing facility during the second quarter of 2018 and we are developing the capability to manufacture product candidates for use in the conduct of our clinical trials. We may not be able to manufacture product candidates or there may be substantial technical or logistical challenges to supporting manufacturing demand for product candidates. We may also fail to comply with cGMP requirements and standards which would require us to not utilize the manufacturing facility to make clinical trial supply.

We plan to rely in part on third-party manufacturers, and their responsibilities will include purchasing from third-party suppliers the materials necessary to produce our product candidates for our clinical trials and regulatory approval. We expect there to be a limited number of suppliers for some of the raw materials that we expect to use to manufacture our product candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our product candidates for our clinical trials, and, if approved, ultimately for commercial sale.

Although we generally do not expect to begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the trial, any significant delay or discontinuity in the supply of a product candidate, or the raw materials or other material components in the manufacture of the product candidate, could delay completion of our clinical trials and potential timing for regulatory approval of our product candidates, which would harm our business and results of operations. We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates and our current costs to manufacture our drug products may not be commercially feasible, and the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, as a drug candidate manufacturer with one manufacturing facility, we are exposed to the following additional risks:

- limited capacity of manufacturing facilities;
- contamination of drug candidates in the manufacturing process;
- natural or other disasters, including hurricanes, earthquakes, volcanoes or fires;
- labor disputes or shortages, including the effects of health emergencies or natural disasters;
- compliance with regulatory requirements;
- changes in forecasts of future demand;
- timing and actual number of production runs and production success rates and yields;
- contractual disputes with our suppliers and contract manufacturers;
- timing and outcome of product quality testing;
- power failures and/or other utility failures;

- breakdown, failure, substandard performance or improper installation or operation of equipment;
- following Biologics License Application, or BLA, approval, a change in the manufacturing site could require additional approval from the U.S. Food and Drug Administration, or the FDA. This approval would require new testing and compliance inspections;
- we may be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- as a drug candidate manufacturer, we are subject to ongoing periodic unannounced inspection by the FDA and some state agencies to ensure strict compliance with cGMPs and other U.S. and corresponding foreign requirements, and we carry the risk of non-compliance with these regulations and standards;

Each of these risks could delay our clinical trials, the marketing approval, if any, of our product candidates, or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we rely on third parties to perform release testing on our product candidates prior to delivery to subjects in our clinical trials. If these tests are not appropriately conducted and test data are not reliable, subjects in our clinical trials, or patients treated with our products, if any are approved in the future, could be put at risk of serious harm, which could result in product liability suits.

Clinical trials are costly, time consuming and inherently risky, and we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, and may never obtain regulatory approval for, or successfully commercialize certain or any of our product candidates.

Clinical development is expensive, time consuming and involves significant risk. We cannot guarantee that any clinical trials 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 development. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate satisfactory preclinical, toxicology or other in vivo or in vitro data or to develop diagnostics capable of supporting the initiation or continuation of clinical trials;
- delays in reaching agreement on acceptable terms with clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays or failure in obtaining required institutional review board, or IRB, approval at each clinical trial site;
- failure to obtain or delays in obtaining a permit from regulatory authorities to conduct a clinical trial;
- delays in recruiting or failure to recruit sufficient eligible patients in our clinical trials;
- failure by clinical trial sites or CROs or other third parties to adhere to clinical trial requirements;
- failure by our clinical trial sites, CROs or other third parties to perform in accordance with the good clinical practices requirements of the FDA or applicable foreign regulatory guidelines;
- patients withdrawing from our clinical trials;
- adverse events or other issues of concern significant enough for the FDA, or comparable foreign regulatory authority, to put a clinical trial or an IND on clinical hold;
- occurrence of adverse events associated with our product candidates;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of our product candidates;
- negative or inconclusive results from our clinical trials which may result in us deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs in other ongoing or planned indications for a product candidate; and
- delays in reaching agreement on acceptable terms with third-party manufacturers and the time for manufacture of sufficient quantities of our product candidates for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for one or more of our product candidates could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional nonclinical studies and/or clinical trials to show that the results obtained from such new formulation are consistent with previous results obtained. Clinical trial delays could also shorten any periods during which our product candidates have patent protection and may allow competitors to develop and bring

products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

The approach we are taking to discover and develop next generation immunotoxin therapies, also commonly known as engineered toxin bodies, or ETBs, is unproven and may never lead to marketable products.

The scientific discoveries that form the basis for our efforts to discover and develop our product candidates are relatively recent. To date, neither we nor any other company has received regulatory approval to market therapeutics utilizing ETBs. The scientific evidence to support the feasibility of developing drugs based on these discoveries is both preliminary and limited. Successful development of ETB therapeutic products by us will require addressing a number of issues, including identifying appropriate receptor targets, screening for and selecting potent and safe ETB product candidates, developing a commercially feasible manufacturing process, successfully completing all required preclinical studies and clinical trials, successfully implementing all other requirements that may be mandated by regulatory agencies from clinical development through post-marketing periods, ensuring intellectual property protection in any territory where an ETB product may be commercialized and commercializing an ETB product successfully in a competitive product landscape. In addition, any product candidates that we develop may not demonstrate in patients the biological and pharmacological properties ascribed to them in laboratory and preclinical testing, and they may interact with human biological systems in unforeseen, ineffective or even harmful ways. If we do not successfully develop and commercialize one or more product candidates based upon this scientific approach, we may not become profitable and the value of our common stock may decline.

Further, our focus on ETB technology for developing product candidates as opposed to multiple, more proven technologies for drug development increases the risk associated with our business. If we are not successful in developing an approved product using ETB technology, we may not be able to identify and successfully implement an alternative product development strategy. In addition, work by other companies pursuing similar immunotoxin technologies may encounter setbacks and difficulties that regulators and investors may attribute to our product candidates, whether appropriate or not.

We are heavily dependent on the success of our product candidates, the most advanced of which is in the early stages of clinical development. Our ETB therapeutic product candidates are based on a relatively novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all. Some of our product candidates have produced results in preclinical settings to date and we cannot give any assurance that we will generate data for any of our product candidates sufficient to receive regulatory approval in our planned indications, which will be required before they can be commercialized. To date, no ETB therapeutics have been approved for marketing in the United States or elsewhere.

We have concentrated our research and development efforts to date on a limited number of product candidates based on our ETB therapeutic platform and identifying our initial targeted disease indications. We have invested substantially all of our efforts and financial resources to identify, acquire and develop our portfolio of product candidates. Our future success is dependent on our ability to successfully further develop, obtain regulatory approval for, and commercialize one or more product candidates. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a product candidate. We currently have one ETB product candidate, MT-3724, with three active clinical trials: one study is a phase I/II monotherapy study and two studies are phase IIa combination studies. A second ETB product candidate, MT-5111, has one Phase I study, which was initiated in the third quarter of 2019, and the remainder of our product candidates are in preclinical development. MT-3724 has been administered in patients with non-Hodgkin's lymphoma. This is only one of the multiple indications for which we plan to develop this product candidate. There can be no assurance that we will not experience problems or delays in developing our product candidates and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved. Additionally, our clinical and preclinical data to date are not validated and we have no way of knowing if after validation our clinical trial data will be complete and consistent. There can be no assurance that the data that we develop for our product candidates in our planned indications will be sufficient to obtain regulatory approval.

None of our ETB product candidates have advanced into a pivotal clinical trial for our proposed indications and it may be years before any such clinical trial is initiated and completed, if at all. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or a comparable foreign regulatory authority, and we may never receive such regulatory approval for any of our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Additionally, the FDA and comparable foreign regulatory authorities have relatively limited experience with ETB therapeutics. No regulatory authority has granted approval to any person or entity, including us, to market or commercialize ETB therapeutics, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. If our ETB product candidates fail to prove to be safe, effective or commercially viable, our product candidate pipeline would have little, if any, value, which would have a material adverse effect on our business, financial condition or results of operations.

The clinical trial and manufacturing requirements of the FDA, the European Medicines Agency, or the EMA, and other regulatory authorities, and the criteria these regulators use to determine the safety and efficacy of a product candidate, vary substantially according to the type, complexity, novelty and intended use and market of the product candidate. The regulatory approval process for novel product candidates such as ETB therapeutics could be more expensive and take longer than for other, better known or more extensively studied product candidates. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the United States or the European Union or elsewhere or how long it will take to commercialize our product candidates, even if approved for marketing. Approvals by the EMA and other regulatory authorities may not be indicative of what the FDA may require for approval, and vice versa, and different or additional preclinical studies and clinical trials may be required to support regulatory approval in each respective jurisdiction. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a product candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be harmed.

We may have difficulty enrolling, or fail to enroll patients, in our clinical trials given the limited number of patients who have the diseases for which our product candidates are being studied, which could delay or prevent clinical trials of our product candidates.

Identifying and enrolling patients to participate in clinical trials of our ETB product candidates is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit patients to participate in clinical trials of our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment.

The eligibility criteria of our planned clinical trials may further limit the available eligible trial participants as we require that patients have specific characteristics that we can measure or meet the criteria to assure their conditions are appropriate for inclusion in our clinical trials. For instance, the estimated incidence of non-Hodgkin's lymphoma in the United States is 74,680 new cases and approximately 19,910 deaths were attributable to non-Hodgkin's B-cell lymphomas in 2018. Our Phase II combination study of MT-3724 with GEMOX requires patients with non-Hodgkin's lymphoma. We may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical trials in a timely manner because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, and the willingness of physicians to participate in our planned clinical trials. If patients are unwilling to participate in our clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of our product candidates may be delayed.

If we experience delays in the completion of, or termination of, any clinical trials of our product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair product candidate development and jeopardize our ability to obtain regulatory approval relative to our current plans. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial viability of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or terminate clinical trials or result in a restrictive label or delay regulatory approval.

In addition, our MT-3724 product candidate has been studied in only a limited number of patients with a confirmed diagnosis of non-Hodgkin's lymphoma, and the most common adverse events were peripheral edema, diarrhea, myalgia, cough, fatigue, constipation, nausea, anemia, stomatitis, pyrexia, dizziness, headache, insomnia, dyspnea, neutropenia, thrombocytopenia, blurry vision, dysphagia, oral pain, chills, pneumonia, dehydration, hypoalbuminemia, hyponatremia, dysgeusia, oropharyngeal pain, and maculo-papular rash. In addition to the side effects that are known to be associated with MT-3724, continued clinical trials could reveal higher incidence of side effects, or AEs, previously unknown side effects, and side effects with greater severity, which could each or all lead to delays in our clinical programs or discontinuation of our trials. There is no guarantee that additional or more severe side effects will not be identified through ongoing clinical trials of our product candidates for current and other indications. Undesirable side effects and negative results for any of our product candidates may negatively impact the development and potential for approval of our product candidates for their proposed indications.

Additionally, even if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such products;

- regulatory authorities may require additional warnings on the label;
- we may be required to create a Risk Evaluation and Mitigation Strategies, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- 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 a product candidate, even if approved, and could significantly harm our business, results of operations, and prospects.

Our product development program may not discover all possible adverse events that patients who take MT-3724 or our other product candidates may experience. The number of subjects exposed to MT-3724 or our other product candidates and the average exposure time in the clinical development program may be inadequate to detect all adverse events, or chance findings, that may only be detected once the product is administered to more patients and for greater periods of time.

Clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of subjects and limited duration of exposure, we cannot be fully assured all severe side effects of MT-3724 or our other product candidates will be uncovered. Such severe side effects may only be uncovered with a significantly larger number of patients exposed to the drug. If such safety problems occur or are identified after MT-3724 or another product candidate reaches the market, the FDA, or comparable foreign regulatory authority, may require that we amend the labeling of the product or temporarily cease marketing the product, or may even withdraw approval for the product.

Our ETB therapeutic approach is novel and negative public opinion and increased regulatory scrutiny of ETB-based therapies may damage public perception of the safety of our product candidates and adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

ETB therapy remains a novel technology, with no ETB therapy product approved to date in the United States or elsewhere worldwide. Public perception may be influenced by claims that ETB therapy is unsafe, and ETB therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians who specialize in the treatment of the diseases targeted by our product candidates prescribing treatments that involve the use of one or more of our approved product candidates in lieu of, or in addition to, existing treatments with which they may be familiar and for which more clinical data may be available. More restrictive government regulations or negative public opinion regarding ETB-based therapeutics could have an adverse effect on our business, financial condition or results of operations and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Serious adverse events in ETB clinical trials for our competitors' products, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results.

Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of larger, later-stage controlled clinical trials. Product candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks or failure in subsequent clinical trials. Our clinical trials to date have been conducted on a small number of patients in limited numbers of clinical trial sites for a limited number of indications. We will have to conduct larger, well-controlled trials in our proposed indications to verify the results obtained to date and to support any regulatory submissions for further clinical development. A number of companies in the biopharmaceutical industry have suffered significant setbacks or failure in advanced clinical trials due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical trials.

Moreover, clinical data is often susceptible to varying interpretations and analyses. We do not know whether any Phase I, Phase II, Phase III or other clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety with respect to the proposed indication for use sufficient to receive regulatory approval or market our product candidates.

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

Because we have limited financial and human resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or more profitable market opportunities. Our spending on current and future research and development programs and future product candidates for specific indications may not yield any commercially viable products. We may also enter into additional strategic collaboration agreements to develop and commercialize some of our programs and potential product candidates in indications with potentially large commercial markets. 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 strategic collaborations, 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, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

We may face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use or misuse of our product candidates harms patients or is perceived to harm patients even when such harm is unrelated to our product candidates, our regulatory approvals, if any, could be revoked or otherwise negatively impacted and we could be subject to costly and damaging product liability claims. If we are unable to obtain adequate insurance or are required to pay for liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage, a material liability claim could adversely affect our financial condition.

The use or misuse of our product candidates in clinical trials and the sale of any products for which we may obtain marketing approval exposes us to the risk of potential product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates and approved products, if any. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. Some of our ETB therapeutics have shown in clinical trials to induce adverse events, including peripheral edema, diarrhea, myalgia, cough, fatigue, constipation, nausea, anemia, stomatitis, pyrexia, dizziness, headache, insomnia, dyspnea, neutropenia, thrombocytopenia, blurry vision, dysphagia, oral pain, chills, pneumonia, dehydration, hypoalbuminemia, hyponatremia, dysgeusia, oropharyngeal pain, and maculo-papular rash, among others. There is a risk that our future product candidates may induce similar or more severe adverse events. Patients with the diseases targeted by our product candidates may already be in severe or advanced stages of disease and have both known and unknown significant preexisting and potentially life-threatening health risks. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which an adverse event is unrelated to our product candidates, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may delay our regulatory approval process or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations.

Although we have product liability insurance covering our clinical trials in the United States for up to $5.0 million per occurrence up to an aggregate limit of $5.0 million, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer. We also will likely be required to increase our product liability insurance coverage for the advanced clinical trials that we plan to initiate. If we obtain marketing approval for any of our product candidates, we will need to expand our insurance coverage to include the sale of commercial products. There is no way to know if we will be able to continue to obtain product liability coverage and obtain expanded coverage if we require it, in sufficient amounts to protect us against losses due to liability, on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. Where we have provided indemnities in favor of third parties under our agreements with them, there is also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. 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 breach of warranties. Claims also could be asserted under state consumer protection acts. Any product liability claim brought against us, with or without merit, could result in:

- withdrawal of clinical trial volunteers, investigators, patients or trial sites or limitations on approved indications;
- the inability to commercialize, or if commercialized, decreased demand for, our product candidates;
- if commercialized, product recalls, withdrawals of labeling, marketing or promotional restrictions or the need for product modification;

- initiation of investigations by regulators;
- loss of revenues;
- substantial costs of litigation, including monetary awards to patients or other claimants;
- liabilities that substantially exceed our product liability insurance, which we would then be required to pay;
- an increase in our product liability insurance rates or the inability to maintain insurance coverage in the future on acceptable terms, if at all;
- the diversion of management's attention from our business; and
- damage to our reputation and the reputation of our products and our technology.

Product liability claims may subject us to the foregoing and other risks, which could have a material adverse effect on our business, financial condition or results of operations.

Our international activities, including clinical trials abroad, expose us to various risks, any number of which could harm our business.

We are subject to the risks inherent in engaging in business across national boundaries, due in part to our clinical trials abroad, any one of which could adversely impact our business. In addition to currency fluctuations, these risks include, among other things: economic downturns; changes in or interpretations of local law, governmental policy or regulation; restrictions on the transfer of funds into or out of the country; varying tax systems; and government protectionism. One or more of the foregoing factors could impair our current or future operations and, as a result, harm our overall business.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

A potential breakthrough therapy designation by the FDA for our 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 a breakthrough therapy designation from the FDA for one or more of our product candidates. A breakthrough therapy is defined as a drug or biological product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biological 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 drugs or biological products that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of a clinical trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs or biologic products designated as breakthrough therapies by the FDA could also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional or other accelerated FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify and are designated as breakthrough therapies, the FDA may later decide that the drugs or biological products no longer meet the conditions for designation and the designation may be rescinded.

We may seek Fast Track designation for one or more of our product candidates, but we might not receive such designation, and even if we do, such designation may not actually lead to a faster development or regulatory review or approval process.

If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation. If we seek Fast Track designation for a product candidate, we may not receive it from the FDA. However, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular time frame. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation if the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

Even if we obtain regulatory approval for a product, we will remain subject to ongoing regulatory requirements.Maintaining compliance with ongoing regulatory requirements may result in significant additional expense to us, and any failure to maintain such compliance could subject us to penalties and cause our business to suffer

If any of our product candidates are approved, we will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing clinical trials and submission of safety, efficacy and other post-approval information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to continuously comply with FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and corresponding foreign regulatory manufacturing requirements. As such, we and our CMOs will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, or other marketing authorization application.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA, EMA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and record keeping for the products will be subject to extensive and ongoing regulatory requirements. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit for our products. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- impose restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- impose fines or issue warning letters;
- issue consent decrees, injunctions or impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our CMOs' facilities; or
- require product seizure or detention, recalls or refuse to permit the import or export of products.

Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to develop and commercialize our products and our value and our operating results would be adversely affected. In addition, regulatory authorities' policies (such as those of the FDA or EMA) may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are otherwise not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Healthcare legislative reform measures may have a material adverse effect on our business, financial condition or results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Health Care and Education Reconciliation Act of 2010, which amended the Patient Protection and

Affordable Care Act, or collectively the ACA, was passed. The ACA was intended to substantially change the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of specified branded prescription drugs, and promotes a new Medicare Part D coverage gap discount program.

The current administration supports a repeal of the ACA and an Executive Order has been signed mandating that federal agencies try to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. The Executive Order also declares that the administration will seek the "prompt repeal" of the law and that the government should prepare to "afford the States more flexibility and control to create a more free and open healthcare market." At this time, the immediate impact of the Executive Order is not clear.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted, and 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 or lower pricing for our product candidates or additional pricing pressures.

We expect that the ACA, 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 will receive for any approved product. Any reduction in payments from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our product candidates, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be subject to various federal and state fraud and abuse laws, including, the federal Anti-Kickback Statute, the federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government, and the states and countries in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- the Health Insurance Portability and Accountability Act of 1996, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the ACA, which requires manufacturers of drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including governmental and private payors, to comply with the

pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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 civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Reliance on government funding for our programs may add uncertainty to our research and commercialization efforts with respect to those programs that are tied to such funding and may impose requirements that limit our ability to take certain actions, increase the costs of commercialization and production of product candidates developed under those programs and subject us to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations.

During the course of our development of our lead product candidate, we have been funded in significant part through state grants, including but not limited to the substantial funding we have received from the Cancer Prevention & Research Institute of Texas, or CPRIT. We entered our first CPRIT award grant contract, or the 2012 CPRIT Agreement, on November 7, 2012. On September 18, 2018, we entered into a second CPRIT award grant contract for our CD38 targeted ETB program, or the 2018 CPRIT Agreement. In addition to the funding we have received to date, we have applied and intend to continue to apply for federal and state grants to receive additional funding in the future, which may or may not be successful. Contracts and grants funded by the U.S. government, state governments and their related agencies, including our contracts with the State of Texas pertaining to funds we have already received, include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- require repayment of all or a portion of the grant proceeds, in certain cases with interest, in the event we violate certain covenants pertaining to various matters that include any potential relocation outside of the State of Texas, failure to achieve certain milestones or to comply with terms relating to use of grant proceeds, or failure to comply with certain laws;
- terminate agreements, in whole or in part, for any reason or no reason;
- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including certain intellectual property rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose the State of Texas or U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- impose the qualifications for the engagement of manufacturers, suppliers and other contractors as well as other criteria for reimbursements;
- suspend or debar the contractor or grantee from doing future business with the government;
- control and potentially prohibit the export of products;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act and similar remedy provisions specific to government agreements; and

- limit the government's financial liability to amounts appropriated by the State of Texas on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

In addition to those powers set forth above, the government funding we may receive could also impose requirements to make payments based upon sales of our products in the future. For example, under the terms of our 2018 CPRIT Agreement, we are required to pay CPRIT a percentage of our revenues from sales of products directly funded by CPRIT, or received from our licensees or sub licensees, at a percentage in the low to mid-single digits until the aggregate amount of such payments equals 400% of the funds we receive from CPRIT, and thereafter at a rate of one-half percent.

We may not have the right to prohibit the State of Texas or, if relevant under possible future federal grants, the U.S. government, from using certain technologies developed by us, and we may not be able to prohibit third-party companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed under U.S. government contracts. These and other provisions of government grants may also apply to intellectual property we license now or in the future.

In addition, government contracts and grants normally contain additional requirements that may increase our costs of doing business, reduce our profits and expose us to liability for failure to comply with these requirements. These requirements include, for example:

- specialized accounting systems unique to government contracts and grants;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract and grant information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

If we fail to maintain compliance with any such requirements that may apply to us now or in the future, we may be subject to potential liability and to termination of our contracts.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition or results of operations.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations; environmental damage resulting in costly clean-up; and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of specified materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such cha nges and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent our product candidates 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 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. 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 drugs and biologic products 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, including from December 22, 2018 through January 25, 2019, 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 affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, 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.

Risks Related to Our Intellectual Property

Our ability to compete effectively may decline if we are unable to establish intellectual property rights or if our intellectual property rights are inadequate to protect our ETB technology, present and future product candidates and related processes for our developmental pipeline.

We rely or will rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect our intellectual property related to our technologies and product candidates. Our commercial success and viability depend in large part on our and any current and potential future licensors' ability to obtain, maintain and enforce patent and other intellectual property protections in the United States, Europe and other countries worldwide with respect to our current and future proprietary technologies and product candidates. If we or our current or future collaboration partners do not adequately protect such intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize product candidates and delay or render impossible our achievement of profitability.

Our strategy and future prospects are based, in part, on our patent portfolio. We and our current and future collaboration partners or licensees will best be able to protect our proprietary ETB technologies, product candidates and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, other regulatory exclusivities or effectively protected trade secrets, cover them. We have sought to protect our proprietary position by filing patent applications in the United States and elsewhere related to our proprietary ETB technologies, product candidates and methods of use that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain meaningful patent protection.

Intellectual property rights have limitations and do not necessarily address all potential threats to our competitive advantage. Our ability to obtain patent protection for our proprietary technologies, product candidates and their uses is uncertain, and the degree of future protection afforded by our intellectual property rights is uncertain due to a number of factors, including, but not limited to:

- we or our current or future collaboration partners may not have been the first to make the inventions covered by pending patent applications or issued patents;
- we or our current or future collaboration partners may not have been the first to file patent applications covering our ETB technology, product candidates, compositions or their uses;
- others may independently develop identical, similar or alternative methods, products, product candidates or compositions and uses thereof;
- we or our current or future collaboration partners' disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our or our current or future collaboration partners' pending patent applications may not result in issued patents;
- we or our current or future collaboration partners may not seek or obtain patent protection in countries that may eventually provide us with a significant business opportunity;
- any patents issued to us or our current or future collaboration partners may not provide a basis for commercially viable products, may not provide any competitive advantages or may be successfully challenged by third parties;
- we or our current or future collaboration partners' products, product candidates, compositions, methods or uses thereof may not be patentable;

- others may design around our or our current or future collaboration partners' patent claims to produce competitive products or uses which fall outside of the scope of our patents or other intellectual property rights;
- others may identify prior art or other bases which could invalidate our or our current or future collaboration partners' patents;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we or our current or future collaboration partners do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in major commercial markets; or
- we or our current or future collaboration partners may not develop additional proprietary technologies or products that are patentable.

Further, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsettled. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or their uses in the United States or in other countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates or their uses, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our ETB technology, product candidates and associated assays and uses. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition or challenge to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If we cannot obtain and maintain effective protection of exclusivity from our regulatory efforts and intellectual property rights, including patent protection or data or market exclusivity for our product candidates or their uses, we may not be able to compete effectively, and our business and results of operations would be harmed.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, 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.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries, particularly some developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to healthcare, medicine, or biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, 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 and our patent applications at risk of not issuing 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 rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may not have sufficient patent terms and regulatory exclusivity protections for our product candidates to effectively protect our competitive position.

Patents have a limited term. In the United States and most jurisdictions worldwide, the statutory expiration of a non-provisional patent is generally 20 years after it is first filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our technologies, product candidates and associated uses are obtained, once the patent life has expired for a product candidate, we may be open to competition from generic, biosimilar or biobetter medications.

Patent term extensions under the Hatch-Waxman Act in the United States, and regulatory extensions in Japan and certain other countries, and under Supplementary Protection Certificates in Europe, may be available to extend the patent or market or data exclusivity terms of our product candidates depending on the timing and duration of the regulatory review process relative to patent term. In addition, upon issuance in the United States, any patent term may be adjusted based on specified delays during patent prosecution caused by the applicant(s) or the United States Patent and Trademark Office, or the USPTO. We will likely seek patent term extensions, and we cannot provide any assurances that any such patent term extensions will be obtained and, if so, for how long. As a result, we may not be able to maintain exclusivity for our product candidates for an extended period after regulatory approval, if any, which would negatively impact our business, financial condition, results of operations and prospects. If we do not have sufficient patent terms or regulatory exclusivity to protect our product candidates, our business and results of operations will be adversely affected.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products, and recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

As is the case with other biotechnology companies, our success is heavily dependent on patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

For our U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. 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 and may also affect patent litigation. The USPTO has promulgated regulations and developed 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 a provisional patent application, did not come into effect until March 16, 2013. 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 or results of operations.

An important change introduced by the Leahy-Smith Act is that, as of March 16, 2013, the United States transitioned to a “first-inventor-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that filed or files a patent application in the USPTO after March 16, 2013 but before we file an application could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the Leahy-Smith Act are changes that limit where a patentee may file a patent infringement suit and new procedures providing opportunities for third parties to challenge any issued patent in the USPTO. Included in these new procedures is a process known as inter partes review, or IPR, which has been generally used by many third parties to invalidate patents. The IPR process is not limited to patents filed after the Leahy-Smith Act was enacted and would therefore be available to a third party seeking to invalidate any of our U.S. patents, even those issued or filed before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

We could be required to incur significant expenses to obtain our intellectual property rights, and we cannot ensure that we will obtain meaningful patent protection for our product candidates.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, it is also possible that we will fail to identify patentable aspects of further inventions made in the course of our development and commercialization activities before they are publicly disclosed, making it too late to obtain patent protection on them. Further, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of a patent that covers an approved product where the permission for the commercial marketing or use of the product is the first permitted commercial marketing or use, and as long as the remaining term of the patent does not exceed 14 years. However, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. 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 laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and these foreign laws may also be subject to change. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Issued patents covering our ETB technologies, product candidates and uses could be found invalid or unenforceable if challenged in court.

Even if our or our current or future collaboration partners' patents do successfully issue and even if such patents cover our product candidates and methods of use, third parties may initiate interference, re-examination, post-grant review, IPR or derivation actions in the USPTO; may initiate third party oppositions in the European Patent Office, or EPO; or may initiate similar actions challenging the validity, enforceability or scope of such patents in other patent administrative proceedings worldwide, which may result in patent claims being narrowed or invalidated. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover competitive technologies, product candidates or methods of use. Further, if we initiate legal proceedings against a third party to enforce a patent covering our technologies, product candidates or uses, the defendant could counterclaim that our relevant patent is invalid or unenforceable. In patent litigation in the United States, certain European and other countries worldwide, it is commonplace for defendants to make counterclaims alleging invalidity and unenforceability in the same proceeding, or to commence parallel defensive proceedings such as patent nullity actions to challenge validity and enforceability of asserted patent claims. Further, in the United States, a third party, including a licensee of one of our or our current or future collaboration partners' patents, may initiate legal proceedings against us in which the third party challenges the validity, enforceability, or scope of our patent(s).

In administrative and court actions, grounds for a patent validity challenge may include alleged failures to meet any of several statutory requirements, including lack of novelty, nonobviousness (or inventive step) and, in some cases clarity, adequate written description or non-enablement of, the claimed invention. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the Examiner during prosecution in the USPTO or made a misleading statement during prosecution in the USPTO, the EPO or elsewhere. Third parties also may raise similar claims before administrative bodies in the USPTO or the EPO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability are unpredictable. With respect to patent claim validity, for example, we cannot be certain that there is no invalidating prior art, of which we or the patent examiner was unaware during prosecution. Further, we cannot be certain that all of the potentially relevant art relating to our patents and patent applications has been brought to the attention of every patent office. If a defendant or other patent challenger were to prevail on a legal assertion of invalidity or unenforceability, we could lose at least in part, and perhaps all, of the patent protection on our ETB technology, product candidates and associated uses.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe our patents or the patents of any of our future licensors. If we or one of our licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, nonobviousness, adequate written description, clarity or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the claimed invention at issue on the grounds that our or our current or future collaboration partners' patent claims do not cover the claimed invention. Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we were to establish infringement of our patent rights by a third party, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the market price of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded and can involve substantial expenses. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority or inventorship of inventions with respect to our patents or patent applications or those of any of our future licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation, interference proceedings, or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation and administrative proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market.

If we are unable to protect the confidentiality of our trade secrets and know-how for our product candidates or any future product candidates, we may not be able to compete effectively in our proposed markets.

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 product candidate 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, scientific advisors, contractors and other third parties. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although our current employment contracts provide for and we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information or technology are expected to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business, financial condition or results of operations. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating trade secrets.

Third-party claims of intellectual property infringement could result in costly litigation or other proceedings and may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technology without infringing the patent rights of third parties. We are currently not aware of U.S. or foreign patents or pending patent applications owned by third parties that cover our ETB product candidates or therapeutic uses of those ETB product candidates. In the future, we may identify such third-party U.S. and non-U.S. issued patents and pending applications. If we identify any such patents or pending applications, we may in the future pursue available proceedings in the U.S. and foreign patent offices to challenge the validity of these patents and patent applications. In addition, or alternatively, we may consider whether to seek to negotiate a license of rights to technology covered by one or more of such patents and patent applications. If any patents or patent applications cover our product candidates or technologies or a requisite manufacturing process, we may not be free to manufacture or market our product candidates, including MT-3724, as planned, absent such a license, which may not be available to us on commercially reasonable terms, or at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to specified limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates.

There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding foreign patent offices. Third parties own numerous U.S. and foreign issued patents and pending patent applications in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical 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.

Parties making patent infringement claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, may involve substantial litigation expense and may require a substantial diversion of employee resources from our business. In the event of a successful claim of patent infringement against us, 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 be unsuccessful in obtaining or maintaining third-partyintellectual property rights necessary to develop our ETB technologies or to commercialize our product candidates and associated methods of use through acquisitions and in-licenses.

Presently, we have intellectual property rights to our ETB technologies under patent applications that we own and to certain CD38 targeting antibody domains through our License Agreement (as defined below). Because our programs may involve a range of ETB targets and antibody domains, which in the future may include targets and antibody domains that require the use of proprietary rights held by third parties, the growth of our business may likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific formulations or manufacturing technologies to work effectively and be manufactured efficiently, and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing 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, cash resources and greater clinical development and commercialization capabilities.

For example, we have previously and may continue to collaborate with federal, state or international academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions grant the rights to the collaborator and retain a non-commercial license to all rights as well as march-in rights in the situation that the collaborator fails to exercise or commercialize certain covered technologies. Regardless of such initial rights, we may be unable to exercise or commercialize certain funded technologies thereby triggering march-in rights of the funding institution. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to it. 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. If we are unable to successfully obtain rights to third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

If we are unable to successfully obtain and maintain rights to required third-party intellectual property, we may have to abandon development of that product candidate or pay additional amounts to the third-party, and our business and financial condition could suffer.

The patent protection and patent prosecution for some of our product candidates may in the future be dependent on third parties.

While we normally seek to gain the right to fully prosecute the patent applications relating to our product candidates, there may be times when certain patents or patent applications relating to our product candidates, their uses or their manufacture may be controlled by our future licensors. If any of our future licensors fail to appropriately and broadly prosecute patent applications and maintain patent protection of claims covering any of our product candidates, their uses or their manufacture, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, importing, and selling competing products. In addition, even where we now have the right to control patent prosecution of patent applications or the maintenance of patents we have licensed from third parties in the future, we may still be adversely affected or prejudiced by actions or inactions of our licensors in effect from actions prior to us assuming control over patent prosecution.

If we fail to comply with obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are and will continue to be a party to a number of intellectual property license collaboration and supply agreements that may be important to our business and expect to enter into additional license agreements in the future. Our existing agreements impose, and we expect that future agreements will impose, various diligence, milestone payment, royalty, purchasing and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, our agreements may be subject to termination by the licensor or other contract party, in which event we would not be able to develop, manufacture or market products covered by the license or subject to supply commitments.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including potential competitors. Although we have written agreements and make every effort to ensure that our employees, consultants and independent contractors do not use the proprietary information or intellectual property rights of others in their work for us, we may in the future be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other requirements during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Our failure to comply with data protection laws and regulations could lead to government enforcement actions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We are subject to data protection laws and regulations that address privacy and data security. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. In the United States, numerous federal and state laws and regulations, including state data 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.

Failure to comply with data protection laws and regulations could result in government enforcement actions, which could include civil or criminal penalties, private litigation and/or adverse publicity and could negatively affect our operating results and business. In addition, in May 2016, the EU Parliament adopted the comprehensive General Data Privacy Regulation, or the GDPR, to, among other things, impose more stringent data protection requirements for processors and controllers of personal data and provide for greater penalties and fines for non-compliance, including fines in amounts up to €20 million or 4% of total worldwide annual turnover, whichever is higher. The GDPR became fully effective in May 2018. In addition, in 2018, California adopted a new privacy law, scheduled to go into effect on January 1, 2020, that borrows heavily from the GDPR. Complying with the enhanced obligations imposed by the GDPR and other applicable international and U.S. privacy laws and regulations may result in significant costs to our business and require us to amend certain of our business practices. Further, enforcement actions and investigations by regulatory authorities related to data security incidents and privacy violations continue to increase. The future enactment of more restrictive laws, rules or regulations and/or future enforcement actions or investigations could have a materially adverse impact on us through increased costs or restrictions on our businesses, and non-compliance could result in regulatory penalties and significant legal liability.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our clinical trials, manufacture our product candidates and perform other services. If these third parties do not successfully carry out their contractual duties, meet expected timelines or otherwise conduct the trials as required or perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates when expected or at all, and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to conduct, monitor and manage our ongoing clinical programs. We rely on these parties for execution of clinical trials and we manage and control only some aspects of their activities. We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with all applicable laws, regulations and guidelines, including those required by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. If we, or any of our CROs or vendors, fail to comply with applicable laws, regulations and guidelines, the results generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be assured that our CROs and other vendors will meet these requirements, or that upon inspection by any regulatory authority, such regulatory authority will determine that efforts, including any of our clinical trials, comply with applicable requirements. Our failure to comply with these laws, regulations and guidelines may require us to repeat clinical trials, which would be costly and delay the regulatory approval process.

If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs in a timely manner or do so on commercially reasonable terms. In addition, our CROs may not prioritize our clinical trials relative to those of other customers, and any turnover in personnel or delays in the allocation of CRO employees by the CRO may negatively affect our clinical trials. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, our clinical trials may be delayed or terminated, and we may not be able to meet our current plans with respect to our product candidates. CROs also may involve higher costs than anticipated, which could negatively affect our financial condition and operations.

We completed the construction of our cGMP manufacturing facility during the second quarter of 2018 and we have developed the capability to manufacture product candidates for use in the conduct of our clinical trials. We may not be able to manufacture product candidates or there may be substantial technical or logistical challenges to supporting manufacturing demand for product candidates. We may also fail to comply with cGMP requirements and standards which would require us to not utilize the manufacturing facility to make clinical trial supply. We plan to rely in part on third-party manufacturers, and their responsibilities will include purchasing from third-party suppliers the materials necessary to produce our product candidates for our clinical trials and regulatory approval. We expect there to be a limited number of suppliers for some of the raw materials that we expect to use to manufacture our product candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our product candidates for our clinical trials, and, if approved, ultimately for commercial sale.

Although we generally do not expect to begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the trial, any significant delay or discontinuity in the supply of a product candidate, or the raw materials or other material components in the manufacture of the product candidate, could delay completion of our clinical trials and potential timing for regulatory approval of our product candidates, which would harm our business and results of operations. We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates and our current costs to manufacture our product candidates may not be commercially feasible, and the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, our reliance on third-party manufacturers exposes us to the following additional risks:

- we may be unable to identify manufacturers to manufacture our product candidates on acceptable terms or at all, because the number of qualified potential manufacturers is limited. Following BLA approval, a change in the manufacturing site could require additional approval from the FDA. This approval would require new testing and compliance inspections;
- our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- our future third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our product candidates;

- drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMPs and other government regulations and corresponding foreign standards, and we do not have control over third-party manufacturers' compliance with these regulations and standards;
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates; and
- our third-party manufacturers could breach or terminate their agreements with us.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates, or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we rely on third parties to perform release testing on our product candidates prior to delivery to subjects in our clinical trials. If these tests are not appropriately conducted and test data are not reliable, subjects in our clinical trials, or patients treated with our product candidates, if any are approved in the future, could be put at risk of serious harm, which could result in product liability suits.

We depend on Takeda for the conduct and funding of the development and commercialization of CD38 SLT-A Fusion Proteins.

In September 2018, we expanded our collaboration with Takeda, focused on the development collaboration of the parties regarding CD38 SLT-A fusion proteins, including TAK-169, by entering into the License Agreement. The primary objective of the strategic alliance is to advance novel therapies for indications associated with oncology, particularly multiple myeloma patients.

Under the License Agreement, we granted Takeda an exclusive license to co-develop one or more licensed products, meaning any product that incorporates or is comprised of one or more of the CD38 SLT-A fusion proteins, up to and including Phase Ia clinical trials, and thereafter we would have an option to continue to co-develop the licensed products.

Pursuant to the terms of the License Agreement, Takeda has the sole discretion to assume or to designate a third party to assume our manufacturing activities under this agreement. Takeda may conduct these activities more slowly or in a different manner than we would. Takeda is also responsible for filing future applications with the FDA or other regulatory authorities for approval of the CD38 SLT-A fusion proteins. We cannot control whether Takeda will devote sufficient attention and resources to the development of the SLT-A fusion proteins or will proceed in an expeditious manner. Even if the FDA or other regulatory agencies approve any of the SLT-A fusion proteins, Takeda may elect not to proceed with the commercialization of the resulting product in one or more countries.

Under the terms of the License Agreement, we will receive payments and royalties upon reaching certain defined milestones. We may not reach any of the milestones that trigger a payment or royalties under the License Agreement and we are subject to reduced payments and royalty rates if we elect to end our co-development. We are also subject to royalty reductions if there exists a biosimilar product or generic product being sold by a third party. If we exercise our option to co-develop the licensed products, we will become responsible for sharing co-development costs with Takeda. We cannot predict these costs and it is possible that if we cannot afford these costs in the future, we may have to terminate the License Agreement and could be subject to lower milestone and royalty payments, which could harm our business.

Takeda may elect to terminate the License Agreement for convenience upon 90 days prior written notice. Takeda also maintains the right to terminate the License Agreement in connection with our material breach and our insolvency. Takeda reserves certain rights, such as to undertake any not yet completed early stage program activities to be conducted by us, solely and exclusively, upon any change in control of us. If Takeda terminates the License Agreement, it will result in a delay in or could prevent us from further developing or commercializing the CD38 SLT-A fusion proteins, and will delay and could prevent us from obtaining revenues for this product candidate.

Disputes may arise between us and Takeda, which may delay or cause the termination of any CD38 SLT-A fusion protein clinical trials, result in significant litigation or cause Takeda to act in a manner that is not in our best interest. If development of the CD38 SLT-A fusion proteins does not progress for these or any other reasons, we would not receive further milestone payments or royalties on product sales from Takeda with respect to the CD38 SLT-A fusion proteins and may owe Takeda certain development milestones and royalties as well as amounts owed by Takeda pursuant to any of its third-party license agreements.

If Takeda terminates the License Agreement prior to regulatory approval of any drug candidates under this License Agreement, we may have to seek a new partner for development or commercialization or undertake and fund the development of the CD38 SLT-A fusion proteins or commercialization of the resulting drug ourselves. If we seek a new partner but are unable to do so on acceptable terms, or at all, or do not have sufficient funds to conduct the development or commercialization of the CD38 SLT-A fusion proteins ourselves, we may have to curtail or abandon that development or commercialization, which could harm our business.

We may be unable to realize the potential benefits of any collaboration.

In addition to the License Agreement, we have multi-target research and development collaborations ongoing with Takeda and expect to seek to collaborate with other partners in the future. Even if we are successful in entering into one or more additional collaborations with respect to the development and/or commercialization of one or more product candidates, there is no guarantee that any of these collaborations will be successful. Collaborations may pose a number of risks, including the following:

- collaborators often have significant discretion in determining the efforts and resources that they will apply to the collaboration, and may not commit sufficient resources to the development, marketing or commercialization of the product or products that are subject to the collaboration;
- collaborators may not perform their obligations as expected;
- any such collaboration may significantly limit our share of potential future profits from the associated program, and may require us to relinquish potentially valuable rights to our current product candidates, potential products or proprietary technologies or grant licenses on terms that are not favorable to us;
- collaborators may cease to devote resources to the development or commercialization of our product candidates if the collaborators view our product candidates as competitive with their own products or product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of product candidates, and might result in legal proceedings, which would be time consuming, distracting and expensive;
- collaborators may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the collaboration;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- the collaborations may not result in us achieving revenues sufficient to justify such transactions; and
- collaborations may be terminated and, if terminated, may result in a need for us to raise additional capital to pursue further development or commercialization of the applicable product candidate.

As a result, a collaboration may not result in the successful development or commercialization of our product candidates.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we have and expect to continue periodically to enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to our product candidates, processes or services made, used, or performed pursuant to the agreements, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to our collaboration agreements, we indemnify our collaborators from any third-party product liability claims that could result from the production or use of the product candidate, as well as for alleged infringements of any patent or other intellectual property right owned by a third party. With respect to consultants, we often indemnify them from claims arising from the good faith performance of their services.

If our obligations under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Risks Related to Commercialization of Our Product Candidates

We currently have limited marketing and sales experience. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although some of our employees may have marketed, launched and sold other pharmaceutical products in the past while employed at other companies, we have no experience selling and marketing our product candidates, and we currently have no marketing or sales organization. To successfully commercialize any products that may result from our development programs, we will need to find one or more collaborators to commercialize our products or invest in and develop these capabilities, either on our own or with others, which would be expensive, difficult and time consuming. Any failure or delay in the timely development of our internal commercialization capabilities could adversely impact the potential for success of our products.

If commercialization collaborators do not commit sufficient resources to commercialize our future products and we are unable to develop the necessary marketing and sales capabilities on our own, we will be unable to generate sufficient product revenue to sustain or grow our business. We may be competing with companies that currently have extensive and well-funded marketing and sales operations, particularly in the markets our product candidates are intended to address. Without appropriate capabilities, whether directly or through third-party collaborators, we may be unable to compete successfully against these more established companies.

We may attempt to form additional collaborations in the future with respect to our product candidates, but we may not be able to do so, which may cause us to alter our development and commercialization plans.

We may attempt to form strategic collaborations, create joint ventures or enter into licensing arrangements with third parties with respect to our programs in addition to those that we currently have that we believe will complement or augment our existing business. We may face significant competition in seeking appropriate strategic collaborators, and the negotiation process to secure appropriate terms is time consuming and complex. We may not be successful in our efforts to establish such a strategic collaboration for any product candidates and programs on terms that are acceptable, or at all. This may be because our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort, our research and development pipeline may be viewed as insufficient, the competitive or intellectual property landscape may be viewed as too intense or risky, and/or third parties may not view our product candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile.

Any delays in identifying suitable collaborators and entering into agreements to develop and/or commercialize our product candidates could delay the development or commercialization of our product candidates, which may reduce their competitiveness even if they reach the market. Absent a strategic collaborator, we would need to undertake development and/or commercialization activities at our own expense. If we elect to fund and undertake development and/or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we are unable to do so, we may not be able to develop our product candidates or bring them to market and our business may be materially and adversely affected.

If the market opportunities for our product candidates are smaller than we believe they are, we may not meet our revenue expectations and, even if a product candidate receives marketing approval, our business may suffer. Because the patient populations in the market for our product candidates may be small, we must be able to successfully identify patients and acquire a significant market share to achieve profitability and growth.

Our estimates for the addressable patient population and our estimates for the prices we can charge for our product candidates may differ significantly from the actual market addressable by our product candidates. For instance, our Phase II combination study of MT-3724 with GEMOX is focused on non-Hodgkin's lymphoma. The estimated incidence of non-Hodgkin's B-cell lymphoma is 74,680 new cases and approximately 19,910 deaths were attributable to the disease in the United States in 2018, only a subset of which may benefit from treatment with MT-3724. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, while we believe that the data in our Phase II clinical trials for MT-3724 will be supportive of application to other indications, there can be no assurance that our clinical trials will successfully address any additional indications. Similarly, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our business, financial condition, results of operations and prospects.

We face substantial competition and our competitors may discover, develop or commercialize products faster or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition from large pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions worldwide with respect to MT-3724 and the other product candidates that we may seek to develop or commercialize in the future. We are aware that companies including the following have therapeutics marketed or in development that could compete directly or indirectly with ETBs: Genentech, Bayer, Takeda, AbbVie, Celgene, Seattle Genetics, Immunogen, Morphosys, Genmab, Bristol Myers Squibb, Novartis, Regeneron, Janssen, Xencor, Amgen, Macrogenics, Astra Zeneca, Lilly, Merck KGaA, Pfizer, Merus, Sanofi, Mentrik Biotech, Merrimack Pharmaceuticals, Spectrum Pharmaceuticals, Unum Therapeutics, Daiichi Sankyo, Karyopharm, Mersana and F-Star. Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than MT-3724 or any other product candidates that we are currently developing or that we may develop, which could render our product candidates obsolete and noncompetitive.

Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Large pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs, including biologics. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

If our competitors obtain marketing approval from the FDA or comparable foreign regulatory authorities for their product candidates more rapidly than we do, it could result in our competitors establishing a strong market position before we are able to enter the market. Third-party payors, including governmental and private insurers, also may encourage the use of generic products. For example, if MT-3724 is ultimately approved, it may be priced at a significant premium over other competitive products. This may make it difficult for MT-3724 or any other future products to compete with these products. Failure of MT-3724 or other product candidates to effectively compete against established treatment options or in the future with new products currently in development would harm our business, financial condition, results of operations and prospects.

The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

Even with the approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our products will depend in part on the health care providers, patients and third-party payors accepting our product candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients and third-party payors. The degree of market acceptance of any of our products will depend on a number of factors, including but not limited to:

- the efficacy of the product as demonstrated in clinical trials and potential advantages over competing treatments;
- the prevalence and severity of the disease and any side effects of the product;
- the clinical indications for which approval is granted, including any limitations or warnings contained in a product's approved labeling;
- the convenience and ease of administration of the product;
- the cost of treatment;
- the willingness of the patients and physicians to accept these therapies;
- the perceived ratio of risk and benefit of these therapies by physicians and the willingness of physicians to recommend these therapies to patients based on such risks and benefits;
- the marketing, sales and distribution support for the product;
- the publicity concerning our products or competing products and treatments; and
- the pricing and availability of third-party insurance coverage and reimbursement.

Even if a product displays a favorable efficacy and safety profile upon approval, market acceptance of the product remains uncertain. Efforts to educate the medical community and third-party payors on the benefits of the products may require significant investment and resources and may never be successful. If our products fail to achieve an adequate level of acceptance by physicians, patients, third-party payors and other health care providers, we will not be able to generate sufficient revenue to become or remain profitable.

We may not be successful in any efforts to identify, license, discover, develop or commercialize additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of our existing product candidates, the success of our business is also expected to depend in part upon our ability to identify, license, discover, develop or commercialize additional product candidates. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development and commercialization for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our product candidates may be shown to have harmful side effects or may have other characteristics that may make them unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that such a product candidate may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license, discover, develop or commercialize additional product candidates, which would have a material adverse effect on our business, financial condition or results of operations and could potentially cause us to cease operations.

Failure to obtain or maintain adequate reimbursement or insurance coverage for products, if any, could limit our ability to market those products and decrease our ability to generate revenue.

The pricing, coverage, and reimbursement of our approved products, if any, must be sufficient to support our commercial efforts and other development programs, and the availability and adequacy of coverage and reimbursement by third-party payors, including governmental and private insurers, are essential for most patients to be able to afford medical treatments. Sales of our approved products, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of our approved products, if any, will be paid for or reimbursed by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or government payors and private payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide products for free or we may not be able to successfully commercialize our products.

In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by the Centers for Medicare and Medicaid Services, or CMS, an agency within the United States Department of Health and Human Services, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel product candidates such as ours and what reimbursement codes our product candidates may receive if approved.

Outside the United States, international operations are generally subject to extensive governmental price controls and other price-restrictive regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of products are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products, if any. Accordingly, in markets outside the United States, the potential revenue may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and private payors in the United States and abroad to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our products if any. We expect to experience pricing pressures in connection with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs in particular, has and is expected to continue to increase in the future. As a result, profitability of our products, if any, may be more difficult to achieve even ifany of them receive regulatory approval.

Risks Related to Ownership of Our Common Stock

The market price of our common stock is expected to be volatile, and the market price of the common stock may drop.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- our ability to obtain regulatory approvals for MT-3724 or other product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates, if approved, to achieve commercial success;
- failure to maintain our existing third-party license and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- failure by securities or industry analysts to publish research or reports about our business, or issuance of any adverse or misleading opinions by such analysts regarding our business or stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of our common stock by us or our stockholders in the future;
- the trading volume of our common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to ETB therapeutics generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with our potential products;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

Additionally, a decrease in our stock price may cause our common stock to no longer satisfy the continued listing standards of The Nasdaq Capital Market. If we are not able to maintain the requirements for listing on The Nasdaq Capital Market, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock.

Future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. As of September 30, 2019, a total of 36,954,510 shares of our common stock were outstanding. Any sales of those shares or any perception in the market that such sales may occur could cause the trading price of our common stock to decline.

In addition, shares of our common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plan will be eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, the Sales Agreement with Cantor, or otherwise, could result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Even after giving effect to the funds raised in the past, we expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner in which we may determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted. Additionally, new investors could gain rights, preferences and privileges senior to those of existing holders of our common stock. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders could cause the market price of our common stock to decline.

Pursuant to our 2018 Equity Incentive Plan, or the 2018 Plan, we are authorized and have available to grant equity awards to our employees, directors and consultants for up to an aggregate of 3.4 million shares of our common stock reserved for issuance pursuant to the 2018 Plan at September 30, 2019, which includes potential forfeitures and cancellations of outstanding stock options from the 2004 Equity Incentive Plan, the 2009 Equity Incentive Plan, and 2014 Equity Incentive Plan. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

Pursuant to the Sales Agreement with Cantor, we may offer and sell up to $50,000,000 of our common stock from time to time through Cantor as our sales agent. Sales of the shares of our common stock, if any, may be made by any means permitted by law and deemed to be an “at-the-market” offering as defined in Rule 415 of the Securities Act and will generally be made by means of brokers' transactions on the NASDAQ Global Market or otherwise at market prices prevailing at the time of sale, or as otherwise agreed with Cantor. To date, we have not sold any shares of our common stock under the Sales Agreement. Whether we choose to affect future sales under the Sales Agreement will depend upon a variety of factors, including, among others, market conditions and the trading price of our common stock relative to other sources of capital. The issuance from time to time of these new shares of common stock under the Sales Agreement or in any other equity offering, or the perception that such sales may occur, could have the effect of depressing the market price of our common stock.

Our management will have broad discretion over the use of the net proceeds from any sale of shares of common stock made under the Sales Agreement and you may not agree with how we use the proceeds and the proceeds may not be invested successfully.

Our management will have broad discretion as to the use of the net proceeds from the sale of shares of common stock under the Sales Agreement. Accordingly, you are relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds will be used appropriately. It is possible that the proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure by our

management to apply these funds effectively could have an adverse effect on our financial condition, results of operations or the trading price of our common stock.

We may incur significant costs from class action litigation due to our expected stock volatility.

Our stock price may fluctuate for many reasons, including as a result of public announcements regarding the progress of our development efforts or the development efforts of future collaborators or competitors, the addition or departure of our key personnel, variations in our quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies.

This risk is especially relevant to us because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years. When the market price of a stock has been volatile, as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, it could result in substantial costs for defending the lawsuit and diversion of the time, attention and resources of our board of directors and management, which could significantly harm our profitability and reputation.

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions that could discourage another company from acquiring us and may prevent attempts by our stockholders to replace or remove our current management.

Provisions of Delaware law, where we are incorporated, our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger or acquisition that our stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace or remove our board of directors. These provisions include:

- authorizing our board of directors to issue "blank check" preferred stock without any need for approval by stockholders;
- providing for a classified board of directors with staggered three-year terms;
- requiring supermajority stockholder votes to effect certain amendments to our amended and restated certificate of incorporation and amended and restated bylaws;
- eliminating the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, or the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and executive officers provide that:

- We will indemnify our directors and executive officers for serving us in those capacities or for serving other related business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

We have never paid dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain for the foreseeable future.

We incur, and will continue to incur, costs and expect significantly increased costs as a result of operating as a public company, and our management is now required to devote substantial time to new compliance initiatives.

As a public company listed on The Nasdaq Capital Market, and particularly after we cease to be an "emerging growth company", a "smaller reporting company", and/or a non-accelerated filer, we are incurring and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company or as a public company prior to the loss of such specified statuses. We are subject to the reporting requirements of the Exchange Act, as well as various requirements imposed by the Sarbanes-Oxley Act, rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, and the Dodd-Frank Wall Street Reform and Consumer Protection Act. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. The listing requirements of The Nasdaq Capital Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct, each of which requires additional attention and effort of management and our board of directors and additional costs.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We also expect that we will need to hire additional accounting, finance and other personnel in connection with our efforts to comply with the requirements of being a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors and committees thereof or as executive officers.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provisions of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine. The 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 other employees. If a court were to find the choice of forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

An active trading market for our common stock may not develop.

Prior to the Merger, there had been no public market for Private Molecular common stock. An active trading market for our shares of common stock may not be sustained. If an active market for our common stock is not sustained, it could put downward pressure on the market price of our common stock and thereby affect the ability of stockholders to sell their shares.

If securities or industry analysts do not publish, or cease publishing, research or reports, or publish unfavorable research or reports, about us, our business or our market, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced, in part, by the research and reports that industry or financial research analysts publish about us and our business. We do not have any control over these analysts. If only a few securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively affected and there can be no assurance that analysts will provide favorable coverage. If securities or industry analysts who initiate coverage downgrade our stock or publish inaccurate or unfavorable research about our business or our market, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and any trading volume to decline.

We have broad discretion in the use of our cash reserves and may not use these reserves effectively or as anticipated by stockholders.

We have broad discretion over the use of our cash reserves, including the proceeds from our previous financings. Our stockholders may not agree with our decisions, and our use of these funds may not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could compromise our ability to pursue our growth strategy, result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash reserves in a manner that does not produce income or that loses value.

Having availed ourselves of scaled disclosure available to smaller reporting companies, we cannot be certain if such reduced disclosure will make our common stock less attractive to investors.

Under Section 12b-2 of the Exchange Act, a "smaller reporting company" is a company that is not an investment company, an asset backed issuer, or a majority-owned subsidiary of a parent company. Effective September 10, 2018, the definition of a “smaller reporting company” was amended to include companies with a public float of less than $250 million as of the last business day of its most recently completed second fiscal quarter or, if such public float is less than $700 million, had annual revenues of less than $100 million during the most recently completed fiscal year. Smaller reporting companies are permitted to provide simplified executive compensation disclosure in their filings; they are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal controls over financial reporting; and they have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. At June 30, 2019, we qualified as a smaller reporting company. For as long as we continue to be a smaller reporting company, we expect that we will take advantage of the reduced disclosure obligations available to us as a result of those respective classifications. Decreased disclosure in our SEC filings as a result of our having availed ourselves of scaled disclosure may make it harder for investors to analyze our results of operations and financial prospects.

Risks Related to Our Business Operations

Our future success depends in part on our ability to retain our Chief Executive Officer and Chief Scientific Officer and to attract, retain, and motivate other qualified personnel.

We are highly dependent on Eric E. Poma, Ph.D., our Chief Executive Officer and Chief Scientific Officer, the loss of whose services may adversely impact the achievement of our objectives. Dr. Poma could leave our employment at any time, as he is an “at will” employee. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be crucial to our success. There is currently a shortage of highly qualified personnel in our industry, which is likely to continue. Additionally, this shortage of highly qualified personnel is particularly acute in the area where we are located. As a result, competition for personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in development and commercialization of our product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel, or the loss of the services of Dr. Poma may impede the progress of our research, development and commercialization objectives and would negatively impact our ability to succeed in our product development strategy.

We will need to continue to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

At September 30, 2019, we had 102 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management

may need to divert its attention away from its day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected or budgeted, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our currently anticipated business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth. Failure to manage this growth could disrupt our business operations and negatively impact our ability to achieve success.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology or loss of data, including any cyber security incidents, could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability which could harm our ability to operate our business effectively and adversely affect our business and reputation.

Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology, or IT, systems. In the ordinary course of our business, we collect and store sensitive data, including personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems. These applications and data encompass a wide variety of business-critical information including research and development information and business and financial information. .

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy. Despite the implementation of security measures, our IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, cyber-attacks, computer viruses, breaches, unauthorized access, interruptions due to employee error or malfeasance or other disruptions, or damage from natural disasters, terrorism, war and telecommunication and electrical failures. Moreover, despite network security and back-up measures, some of our and our vendors' servers are potentially vulnerable to physical or electronic break-ins, including cyber-attacks, computer viruses and similar disruptive problems. These events could lead to the unauthorized access, disclosure and use of non-public information including our intellectual property or proprietary business information. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated or remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. There can be no assurance that we will promptly detect any such disruption or security breach, if at all. If our computer systems are compromised, we could be subject to fines, damages, reputational harm, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business, in addition to possibly requiring substantial expenditures of resources to remedy. For example, the loss of data from clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce data and a cybersecurity breach could adversely affect our reputation and could result in other negative consequences, including disruption of our internal operations, increased cyber security protection costs, lost revenues or litigation. Despite precautionary measures to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

As part of its ongoing review of the Company's legacy program, Evofosfamide, the Company has had various exploratory discussions with third parties about a potential strategic transaction involving Evofosfamide, including a potential sale of that legacy program, which the Company acquired from Threshold Pharmaceuticals in 2017. As of the third quarter, for accounting purposes, the Company determined to classify the in-process research and development asset on its balance sheet that is associated with Evofosfamide as an asset held for sale. Further, the Company obtained a fair value estimate, from a third party specialist as of August 1, 2019, and determined the asset was impaired during the third quarter and recorded a non-cash impairment charge of $22.1 million. See Note 11 to the financial statements. Specifically, the Audit Committee of the Board of Directors made this determination in connection with the review of the financial statements required to be included in this Current Report. There can be no assurances whether any transaction will result involving Evofosfamide or, if any such transaction were to occur, its timing or value, or whether there may be additional future impairments regarding this legacy program.

ITEM 6. EXHIBITS

EXHIBIT INDEX

The exhibits listed on the accompanying index to exhibits are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

Exhibit Number	Description
10.1 #	First Amendment to the Development Collaboration and Exclusive License Agreement, dated as of July 18, 2019, by and between Molecular Templates, Inc. and Millennium Pharmaceuticals, Inc.
31.1	Certification of Principal Executive Officer required by Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934 as amended.
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934 as amended.
32.1*	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350).
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

* Furnished herewith. This certification is not deemed filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and is not deemed to be incorporated by reference into any filing under the Securities the Exchange Act.

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.

Molecular Templates, Inc.

Date: November 12, 2019

/s/ Eric E. Poma

Eric E. Poma, Ph.D.
Chief Executive Officer and Chief Scientific Officer
(Principal Executive Officer)

Date: November 12, 2019

/s/ Adam Cutler

Adam Cutler
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

FIRST AMENDMENT TO DEVELOPMENT COLLABORATION AND EXCLUSIVE LICENSE AGREEMENT

This First Amendment to Development Collaboration and Exclusive License Agreement (this "**Amendment**") is made and entered into as of July 18, 2019 (the "**Amendment Effective Date**") by and between **MOLECULAR TEMPLATES, INC.**, a Delaware corporation, having its principal place of business at 9301 Amberglen Boulevard, Suite 100, Austin, TX 78729 ("**MTEM**"), and **MILLENNIUM PHARMACEUTICALS, INC.**, a Delaware corporation and a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited, having its principal place of business at 40 Landsdowne Street, Cambridge, MA 02139 ("**Takeda**"). MTEM and Takeda may be referred to herein collectively as the "**Parties**" and individually as a "**Party**."

RECITALS

WHEREAS, MTEM and Takeda entered into that certain Development Collaboration and Exclusive License Agreement dated as of September 18, 2018 (the "**Agreement**");

WHEREAS, MTEM and Takeda have agreed that MTEM may exercise the Co-Development Option (as defined below) at any time, and the Parties wish to amend the Agreement to clarify certain provisions relating to MTEM's exercise of the Co-Development Option; and

WHEREAS, there was a drafting error in one of the milestone provisions of the Agreement that the Parties wish to correct.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

1. All capitalized terms used in this Amendment and not otherwise defined herein shall have the same meaning as defined in the Agreement.

2. The sixth recital in the Agreement is hereby amended to delete the word, "thereafter."

3. Section 1.1.28 of the Agreement (definition of "Co-Development Period") is hereby amended by adding the following proviso at the end of such Section:

> "; provided, however, if MTEM exercises the Co-Development Option prior to completion of the Early Stage Program and provides a Co-Development Termination Notice prior to completion of the Early Stage Program, the Co-Development Period shall remain in effect and shall end upon completion of the Early Stage Program."

[***] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY BRACKETS, HAS BEEN OMITTED BECAUSE THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

4. The first sentence of Section 2.1.2(a) of the Agreement is hereby amended by deleting such sentence and replacing it in its entirety with the following:

"Upon Takeda's election, but in no case later than [***] following completion (as described in the Early Stage Program Plan) of the Early Stage Program Plan, Takeda shall deliver the Post Phase la Program Plan to MTEM."

5. Section 2.1.2(b)(i) of the Agreement is hereby amended by deleting such Section and replacing it in its entirety with the following:

"Subject to the provisions of this Agreement, in addition to MTEM's rights and obligations hereunder with respect to the Early Stage Program, Takeda grants to MTEM an option to continue to Co-Develop the Licensed Products that are under Development in accordance with this Agreement during and after the Post Phase Ia Program, as further set forth herein ("***Co-Development Option***"). For clarity, MTEM's rights and obligations under the Co-Development Option shall extend to any or all Licensed Products that are Developed under this Agreement during the Term. If MTEM desires to exercise its Co-Development Option, then it shall do so by written notice to Takeda at any time during the period from the Effective Date to the date that is [***] after Takeda delivers the Post Phase Ia Program Plan to MTEM as set forth in Section 2.1.2(a), provided, however, that MTEM may not exercise its Co-Development Option unless it has paid all Co-Development Costs that have come due pursuant to this Agreement as of the date of such election."

6. The first sentence of Section 2.1.2(b)(ii) of the Agreement is hereby amended by deleting such sentence and replacing it in its entirety with the following:

"If MTEM exercises the Co-Development Option, then [***], at the beginning of[***], commencing [***], the Joint Steering Committee or designated subcommittee shall prepare an updated Post Phase Ia Program Plan that covers future Development and Commercialization of Licensed Product(s) with a [***] detailed projection on costs and activities for MTEM's budgeting process."

7. Section 5.2 of the Agreement is hereby amended by deleting such Section and replacing it in its entirety with the following:

"Without limitation to MTEM's obligations under Section 3.9, at Takeda's request, for each Licensed Product, MTEM shall, at MTEM's and Takeda's expense (50:50) prior to the end of the Co-Development Termination Notice Period (subject to a mutually agreed reasonable budget with internal time to be calculated on an FTE basis based on a rate that reflects MTEM's actual costs for such FTE) and thereafter at Takeda's expense, transfer the Manufacturing process for such Licensed Product and any CD38 SLT-A Fusion Proteins and components thereof to Takeda or any of Takeda's designees (each, a "**Technology Recipient**") as set forth in this Section 5.2, which transfer or transfers will

comprise all necessary and available Know-How, documentation, methods, reagents, processes and other components to enable Takeda or any of Takeda's designees to independently Manufacture Licensed Products (each such transfer, a "**Technology Transfer**"). The Parties contemplate that there may be more than one Technology Transfer. After any Technology Transfer, the Parties contemplate, including pursuant to Section 5.3 hereof, that MTEM may continue to assist Takeda and provide clinical supplies to Takeda pursuant to the Supply Agreement."

8. Section 5.2.6 of the Agreement is hereby amended by deleting such Section and replacing it in its entirety with the following:

"Takeda and MTEM shall share the reasonable, out-of-pocket costs and expenses incurred in the performance of MTEM's activities under this Section 5.2 (in which case such amounts paid shall be included as Co-Development Costs), unless the applicable Technology Transfer is a response by Takeda to a material breach by MTEM of its supply obligations hereunder that is not cured by MTEM pursuant to this Agreement, in which case MTEM shall bear all of its own costs and expenses for the performance of its activities under this Section 5.2."

9. Section 6.5.2 of the Agreement is hereby amended by deleting such Section and replacing it in its entirety with the following:

"Subject to Section 6.5.3, if MTEM has exercised the Co-Development Option in accordance with Section 2.1.2(b), MTEM and Takeda shall [***] of the Co-Development Costs with respect to the Post Phase Ia Program (whether incurred by MTEM or Takeda or their respective Affiliates, licensees, or Sublicensees), subject to Section 2.1.2(b) and Article IV, until, in the case of the delivery of a Co-Development Termination Notice pursuant to this Section 6.5.2, the effective date of termination of MTEM's Co-Development Option as provided in this Section 6.5.2. If, at any point after MTEM's exercise of the Co-Development Option, MTEM elects to end its Co-Development hereunder, it may do so by providing Takeda with written notice of termination (the "**Co-Development Termination Notice**"). Upon MTEM's delivery of a Co-Development Termination Notice, the effective date of termination of MTEM's Co-Development Option shall be as follows: (a) if MTEM has exercised the Co-Development Option in accordance with Section 2.1.2(b) prior to Takeda's delivery of the Post Phase Ia Program Plan to MTEM pursuant to Section 2.1.2(a) and if MTEM provides the Co-Development Termination Notice on or before the date that is [***] after Takeda's delivery of the Post Phase Ia Program Plan to MTEM, then the effective date of termination of MTEM's Co-Development Option shall be the date of the Co-Development Termination Notice; (b) if MTEM has exercised the Co-Development Option in accordance with Section 2.1.2(b) prior to Takeda's delivery of the Post Phase Ia Program Plan to MTEM pursuant to Section 2.1.2(a) and if MTEM provides the Co-Development Termination Notice after the date that is [***] after Takeda's delivery of the Post Phase Ia Program Plan to MTEM, then the

effective date of termination of MTEM's Co-Development Option shall be the date that is [***] after the date of the Co-Development Termination Notice; or (c) if MTEM has exercised the Co-Development Option in accordance with Section 2.1.2(b) after Takeda's delivery of the Post Phase Ia Program Plan to MTEM pursuant to Section 2.1.2(a), then the effective date of termination of MTEM's Co-Development Option shall be the date that is [***] after the date of the Co-Development Termination Notice. As used throughout this Agreement, the term "**Co-Development Termination Notice Period**" (and the phrases "end of the Co-Development Termination Notice Period" or "through the Co-Development Termination Notice Period") shall mean the period ending on the effective date of termination of MTEM's Co-Development Option as provided in the preceding clauses (a), (b) and (c) (i.e., the effective date of termination referenced in clause (a) or the expiration of the [***] period referenced in clause (b) or clause (c), as applicable). MTEM shall continue to be responsible for [***] of the Co-Development Costs incurred prior to the end of the Co-Development Termination Notice Period in accordance with this Section 6.5.2 and, if MTEM provides the Co-Development Termination Notice before completion of the Early Stage Program, MTEM shall continue to be responsible for [***] of the Co-Development Costs with respect to the Early Stage Program in accordance with Section 6.5.1. MTEM shall not be obligated to pay for any Co-Development Costs incurred after the end of the Co-Development Termination Notice Period except, if applicable, any Co-Development Costs with respect to the Early Stage Program if incurred after the end of the Co-Development Termination Notice Period. For the avoidance of doubt, MTEM's delivery of a Co-Development Termination Notice shall not terminate or otherwise alter MTEM's obligation to fund [***] of the Co-Development Costs with respect to the Early Stage Program in accordance with Section 6.5.1 (if any after the end of the Co-Development Termination Notice Period) and, notwithstanding MTEM's delivery of a Co-Development Termination Notice, if delivered prior to the end of the Early Stage Program, the Co-Development Period shall remain in effect and shall end upon completion of the Early Stage Program. Effective as of the end of Co-Development Termination Notice Period, Takeda's milestone obligations under this Article VI shall be reduced to the lower amounts in Column 1 of each applicable table (as if MTEM had not exercised its Co-Development Option), and Takeda shall continue to be obligated to pay royalties at the higher rate set forth in Column 2 of the table in Section 6.4 until the amount of royalties paid to MTEM by Takeda equals, in the aggregate, the MTEM Co-Development Cost Amount (the "**Transition Point**"), after which, Takeda shall pay royalties at the lower rate set forth in Column I of the table in Section 6.4

10. The Milestone Event set forth in milestone number 16 in Section 6.2 is hereby amended by deleting it and replacing it in its entirety with the following:

[***]

11. Each Party hereby represents and warrants to the other that it has the corporate power and authority to enter into this Amendment and this Amendment constitutes a legal, valid and binding obligation, enforceable against such Party in accordance with its terms.

12. This Amendment shall be effective on the Amendment Effective Date.

13. Except as expressly modified by this Amendment, all of the terms and conditions of the Agreement shall remain in full force and effect. To the extent that there are any inconsistencies between this Amendment and the Agreement, the terms of this Amendment shall govern and shall supersede the Agreement.

14. This Amendment may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party may execute this Amendment by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail. Facsimile or PDF signatures of authorized signatories of the Parties will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Amendment.

[Signature Page Follows]

In Witness Whereof, the Parties have caused this Amendment to be executed by their duly authorized representatives as of the Amendment Effective Date.

MOLECULAR TEMPLATES, INC.

By: /s/ Eric Poma
Name: Eric Poma
Title: CEO

MILLENNIUM PHARMACEUTICALS, INC.

By: /s/ Teresa Bitetti
Name: Teresa Bitetti
Title: President

Exhibit 31.1

CERTIFICATIONS UNDER SECTION 302

I, Eric E. Poma, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Molecular Templates, 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.

Date: November 12, 2019

/s/ Eric E. Poma, Ph.D.
Eric E. Poma, Ph.D.

Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATIONS UNDER SECTION 302

I, Adam Cutler, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Molecular Templates, 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.

Date: November 12, 2019

/s/ Adam Cutler
Adam Cutler

Chief Financial Officer
(principal financial officer and principal accounting officer)

Exhibit 32.1

CERTIFICATIONS UNDER SECTION 906

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Molecular Templates, Inc., a Delaware corporation (the "Company"), does hereby certify, to such officer's knowledge, that:

The Quarterly Report for the quarter ended September 30, 2019 (the "Form 10-Q") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 12, 2019

/s/ Eric E. Poma, Ph.D.
Eric E. Poma, Ph.D.
Chief Executive Officer
(principal executive officer)

Dated: November 12, 2019

/s/ Adam Cutler
Adam Cutler
Chief Financial Officer
(principal financial officer and principal accounting officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon