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 March 31, 2020

or

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

For the transition period from_____ to _____

Commission File Number: 001-32979

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 May 8, 2020, there were 45,707,785 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, including the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations", 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 (ETB) biologic candidates;
- the timing and our ability to advance the development of our drug or biologic 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 biologic candidates;
- our financial condition, including our ability to obtain the funding necessary to advance the development of our drug or biologic candidates;
- the anticipated progress of our drug or biologic 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 drug or biologic candidates;
- our ability to establish and maintain intellectual property rights for our drug or biologic candidates;
- whether any drug or biologic 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 drug or biologic candidates suitable for clinical testing;
- our ability to identify, in-license or otherwise acquire additional drug or biologic candidates and development programs;
- our anticipated research and development activities and projected expenditures;
- our ability to complete preclinical and clinical testing successfully for new drug or biologic candidates that we may develop or license;
- our ability to have manufactured active pharmaceutical ingredient, or API, and drug or biologic 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 anticipated use of proceeds from any financing activities;
- our ability to retain and hire necessary employees and appropriately staff our development programs;
- the extent to which COVID-19 may impact our business operations or financial condition;
- our projected financial performance; and
- the sufficiency of our cash resources; and other risks and uncertainties, including those listed under Part I, 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.

As used in this Quarterly Report on Form 10-Q, unless otherwise stated or the context otherwise indicates, references to “Molecular,” the “Company,” “we,” “our,” “us” or similar terms refer to Molecular Templates, Inc., and our wholly owned subsidiaries.

Molecular Templates, Inc.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	March 31, 2020 (unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,444	$ 85,451
Marketable securities, current	70,544	39,633
Prepaid expenses	3,727	2,318
Grants revenue receivable	9,441	7,100
Accounts receivable, related party	1,300	408
In-process research and development - held for sale	4,500	4,500
Other current assets	242	489
Total current assets	124,198	139,899
Marketable securities, non-current	3,010	1,510
Operating lease right-of-use assets, non-current	9,617	9,959
Property and equipment, net	19,301	18,158
Other assets	4,617	4,676
Total assets	$ 160,743	$ 174,202
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,770	$ 1,465
Accrued liabilities	11,531	14,544
Deferred revenue, current	11,465	8,511
Deferred revenue, current, related party	8,773	8,780
Other current liabilities, related party	7,754	—
Other current liabilities	2,543	2,501
Total current liabilities	43,836	35,801
Deferred revenue, long-term	14,523	18,944
Deferred revenue, long-term, related party	1,355	441
Long-term debt, net	2,888	2,940
Operating lease liabilities, non-current	11,232	11,682
Other liabilities	3,143	1,366
Total liabilities	76,977	71,174
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $0.001 par value:		
Authorized: 2,000,000 shares at March 31, 2020 and December 31, 2019; issued and outstanding: 250 shares at March 31, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value:		
Authorized: 150,000,000 shares; issued and outstanding: 45,703,934 shares at March 31, 2020 and 45,589,157 shares at December 31, 2019	46	46
Additional paid-in capital	269,581	267,089
Accumulated other comprehensive income	282	18
Accumulated deficit	(186,143)	(164,125)
Total stockholders' equity	83,766	103,028
Total liabilities and stockholders' equity	$ 160,743	$ 174,202

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 March 31,	
	2020	2019
Research and development revenue, related party	$ 333	$ 6,413
Research and development revenue, other	1,467	—
Grant revenue	2,341	595
Total revenue	4,141	7,008
Operating expenses:		
Research and development	20,631	8,454
General and administrative	5,647	4,935
Total operating expenses	26,278	13,389
Loss from operations	22,137	6,381
Interest and other income, net	472	510
Interest and other expense, net	(348)	(293)
Change in fair value of warrant liabilities	—	(4)
Loss before provision for income taxes	22,013	6,168
Provision for income taxes	5	—
Net loss	22,018	6,168
Net loss attributable to common shareholders	$ 22,018	$ 6,168
Net loss per share attributable to common shareholders:		
Basic and diluted	$ 0.48	$ 0.17
Weighted average number of shares used in net loss per share calculations:		
Basic and diluted	45,649,065	36,738,993

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 March 31,	
	2020	2019
Net loss	$ (22,018)	$ (6,168)
Other comprehensive income:		
Unrealized gain on available-for-sale securities	264	—
Comprehensive loss	$ (21,754)	$ (6,168)

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 March 31,	
	2020	2019
Total Stockholders' Equity (Deficit), beginning balances	$ 103,028	$ 100,906
Preferred Stock:		
Beginning balance	—	—
Issuance of preferred stock	—	—
Ending balance	—	—
Common Stock:		
Beginning balance	46	37
Issuance of common stock pursuant to stock plans	—	—
Ending balance	46	37
Additional Paid-In Capital		
Beginning balance	267,089	195,573
Issuance of common stock pursuant to stock plans	300	38
Stock-based compensation	2,192	1,361
Ending balance	269,581	196,972
Accumulated Other Comprehensive Income:		
Beginning balance	18	—
Other comprehensive income	264	—
Ending balance	282	—
Accumulated deficit:		
Beginning balance	(164,125)	(94,704)
Net loss	(22,018)	(6,168)
Ending balance	(186,143)	(100,872)
Total Stockholders' Equity	$ 83,766	$ 96,137

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)

	Three Months Ended March 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ 22,018	$ 6,168
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation, amortization and other	618	177
Stock-based compensation expense	2,192	1,360
Amortization of debt discount and accretion related to debt	148	105
Change in common stock warrant fair value	—	4
Accretion of asset retirement obligations	32	11
Loss on disposal of equipment	—	—
Changes in operating assets and liabilities:		
Prepaid expenses	(1,409)	239
Accounts receivable, related party	(892)	(55)
Grants revenue receivable	(2,341)	(2)
Other assets	293	(338)
Operating lease right-of-use assets and liabilities	(60)	—
Accounts payable	260	802
Accrued liabilities	(3,912)	622
Other liabilities	1,746	(204)
Other liabilities, related party	7,754	—
Deferred revenue	(1,467)	
Deferred revenue, related party	907	(7,529)
Net cash used in operating activities	(18,149)	(10,976)
Cash flows from investing activities:		
Purchases of property and equipment	(938)	(625)
Purchase of marketable securities	(50,463)	(36,588)
Sales of marketable securities	18,450	1,293
Net cash used in investing activities	(32,951)	(35,920)
Cash flows from financing activities:		
Repayment of long-term debt	(200)	—
Proceeds from stock option exercises	300	38
Proceeds from issuance of common stock and warrants, net of offering expenses	(7)	(8)
Net cash provided by financing activities	93	30
Net (decrease) increase in cash, cash equivalents, and restricted cash	(51,007)	(46,866)
Cash, cash equivalents and restricted cash, beginning of period	88,451	87,721
Cash, cash equivalents and restricted cash, end of period	$ 37,444	$ 40,855
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 34,444	$ 37,855
Restricted cash included in Other assets	3,000	3,000
Total cash, cash equivalents and restricted cash	$ 37,444	$ 40,855
Supplemental Cash Flow Information		
Cash paid for interest	$ 163	$ 174
Non-Cash Investing and Financing Activities		
Fixed asset additions in accounts payable and accrued expenses	$ 944	—
Right-of-use asset obtained in exchange for operating lease obligations	—	7,234
Adoption of ASC 842	—	$ 4,179
Total non-cash investing and financing activities	$ 944	$ 11,413

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").

On August 1, 2017, the Company, formerly known as Threshold Pharmaceuticals, Inc. (Nasdaq: THLD) ("Threshold"), completed its business combination with Private Molecular, in accordance with the terms of the Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), dated as of March 16, 2017, by and among Threshold, the Merger Sub, a wholly owned subsidiary of Threshold, and Private Molecular, pursuant to which Merger Sub merged with and into Private Molecular, with Private Molecular, surviving as a wholly-owned subsidiary of Threshold (the "Merger"). Immediately upon completion of the Merger, the former stockholders of Private Molecular held a majority of the voting interest of the combined company.

In March 2020, the outbreak of COVID-19 caused by a novel strain of the coronavirus was recognized as a pandemic by the World Health Organization. While the COVID-19 pandemic has not had a material adverse impact on the Company's operations to date, the full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain. Additionally, the economic impact of COVID-19 on local, regional, national and international customers and markets may have a material adverse impact on the Company. Refer to Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q for a complete description of risks.

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America and include the accounts of the Company and its wholly owned subsidiary, and reflect the elimination of intercompany accounts and transactions.

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, 2019 included in the Company's Annual Report on Form 10-K filed with the SEC on March 13, 2020.

Reclassifications

Certain amounts in the prior year's presentation have been reclassified to conform to the current presentation. The condensed consolidated balance sheet at December 31, 2019 included herein was derived from the audited financial statements at that date, but includes a reclassification of $8.8 million from Deferred revenue, current to Deferred revenue, current, related party and $0.4 million from Deferred revenue, non-current to Deferred revenue, non-current, related party in order to conform to current period presentation. The condensed consolidated statements of cash flow for the three months ended March 31, 2019 included herein includes a reclassification of $7.5 million from Deferred revenue to Deferred revenue, related party.

Liquidity

At March 31, 2020, we had cash, cash equivalents, and marketable securities of $108.0 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. We expect that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into 2022.

Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies during the three months ended March 31, 2020, 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, 2019.

Cash and Cash Equivalents

The Company considers temporary investments having 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 March 31, 2020.

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. Vertex accounted for approximately 35% and 0% of total revenues for the three months ended March 31, 2020 and 2019, respectively. The Company's exposure to credit risk associated with non-payment will be affected principally by conditions or occurrences within Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Ltd. ("Takeda"). Takeda accounted for approximately 8% and 92% of total revenues for the three months ended March 31, 2020 and 2019, respectively.

Drug or biologic 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 or biologic 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 August 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-13, Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement ("ASU 2018-13"). ASU 2018-13 is intended to improve the effectiveness of disclosures in the notes to financial statements related to fair value measurements in Topic 820. This ASU was effective for annual periods beginning after December 15, 2019, including interim periods within that period. The impact of the adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, Intangibles - Goodwill and Other - Internal-Use Software -Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract ("ASU 2018-15"). ASU 2018-15 aligns the accounting for implementation costs incurred in a hosting arrangement that is a service contract with the guidance on capitalizing costs associated with developing or obtaining internal-use software. This ASU was effective for annual periods beginning after December 15, 2019, including interim periods within that period, and early adoption is permitted. The impact of the adoption of this standard did not have a material impact on the Company's 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 was effective for the Company beginning January 1, 2020. The impact of the adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses, which requires recognizing credit losses on financial instruments based on an estimate of current expected credit losses. The new guidance applies to loans, accounts receivable, trade receivables, other financial assets measured at amortized cost, loan commitments and other off-balance sheet credit exposures. The new guidance also applies to debt securities and other financial assets measured at fair value through other comprehensive income. This guidance was effective for the Company beginning January 1, 2020. The impact of the adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740: Simplifying the Accounting for Income Taxes), which removes certain exceptions to the general principles in Topic 740. ASU 2019-12 is effective for the fiscal years beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

In March 2020, the FASB issued ASU No. 2020-04, Reference Rate Reform (Topic 848: Facilitation of the Effects of Reference Rate Reform on Financial Reporting). The new guidance provides optional guidance for a limited period of time for applying generally accepted accounting principles (GAAP) to contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. The guidance will be effective prospectively as of March 12, 2020 through December 31, 2022 and interim periods within those fiscal years. 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 utilizing the two-class method. Preferred Stock Shareholders participate equally with Common Stock Shareholders in earnings, but do not participate in losses, and are excluded from the basic net loss calculation. Diluted net loss per share is computed by giving effect to all potential dilutive common shares, including outstanding options, warrants and convertible preferred stock. More specifically, at March 31, 2020 and March 31, 2019, stock options, warrants and, if converted, preferred stock totaling approximately 9,688,920 and 8,817,000 common 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 March 31,	
	2020	2019
Japan	$ 333	$ 6,413
United States	1,467	—
Total research and development revenue	$ 1,800	$ 6,413

Related Party Collaboration Agreement - Takeda

Research and development revenue from related party relates to revenue from research and development agreements with Millennium Pharmaceuticals, Inc., a wholly-owned subsidiary of Takeda Pharmaceutical Company Ltd. (“Takeda”) and were as follows (in thousands):

	Three Months Ended March 31,	
	2020	2019
Takeda Individual Project Agreement	—	54
Takeda Development and License Agreement	147	6,114
Takeda Multi-Target Agreement	186	245
Total research and development revenue	$ 333	$ 6,413

At March 31, 2020 and December 31, 2019, the Company had $36.1 million and $36.7 million, respectively, of Deferred revenue related to research and development agreements. Deferred revenue, other liabilities for co-share payments and accounts receivable balances from the research and development agreements with Takeda, who is a related party, were as follows (in thousands):

	March 31, 2020	December 31, 2019
Assets		
Accounts receivable	$ 1,300	$ 408
Liabilities		
Other current liabilities	$ 7,754	—
Deferred revenue, current	8,773	8,780
Deferred revenue, non-current	1,355	441
Other liabilities	1,746	—
Total liabilities	$ 19,628	$ 9,221

Takeda Development and License Agreement

On September 18, 2018, the Company entered into a Development Collaboration and Exclusive License Agreement with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited ("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, exercised its co-development option in July 2019 and as a result 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.

The Company 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 following the Company's exercise of its option to co-develop, and from high-single digits to low teens if the Company elects to end its co-development.

The Company identified one performance obligation at the inception of the Takeda Development and License Agreement, the research and development services for the CD38-targeted SLT-A fusion protein, 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 $29.8 million consists of (1) the $30.0 million upfront payment, (2) a $10.0 million development milestone payment that was received in the first quarter of 2020, (3) minus $10.2 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 March 31, 2020, 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 March 31, 2020.

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.

In July 2019, the Company exercised its co-development option and 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.

At March 31, 2020 and December 31, 2019, total deferred revenue related to the performance obligation was $7.2 million and $6.1 million, respectively.

Takeda Multi-Target Agreement

In June 2017, The Company entered into a Multi-Target Collaboration and License Agreement with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited (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.

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:

- $30.0 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 all option periods (three months after the completion of the evaluation of materials for the designated targets) for the designated targets if Takeda does not exercise its options, or, following exercise of any option, on the expiration of the last Royalty Term (the latest of the expiration of patent rights claiming the licensed ETB, expiration of regulatory exclusivity for the licensed ETB or ten years from first commercial sale of the licensed ETB). The Takeda Multi-Target Agreement may be terminated sooner by Takeda for convenience or upon a material change of control of the Company, 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 immediately upon written notice, under certain defined circumstances.

The Company evaluated the Takeda Multi-Target Agreement's termination clause and concluded that it was a non-substantive termination provision. As such, the Company believes that an initial contract term is 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-Target Agreement 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.

At March 31, 2020 and December 31, 2019, deferred revenue related to the performance obligation was $2.9 million and $3.1 million, respectively.

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 Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Ltd., in June 2018, that was amended and restated 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 received $2.2 million in compensation that included 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, the Company recognized $0.0 million and less than $0.1 million of research and development revenue for the three months ended March 31, 2020 and March 31, 2019 respectively. This revenue is deemed to be revenue from a related party (as discussed further in Note 7, Related Party Transactions).

Vertex Collaboration Agreement

In November 2019, the Company entered into a Master Collaboration Agreement (the "Vertex Collaboration Agreement") with Vertex Pharmaceuticals Incorporated ("Vertex"), to perform strategic research leveraging the Company's engineered toxin body ("ETB") technology platform to discover and develop novel targeted biologic therapies for applications outside of oncology.

Pursuant to the terms of the Vertex Collaboration Agreement, the Company granted Vertex an exclusive option to obtain an exclusive license under the Company's licensed technology to exploit one or more ETB products that are discovered by the Company against up to two designated targets. Vertex has selected an initial target and has the option to designate one additional target within specified time limits.

Vertex payed the Company an upfront payment of $38 million, consisting of $23 million in cash and a $15 million equity investment pursuant to a Share Purchase Agreement (the "SPA"). In addition to the upfront payments, the Company may also receive an additional $22 million through the exercise of the options to license ETB products or to add an additional target. Additionally, Vertex will reimburse the Company for certain mutually agreed manufacturing technology transfer activities. The Company had $11.5 million of Deferred revenue, current, and $14.5 million of Deferred revenue, non-current, at March 31, 2020 related to the Vertex Collaboration Agreement. The Company had $8.5 million of Deferred revenue, current, and $19.0 million of Deferred revenue, non-current, at December 31, 2019 related to the Vertex Collaboration Agreement.

The Company may, for each target under the Vertex Collaboration Agreement, receive up to an additional $180 million in milestone payments upon the achievement of certain development and regulatory milestone events and up to an additional $70 million in milestone payments upon the achievement of certain sales milestone events. The Company will also be entitled to receive, subject to certain reductions, tiered mid-single digit royalties as percentages of calendar year net sales, if any, on any licensed product.

The Company will be responsible for conducting the research activities through the designation, if any, of one or more development candidates. Upon the exercise by Vertex of its option for a development candidate, Vertex will be responsible for all development, manufacturing, regulatory and commercialization activities with respect to that development candidate.

Unless earlier terminated, the Vertex Collaboration Agreement will expire (i) on a country-by-country basis and licensed product-by-licensed product basis on the date of expiration of all payment obligations under the Vertex Collaboration Agreement with respect to such licensed product in such country and (ii) in its entirety upon the expiration of all payment obligations thereunder with respect to all licensed products in all countries or upon Vertex's decision not to exercise any option on or prior to the applicable deadlines. Vertex has the right to terminate the Vertex Collaboration Agreement for convenience upon prior written notice to the Company. Either party has the right to terminate the Vertex Collaboration Agreement (a) for the insolvency of the other party or (b) subject to specified cure periods, in the event of the other party's uncured material breach.

The Company identified one performance obligation at the inception of the Vertex Collaboration Agreement consisting of research and development services. The Company recognizes revenue under the Vertex Collaboration Agreement using a cost-based input measure. In applying the cost-based input method of revenue recognition, the Company will use actual costs incurred relative to budgeted costs expected to be incurred. 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.

In connection with the Vertex Collaboration Agreement, the Company and Vertex entered into a SPA pursuant to which Vertex agreed to purchase 1,666,666 shares of the Company's common stock, par value $0.001 per share, at a price per share of $9.00. As the price per share was in excess of the fair value of the Company's common stock, the Company allocated $4.5 million of this consideration to the Vertex Collaboration Agreement. The issuance of these shares were pursuant to a private placement exemption from registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D thereunder.

In addition to the SPA, the Vertex Collaboration Agreement contemplates that the Company may enter into certain other ancillary arrangements with Vertex.

Grant Agreements

In September 2018, the Company entered into a Cancer Research Agreement (the "CD38 CPRIT Agreement") with the Cancer Prevention and Research Institute of Texas ("CPRIT"). The CD38 CPRIT Agreement was extended in November 2019, 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 2011, the Company entered into a Cancer Research Agreement (the "CPRIT Agreement") with CPRIT under which CPRIT awarded a $10.6 million product development grant for the CD20-targeting ETB MT-3724. This product development grant ended in November 2019. At March 31, 2020 the Company had received $9.6 million and has a remaining receivable of $1.0 million.

During the three months ended March 31, 2020 and March 31, 2019, the Company recognized $2.3 million and $0.6 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 March 31, 2020 and December 31, 2019, the Company had $9.4 million and $7.1 million, respectively, recorded in Grants revenue receivable.

NOTE 4 — RELATED PARTY TRANSACTIONS

Takeda Agreements

In connection with the Takeda Multi-Target Agreement described in Note 3 "Research and Development Collaboration Agreements", Takeda became a related party, following the Takeda Stock Purchase Agreement described in Note 11 "Stockholders' Equity", of the Company's previously filed Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 13, 2020. Refer to Note 3, Research and Development Collaboration Agreements, for more details about the Takeda Collaboration Agreement, the Takeda Multi-Target Agreement and the Takeda Development and License Agreement. Jonathan Lanfear, a director of the Company, is the Vice President and Global Head of Oncology and Neuroscience Business Development for Takeda.

NOTE 5 —MARKETABLE SECURITIES AND FAIR VALUE MEASUREMENTS

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		
	March 31, 2020	Level 1	Level 2	Level 3
Money market funds	$ 24,973	$ 24,973	$ —	$ —
Commercial paper	37,821	—	37,821	—
United States Treasury Bills	31,427	—	31,427	—
United States government-related debt securities	10,057	—	10,057	—
Corporate bonds	1,250	—	1,250	—
Total	$ 105,528	$ 24,973	$ 80,555	$ —
Amounts included in:				
Cash and cash equivalents	$ 31,974			
Marketable securities, current	70,544			
Marketable securities, non-current	3,010			
Total cash equivalents and marketable securities	$ 105,528			

	December 31, 2019	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	$ 79,970	$ 79,970	$ —	$ —
Commercial paper	20,436	—	20,436	—
United States Treasury Bills	16,738	—	16,738	—
United States government-related debt securities	7,010	—	7,010	—
Corporate bonds	1,351	—	1,351	—
Total	$ 125,505	$ 79,970	$ 45,535	$ —
Amounts included in:				
Cash and cash equivalents	$ 84,362			
Marketable securities, current	39,633			
Marketable securities, non-current	1,510			
Total cash equivalents and marketable securities	$ 125,505			

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

	March 31, 2020			
	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Cash equivalents - money market funds, commercial paper and corporate bonds	$ 31,972	$ 2	$ —	$ 31,974
Marketable securities, current - commercial paper, Treasury bills and corporate bonds	70,274	273	(3)	70,544
Marketable securities, non-current - Treasury bills	$ 3,000	$ 10	$ —	$ 3,010

	December 31, 2019			
	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Cash equivalents - money market funds, commercial paper and corporate bonds	$ 84,361	$ 1	$ —	$ 84,362
Marketable securities, current - commercial paper, Treasury bills and corporate bonds	39,616	17	—	39,633
Marketable securities, non-current - Treasury bills	1,510	—	—	1,510

The following summarized the contractual maturities of the Company's available-for-sale investments:

	March 31, 2020	
	Cost Basis	Fair Value
Due in one year or less	$ 102,247	$ 102,518
Due after one year through five years	3,000	3,010
Total	$ 105,247	$ 105,528

	December 31, 2019	
	Cost Basis	Fair Value
Due in one year or less	$ 123,977	$ 123,995
Due after one year through five years	1,510	1,510
Total	$ 125,487	$ 125,505

The Company received no proceeds and $1.3 million of proceeds from the sale of available-for-sale securities for the three months ended March 31, 2020 and March 31, 2019, respectively, with an immaterial realized gain for the three months ended March 31, 2019. 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):

	March 31, 2020	December 31, 2019
Accrued liabilities:		
General and administrative	$ 2,034	$ 4,521
Clinical trial related costs	1,696	1,383
Non-clinical research and manufacturing operations	6,119	5,774
Payroll related	1,659	2,849
Other accrued expenses	23	17
Total Accrued liabilities	$ 11,531	$ 14,544

NOTE 7—PROPERTY AND EQUIPMENT

Property and equipment consists of the following (in thousands):

	March 31, 2020	December 31, 2019
Laboratory equipment	$ 11,604	$ 10,587
Leasehold improvements	11,212	10,383
Furniture and fixtures	150	150
Computer and equipment	368	331
	23,334	21,451
Less: Accumulated depreciation	(4,033)	(3,293)
Total property and equipment, net	$ 19,301	$ 18,158

Depreciation expense was $0.7 million and $0.4 million for the three months ended March 31, 2020 and March 31, 2019, respectively.

In connection with the continued expansion of the Company's facilities, at March 31, 2020 and December 31, 2019, the Company had net ARO assets totaling $0.9 million and $1.0 million, respectively. The ARO assets are included in Leasehold improvements.

NOTE 8 — 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 that can be drawn down at a future date. The principal on the facility accrues interest at an annual rate equal to a 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 March 31, 2020 was 12.91%. 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 $100,000 on a pro rata basis on the maturity date or the earlier date of repayment of the term loans in full. Additionally, the Company incurred $0.5 million in deferred finance costs and issued the debt net of a $1.5 million discount. The exit fee, deferred finance costs and discount are being accreted to interest expense over the term of the Perceptive Credit Facility using the effective interest method.

For the three months ended March 31, 2020 and March 31, 2019, the Company recorded $0.2 million and $0.2 million of interest expense, respectively. For the three months ended March 31, 2020 and March 31, 2019, the Company recorded $0.1 million and $0.1 million of amortization of debt discount related to the Perceptive Credit Facility for both periods.

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 $9.5792, subject to certain adjustments as specified in the Warrant. For more information refer to Note 11, "Stockholders Equity" included in the Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 13, 2020. 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

As of March 31, 2020 and December 31, 2019 the Perceptive Credit Facility principal balance was $4.8 million and $5.0 million, respectively, with principal payment due one calendar year, or more, from the balance sheet being classified as non-current. As of March 31, 2020, the Company was in compliance with the non-financial covenants of the Perceptive Credit Facility.

As of March 31, 2020 and December 31, 2019 the carrying value of the long-term debt was $3.7 million and $3.7 million, respectively.

Future required principal and final payments on the Perceptive Credit Facility were as follows at March 31, 2020 (in thousands):

2020 (remaining)	600
2021	800
2022	3,500
2023	—
Total	4,900

NOTE 9 – 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" of the Company's previously filed Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 13, 2020 for further discussion of the Company's Lease accounting policy.

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 eight years, and the finance leases have remaining terms of less than one year. 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 payment s 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 three 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.

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 March 31, 2020.

At March 31, 2020, 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 March 31, 2020
Operating leases	
Operating lease expense	$ 561
Variable lease expense	130
Total operating lease expense	$ 691
Finance leases	
Amortization of right-of-use asset	$ 2
Interest on lease liabilities	-
Total finance lease expense	$ 2

The following table summarizes the balance sheet classification of leases at March 31, 2020 (in thousands):

Operating leases	
Operating lease right-of-use assets, non-current	$ 9,617
Operating lease liabilities, current[1]	$ 1,731
Operating lease liabilities, non-current	11,232
Total operating lease liabilities	$ 12,963
Finance leases	
Property and equipment, at cost	$ 77
Accumulated depreciation	43
Property and equipment, net	$ 34
Finance lease liabilities, current[1]	$ 12

1. Included in other current liabilities.

The following table presents other information on leases as of March 31, 2020:

	Weighted Average Remaining Lease Term	Weighted Average Discount Rate
Operating leases	7.0	6.72 %
Finance leases	0.6	6.81 %

Maturities of lease liabilities were as follows as of March 31, 2020 (in thousands):

	Operating Leases	Finance Leases
2020, remainder	$ 1,895	$ 12
2021	2,589	
2022	2,650	
2023	1,961	
2024	1,474	
2025	1,517	
Thereafter	4,246	
Total lease payments	16,332	12
Less:		
Imputed interest	(3,369)	—
Total lease liabilities	$ 12,963	$ 12

Supplemental cash flow information related to the Company's leases were as follows for the three months ended March 31, 2020 (in thousands):

Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$	515
Operating cash flows from finance leases	$	—
Financing cash flows from finance leases	$	7

NOTE 10 — CONTRACTUAL COMMITMENTS

The Company has entered into project work orders for each of its clinical trials with clinical research organizations (each being a "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 $2.6 million at March 31, 2020. 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 drug or biologic candidates. The Company was contractually obligated for up to approximately $43.2 million of future services under these agreements at March 31, 2020, 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 which in total range from $14.3 million to $15.0 million and include signed orders for capital equipment.

As a result of the Takeda Development and License Agreement, 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 11 — STOCK-BASED COMPENSATION

Stock-based compensation expense, which consists of the compensation cost for employee stock options and the value of options issued to non-employees for services rendered, was allocated to research and development and general and administrative in the consolidated statements of operations as follows (in thousands):

	Three Months Ended March 31,	
	2020	2019
Research and development	$ 1,128	$ 453
General and administrative	1,064	908
Total stock-based compensation	$ 2,192	$ 1,361

At March 31, 2020, the total unrecognized compensation cost related to unvested stock-based awards granted to employees under the Company's equity incentive plans was approximately $33.1 million. This cost will be recorded as compensation expense on a ratable basis over the remaining weighted average requisite service period of approximately 2.98 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 March 31,	
	2020	2019
Employee Stock Options:		
Risk-free interest rate	1.83 %	2.59 %
Expected term (in years)	6.08	6.08
Dividend yield	—	—
Volatility	110.00 %	109.00 %
Weighted-average fair value of stock options granted	$ 12.13	$ 3.93

Equity Incentive Plans

These plans consist of the 2018 Equity Incentive Plan, the 2014 Equity Incentive Plan, as amended; the 2004 Amended and Restated Equity Incentive Plan; and the Amended and Restated 2004 Employee Stock Purchase Plan. As of May 31, 2018, the 2014 Equity Incentive Plan; and the 2004 Equity Incentive Plan were terminated, and no further shares will be granted from those plans.

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, 2019	4,743,990	$ 6.37	8.2	$ 36.5
Granted	1,713,706	$ 14.51		
Exercised	(114,777)	$ 2.62		
Forfeitures	(48,457)	$ 11.07		
Outstanding at March 31, 2020	6,294,462	$ 8.62	8.5	$ 31.8
Exercisable at March 31, 2020	2,028,825	$ 6.17	7.2	$ 14.8

The total intrinsic value of stock options exercised during the three months ended March 31, 2020 and 2019, was $1.3 million and $0.1 million, respectively, as determined at the date of the option exercise.

Cash received from stock option exercises was $0.3 million and less than $0.0 million for the three months ended March 31, 2020 and 2019, 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 12 – 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 merger agreement with Threshold. For more information regarding the merger refer to Note 1 "Organization and Summary of Significant Accounting Policies".

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. 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 fully recoverable. During the year ended December 31, 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 classifies 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.

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, 2019 filed with the SEC on March 13, 2020.

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, 2019.

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

Molecular Templates is a clinical-stage company focused on the discovery and development of targeted biologic therapeutics. Our proprietary drug platform technology, known as engineered toxin bodies, or ETBs, leverages the resident biology of a genetically engineered form of Shiga-like Toxin A subunit, or SLTA to create novel therapies with potent and differentiated mechanisms of action for cancer and other serious diseases.

Business

ETBs use a genetically engineered version of the SLTA. In its wild-type form, Shiga-like Toxin, or 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 with no cognate SLTB component is genetically fused to antibody domains or fragments specific to a target, resulting in a biologic therapeutic that can identify the particular target and specifically kill the 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 and other serious diseases.

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 the Phase I monotherapy 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 were presented at the American Society of Hematology (ASH) Annual Meeting, December 7-10, 2019 in Orlando, FL. Of the 13 serum rituximab negative (RTX-neg) diffuse large B cell lymphoma, or DLBCL or mixed DLBCL/FL subjects, 5 responded (38% objective response rate) across the range of 5 to 100 µg/kg doses. Of the 5 responses, 2 were complete responses (CRs) and 3 were partial responses (PRs). Three patients had stable disease (including 2 patients with 49% and 47% tumor reductions) and 5 patients had progressive disease. Of the 5 serum RTX-neg subjects with DLBCL who received MT-3724 at 50 µg/kg, the maximum tolerated dose (MTD), 3 responded (2 CRs, 1 PR).

In the first quarter of 2019, we initiated a Phase II cohort for the monotherapy trial 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 an earlier line of treatment for DLBCL and a second Phase II combination study with MT-3724 and Revlimid® (lenalidomide), also in an earlier line of DLBCL treatment . The combination study with lenalidomide has demonstrated preliminary evidence of tolerability and efficacy with lenalidomide at standard doses and MT-3724 at 10 µg/kg. MT-3724 dosing at higher doses with lenalidomide is ongoing. The combination study with GemOx has demonstrated preliminary evidence of efficacy but grade 2 innate immune adverse effects were seen with standard doses of gemcitabine and oxaliplatin and 10 µg/kg doses of MT-3724. The study protocol has been amended to include a revised schedule where MT-3724 dosing is initially sequenced with GemOx dosing. We expect to provide updates on all three Phase II studies of MT-3724 in the second half of 2020.

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 updates on this study throughout 2020. Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Ltd. (“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 began in the first quarter of 2020. We anticipate filing an IND for our ETB targeting PD-L1 in the second half of 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 Current Good Manufacturing Process, or cGMP standards and continue to make improvements to its manufacturing processes.

We have conducted multiple cGMP 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.

Impact of COVID-19

In March 2020, the outbreak of COVID-19 caused by a novel strain of the coronavirus was recognized as a pandemic by the World Health Organization. The Company is carefully and continually evaluating the potential individual patient risk associated with continuing to enroll in our existing studies during the ongoing COVID-19 pandemic. We have decided, in collaboration with treating investigators, to allow MTEM’s studies to remain open and able to treat enrolled patients and screen new patients. This decision is predicated on the treating investigator determining that the potential benefit to the patient of investigational therapy outweighs the potential risk of contracting COVID-19. Patients enrolled in MTEM trials have relapsed or refractory incurable malignancies with few or no standard-of-care therapeutic options and limited life expectancy. COVID-19 has led to a significant slowdown in the pace of site initiations and patient enrollment in our clinical studies. The degree of disruption is variable by geography and individual clinical site, with some sites closed to new enrollment, some screening and enrolling only patients with an urgent need for treatment, and a small minority attempting to operate as usual. The COVID-19 pandemic has resulted in a significant slowdown in the pace of site initiations and patient enrollment across our MT-3724 phase II programs. As a CD20-targteting agent for the treatment of hematological malignancy, MT-3724 may impair the ability to generate humoral immunity to coronavirus infection. MT-5111 screening and enrollment has been less impacted than MT-3724 but is still enrolling at slower pace than was projected pre-COVID-19. To date, we have been able to continue to work at our cGMP manufacturing facility and laboratories without interruption from COVID-19. As a result, manufacturing of product supply for clinical trials and research activities to support advancement of our preclinical pipeline (including partnered programs) have not been impacted by COVID-19.

Collaboration Agreements

Takeda Pharmaceuticals

Takeda Collaboration and Individual Project Agreements

In October 2016, we entered into a collaboration and option agreement (the "Takeda Collaboration Agreement") with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Ltd. ("Takeda") to discover and develop CD38-targeting ETBs, which includes MT-4019, for evaluation by Takeda. Under the terms of the agreement, we are responsible for providing to Takeda (i) new ETBs generated using Takeda's proprietary antibodies targeting CD38 and (ii) MT-4019 for *in vitro* and *in vivo* pharmacological and anti-tumor efficacy evaluations. We granted Takeda an exclusive option to negotiate and obtain an exclusive worldwide license to develop and commercialize any ETB that might result from this collaboration, including MT-4019. We were entitled to receive up to $2.0 million in technology access fees and cost reimbursement associated with our performance and completion of our obligations under the Takeda Collaboration Agreement. To date, the Company has received the $2.0 million under this Takeda Collaboration Agreement.

In connection with the Takeda Collaboration Agreement, we entered into an Individual Project Agreement (the "Takeda Individual Project Agreement") with Takeda in June 2018 that was amended and restated in July 2018. Under the Takeda Individual Project Agreement, we are 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, we were entitled to receive up to $2.2 million in compensation. To date, the Company has received the $2.2 million under the TakedaIndividual Project Agreement.

Takeda Development and License Agreement

On September 18, 2018, we entered into a development collaboration and exclusive license agreement (the "Takeda Development and License Agreement") with Takeda 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.

Pursuant to the Takeda Development and License Agreement, we will initially co-develop with Takeda one or more of the Licensed Products up to and including Phase Ia clinical trials, with us having an option to continue to co-develop the Licensed Products following Phase Ia clinical trials. Pursuant to the terms of the Takeda Development and License Agreement, Takeda will be responsible for all regulatory activities and commercialization of the Licensed Products. We have granted Takeda specified intellectual property licenses to enable Takeda to perform its obligations and exercise its rights under the Takeda Development and License Agreement, including exclusive license grants to enable Takeda to conduct development, manufacturing, and commercialization activities pursuant to the terms of the Takeda Development and License Agreement.

The Takeda Development and License Agreement has a total transaction price of $29.8 million, consisting of (1) the $30.0 million upfront payment, (2) a $10.0 million development milestone payment which was achieved in the first quarter of 2020, (3) minus $10.2 million in expected co-share payments payable to Takeda during Early Stage Development. In July 2019, we exercised our co-development option and the agreed upon collaboration budget was increased to cover additional research and development activities whereby both parties will continue to cost share. If we continue our option to co-develop, we will be 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 $325.0 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 $175.0 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 continue to exercise our option to co-develop, and from high-single digits to low teens if we do not continue to exercise our option to co-develop.

In July 2019, we exercised our co-development option and the agreed upon collaboration budget was increased to cover additional research and development activities whereby both parties will continue to cost share. 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 License Agreement at any time upon prior written notice to us. The Company, 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.

Takeda Multi-Target Agreement

In June 2017, we entered into a Multi-Target Collaboration and License Agreement with Takeda ("Takeda Multi-Target Agreement") in which we 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 we 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 our 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.

The Company received an upfront fee of $1.0 million and an additional $2.0 million following the designation of each of the two targets in December 2017.As of December 31, 2019, the Company has received $5.0 million from Takeda pursuant to the Takeda Multi-Target Agreement.

We may also receive an additional $30.0 million in aggregate through the exercise of the option to license ETBs. Additionally, we might also be entitled to receive 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. We might also be entitled to receive 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. 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 (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 might be sooner terminated by Takeda for convenience or upon a change of control in our ownership, or by either party for an uncured material breach of the agreement.

Vertex Pharmaceuticals

On November 18, 2019, we entered into a Master Collaboration Agreement ("Vertex Collaboration Agreement") with Vertex Pharmaceuticals Incorporated ("Vertex"), in which the parties agreed to enter into a strategic research collaboration to leverage the Company's ETB technology platform to discover and develop novel targeted biologic therapies for applications outside of oncology.

Pursuant to the Vertex Collaboration Agreement, Vertex will pay the Company an upfront payment of $38.0 million, consisting of $23.0 million in cash and a $15.0 million equity investment pursuant to a Share Purchase Agreement (the "SPA"), described further below. In addition to the upfront payments, the Company might also receive an additional $22.0 million through the exercise of the options to license ETB products or to add an additional target. The Company shall provide, and Vertex will reimburse the Company for, certain mutually agreed manufacturing technology transfer activities.

The Company might, for each target under the Vertex Collaboration Agreement, receive up to an additional $180.0 million in milestone payments upon the achievement of certain development and regulatory milestone events and up to an additional $70.0 million in milestone payments upon the achievement of certain sales milestone events. The Company will also be entitled to receive, subject to certain reductions, tiered mid-single digit royalties as percentages of calendar year net sales, if any, on any licensed product.

The Company will be responsible for conducting the research activities through the designation, if any, of one or more development candidates. Upon the exercise by Vertex of its option for a development candidate, Vertex will be responsible for all development, manufacturing, regulatory and commercialization activities with respect to that development candidate. In connection with the Vertex Collaboration Agreement, the Company and Vertex will enter into the SPA pursuant to which Vertex agreed to purchase 1,666,666 shares of the Company's common stock, par value $0.001 per share, at a price per share of $9.00. The issuance of these shares shall be pursuant to a private placement exemption from registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D thereunder.

For more information concerning our collaboration agreements, refer to Note 3, "Research and Development Agreements" to our unaudited consolidated financial statements for the three months ended March 31, 2020, included in this Quarterly Report on Form 10-Q.

Grant Agreements

CPRIT Grant Contract

In September 2018, we entered into a Cancer Research Grant Contract (the "CD38 CPRIT Agreement") with the Cancer Prevention and Research Institute of Texas ("CPRIT"), which was extended in November 2019, 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 (the "Award"). Pursuant to the CD38 CPRIT Agreement, we might 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 CD38 CPRIT Agreement and subject to CPRIT's ability to perform its obligations under the CD38 CPRIT Agreement as well as our progress towards achievement of specified milestones, among other contractual requirements.

In 2011, Private Molecular was awarded a $10.6 million product development grant from CPRIT for its CD20 targeting ETB MT-3724.

Subject to the terms of the CD38 CPRIT Agreement, full ownership of any CPRIT funded technology and CPRIT funded intellectual property rights developed pursuant to the CD38 CPRIT Agreement will be retained by us, our Collaborators (as defined in the CD38 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 CD38 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 CD38 CPRIT Agreement. If we are required to obtain a license from a third party to sell any such product, the revenue sharing percentages might be reduced. In addition, once we pay CPRIT 400% of the monies the Company has received under the CD38 CPRIT Agreement, we will continue to pay CPRIT a revenue-sharing percentage of 0.5%.

The CD38 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 CD38 CPRIT Agreement) by us, (iii) by CPRIT if allocated funds should become legally unavailable during the term of the CD38 CPRIT Agreement and CPRIT is unable to obtain additional funds or (iv) by us for convenience. CPRIT might approve a no cost extension for the CD38 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 CD38 CPRIT Agreement.

For more information about our grant agreements, please see Note 3, "Research and Development Agreements" to our unaudited consolidated financial statements for the three months ended March 31, 2020, included in this Quarterly Report on Form 10-Q

Financial Operations Overview

Revenue

To date, we have not generated any revenue from product sales to customers. We do not expect to receive any revenue from any ETB candidates that we or our collaboration partners develop, including MT-3724, MT-5111, TAK-169 and other pre-clinical ETB candidates, until we obtain regulatory approval and commercialize such biologics. Our revenue consists principally of collaboration revenue and grant revenue.

Research and Development revenue primarily relates to our collaboration agreements with Takeda and Vertex which are accounted for using the percentage-of-completion cost-to-cost method.

Grant revenue relates to our CPRIT grants for a CD20 ETB (MT-3724) and a CD38 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, "Organization and Summary of Significant Accounting Policies"to our audited consolidated financial statements for the year ended December 31, 2019, included in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC March 13, 2020.

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 or biologic materials for clinical trials. We expect research and development expenses to increase as we advance the clinical development of MT-3724, MT-5111 and/or TAK-169 and further advance the research and development of our pre-clinical ETB candidates, and other earlier stage drugs or biologics. 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, MT-5111, TAK-169 or any other ETB candidate that we or our collaboration partners 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 FDA the European Medicines Agency ("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 March 31,			
	2020	2019	Change ($)	Change (%)
Research and development revenue - from related party	$ 333	$ 6,413	$ (6,080)	-95%
Research and development revenue - other	1,467	—	1,467	100%
Grant revenue	2,341	595	1,746	293%
Total revenue	$ 4,141	$ 7,008	$ (2,867)	-41%

Research and Development Revenue – from related party

The decrease in research and development revenue – from related parties for the three months ended March 31, 2020 was primarily due to research and development revenues that were recognized from the services provided under the Takeda Development and License Agreement (TAK-169) which was entered into in September 2018.

For more information about our collaboration agreements, please see Note 3 “Research and Development Agreements” to our unaudited consolidated financial statements for the three months ended March 31, 2020, included in this Quarterly Report on Form 10-Q.

Research and Development Revenue – other

The increase in research and development revenue – other is a result of recognizing revenue associated with the Vertex Collaboration Agreement. For more information about our collaboration agreements, please see Note 3 “Research and Development Agreements” to our unaudited consolidated financial statements for the three months ended March 31, 2020, included in this Quarterly Report on Form 10-Q.

Grant Revenue

The increase in grant revenue for the three months ended March 31, 2020 was primarily due to the Company incurring additional expenses for the CD38 CPRIT Agreement grant during the quarter.

Operating Expenses

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

	Three Months Ended March 31,			
	2020	2019	Change ($)	Change (%)
Research and development expenses	$ 20,631	$ 8,454	$ 12,177	144 %
General and administrative expenses	5,647	4,935	712	14 %
Total operating expenses	$ 26,278	$ 13,389	$ 12,889	96 %

Research and Development Expenses

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

	Three Months Ended March 31,			
	2020	2019	$ Change	% Change
Program costs	$ 10,192	$ 4,031	$ 6,161	153 %
Employee compensation	6,678	2,998	3,680	123 %
Laboratory costs	968	637	331	52 %
Other research and development costs	2,793	788	2,005	254 %
Total research and development expenses	$ 20,631	$ 8,454	$ 12,177	144 %

Research and development ("R&D") expenses increased $12.2 million during the three months ended March 31, 2020 primarily due to research and development expenses related to the discovery and development of ETBs. Additionally, 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.

Program costs increased $6.2 million during the three months ended March 31, 2020 compared to the three months ended March 31, 2019. The programs driving the increase were $2.8 million for MT-3724, $1.4 million for TAK-169, $1.2 million for PD-L1.

Headcount increased in R&D 123% from March 31, 2019 to March 31, 2020 in support of increased clinical trials and ramp up of cGMP manufacturing facilities and support staff. This staffing increase resulted in an increase in employee compensation costs of $3.7 million for the three months ended March 31, 2020 compared to the three months ended March 31, 2019, respectively.

Laboratory costs increased $0.3 million during the three months ended March 31, 2020 compared to the three months ended March 31, 2019. New lab facilities have been created to increase and refine the Company's research and manufacturing capabilities. The increase in expense reflects the costs of outfitting, supplying and maintaining these facilities.

Other R&D costs increased $2.0 million during the three months ended March 31, 2020 compared to the three months ended March 31, 2019, respectively. This increase was driven by consulting and recruiting fees.

General and Administrative Expenses

General and administrative expenses increased $0.7 million during the three months ended March 31, 2020 compared to the three months ended March 31, 2019. The main driver of this increase being payroll and related costs.

Nonoperating activities

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

	Three Months Ended March 31,			
	2020	2019	Change ($)	Change (%)
Interest and other income, net	$ 472	$ 510	$ (38)	-7 %
Interest expense	$ (348)	$ (293)	$ (55)	19 %
Change in fair value of warrant liabilities	$ —	$ (4)	$ 4	-100 %

Interest and Other Income and Interest Expense

The decrease in interest and other income for the three months ended March 31, 2020, compared to the three months ended March 31, 2019, was primarily due to lower interest related to our marketable securities.

The increase in interest expense for the three months ended March 31, 2020, compared to the three months ended March 31, 2019, was primarily due to the interest in our in debt holdings which matures in February 2022.

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 or our collaboration partners continue to advance MT-3724, MT-5111, 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 drug or biologic 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 drugs or biologics, 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 drugs or biologics, 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.

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. For the three months ended March 31, 2020 and 2019, we incurred net losses of $22.0 million and $6.2 million, respectively. At March 31, 2020, we had an accumulated deficit of $186.1 million.

To date, we have financed our operations through public offerings of common and preferred stock, private placements of equity securities, a reverse merger, and upfront and milestone payments received from our collaboration 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 Bank. 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 CD38 CPRIT Agreement for a research grant related to CD38 targeting ETB of approximately $15.2 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 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 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.

In November 2019, (i) we entered into the Vertex Collaboration Agreement and the SPA with Vertex pursuant to which Vertex agreed to pay us an upfront payment of $38.0 million, consisting of $23.0 million in cash and a $15.0 million equity investment through the purchase of 1,666,666 shares of our common stock at a price per share of $9.00 (issued pursuant to a private placement exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D thereunder) and (ii) we completed a public offering of 6,900,000 shares of common stock at an offering price of $8.00 per share, and 250 shares of newly designated Series A Convertible Preferred Stock at an offering price of $8,000.00 which included the exercise in full by the underwriters of their option to purchase up to 900,000 additional shares of common stock. We received net proceeds of approximately $53.4 million from this public offering, after deducting underwriting discounts and stock issuance costs.

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.

At March 31, 2020 and December 31, 2019, we had cash, cash equivalents and marketable securities of $108.0 million and $126.6 million, respectively and grants revenue receivable of $9.4 million and $7.1 million, respectively. We expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into 2022. 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.

Cash Flows

Comparison of Three Months Ended March 31, 2020 and 2019

The table below summarizes our cash flows for the three months ended March 31, 2020 and 2019.

	Three Months Ended March 31,	
	2020	2019
Net cash used in operating activities	$ (18,149)	$ (10,976)
Net cash used in investing activities	(32,951)	(35,920)
Net cash provided by financing activities	93	30
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (51,007)	$ (46,866)

The increase in net cash used in operating activities for the three months ended March 31, 2020 was primarily due to an increase in operating cash disbursements as result of an increase in operating activities.

The increase in net cash provided by financing activities was primarily due to proceeds from stock option exercises which was partially offset by repayment of long term debt.

Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and had an accumulated deficit of $186.1 million at March 31, 2020. 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 and MT-5111, co-development activities related to TAK-169, collaboration with Vertex, 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;

- research activities through the designation of the development candidate(s) with Vertex
- 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 drugs 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 were interest only, paid quarterly until March 31, 2020. Upon 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 of our assets.

The Company's expansion of its cGMP manufacturing facility is expected to be completed during 2020. Additional costs may be incurred as a result of delays and/or other issues that may arise during the course of construction.

Because of the numerous risks and uncertainties associated with the development of MT-3724, co-development of TAK-169, collaboration with Vertex 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, MT-5111, 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 drugs or biologics 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.

Controlled Equity Offering℠ Sales Agreement

On December 21, 2018, we entered into aControlled Equity Offering℠ Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., or Cantor, which provides that, upon the terms and subject to the conditions and limitations set forth in the Sales Agreement, we may elect to issue 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 agent.

Subject to the terms and conditions of the Sales Agreement, upon placement of a delivery notice by us, Cantor may sell our common stock by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act. We may instruct Cantor not to sell common stock if the sales cannot be effected at or above the price designated by us from time to time. We or Cantor may suspend the offering of common stock upon notice and subject to other conditions.

We will pay Cantor an amount equal to 3.0% of the gross proceeds of any shares of common stock sold under the Sales Agreement. In connection with the sale of common stock on our behalf, Cantor will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Cantor will be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to Cantor with respect to certain liabilities, including liabilities under the Securities Act or the Securities Exchange Act of 1934, as amended.

The offering of our common stock pursuant to the Sales Agreement will terminate upon the earlier of (1) the sale of all shares of our common stock subject to the Sales Agreement or (2) termination of the Sales Agreement as permitted therein. We and Cantor may each terminate the Sales Agreement at any time upon 10 days' prior notice and Cantor may terminate the Sales Agreement at any time in certain circumstances, including the occurrence of a material and adverse change in our business or financial condition that makes it impractical or inadvisable to market our common stock or to enforce contracts for the sale of our common stock.

The shares subject to the Sales Agreement are registered pursuant to a registration statement on Form S-3 (File No. 333-228975), filed with the SEC on December 21, 2018, as amended, and declared effective by the SEC on February 14, 2019. To date, we have not sold any shares under the Sales Agreement and may choose to sell shares of our common stock having an aggregate offering price of up to $50.0 million in the future.

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, 2019, which we filed with the SEC on March 13, 2020.

Recently Adopted Accounting Pronouncements

For a discussion of recently adopted account pronouncements see the discussion in our Annual Report on Form 10-K for the year ended December 31, 2019, which we filed with the SEC on March 13, 2020.

Recent Accounting Pronouncements Not Yet Adopted

For a discussion of recently issued accounting pronouncements and interpretations not yet adopted by us, see Note 1, Organization and Summary of Significant Accounting Policies, to our unaudited condensed financial statements for the three months ended March 31, 2020, included in this Quarterly Report on Form 10-Q.

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

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

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 March 31, 2020. 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 March 31, 2020, our principal executive officer and principal financial officer concluded that the disclosure controls and procedures were not effective as of such date due to the material weakness in internal control over financial reporting as disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2019.

Changes in internal controls over financial reporting.

Except for the remediation plan below 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 March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Remediation

As previously described in Part II, Item 9A, Controls and Procedures, of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, management has implemented and continues to implement a remediation plan to address the root causes which contributed to the material weakness. During the quarter ended March 31, 2020, we continued to make progress on our remediation, including, removing all inappropriate user access rights. The material weakness will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing that these controls are operating effectively. The Company expects that the remediation of this material weakness will be completed during 2020.

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 predicted 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 $22.0 million for the three months ended March 31, 2020. At March 31, 2020, we had an accumulated deficit of $186.1 million.

At March 31, 2020, we had cash, cash equivalents, and marketable securities of $108.0 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. In November 2019, we completed a public offering of 6,000,000 shares of common stock at an offering price of $8.00 per share and 250 shares of newly designated Series A convertible preferred stock at an offering price of $8,000.00 per share, which included the exercise in full by the underwriters of their option to purchase up to 900,000 additional shares of common stock. We received net proceeds of approximately $53.4 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. 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 drug or biologic candidates.

We have devoted substantially all of our financial resources to identify, acquire, and develop our drug or biologic 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 drug or biologic candidates. We have not yet commenced pivotal clinical trials for any drug or biologic candidate and it may be several years, if ever, before we complete pivotal clinical trials and have a drug or biologic candidate approved for commercialization. We expect to invest significant funds into the research and development of our current drug or biologic candidates to determine the potential to advance these drug or biologic 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 drug or biologic candidates may receive approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors and adequate market share for our drug or biologic candidates in those markets. Even if we obtain adequate market share for one or more products, because the potential markets in which our drug or biologic 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 drug or biologic candidates;
- continue efforts to discover or acquire via assignment or in-license new drug or biologic candidates;
- undertake the manufacturing of our drug or biologic 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 drug or biologic candidates;
- seek regulatory and marketing approvals and reimbursement for our drug or biologic 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 drug or biologic candidates;
- make milestone, royalty or other payments under third-party license agreements;
- seek to maintain, protect, and expand our intellectual property portfolio;
- evaluate possible, or participate in actual, development partnerships with one or more third parties
- 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.

We currently have federal net operating loss carryforwards, some of which will begin to expire in 2024, if not utilized, and the remainder of which can be carried forward indefinitely. Tax loss carryforwards that were created prior to December 31, 2017 expire through 2037, all tax loss carryforwards created after that date do not expire. In the United States, utilization of the net operating loss carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions due to ownership change limitations that have occurred previously or that could occur in the future. 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. If we were to lose the benefits of these loss carryforwards, our future earnings and cash resources would be materially and adversely affected. 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 have identified a material weakness in our internal control over financial reporting, and if we are unable to remediate such material weakness and to maintain effective internal control over financial reporting in the future, there could be an elevated possibility of a material misstatement, and such a misstatement could cause investors to lose confidence in our financial statements, which could have a material adverse effect on our stock price.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on the effectiveness of our internal control over financial reporting. In addition, our independent registered public accounting firm must report on its evaluation of our internal control over financial reporting. As disclosed in Item 9A of this report, we have identified a material weakness as of December 31, 2019 in our internal control over financial reporting related to our information technology general controls over systems that are relevant to our financial statements. As a result of the material weakness, our external auditors have issued an adverse opinion indicating that we have not maintained effective internal control over financial reporting as of December 31, 2019.

Our management team has taken action to begin to remediate the material weakness, primarily through improved processes, policies, training and skilled personnel, but we cannot be certain when the remediation will be completed. If we fail to fully remediate the material weakness or fail to maintain effective internal controls, it could result in a material misstatement of our financial statements, which could cause investors to lose confidence in our financial statements or cause our stock price to decline. In future periods, we may identify additional deficiencies in our system of internal control over financial reporting during the course of our remediation efforts that may require additional work to address. Any future material weaknesses in internal control over financial reporting could result in material misstatements in our financial statements and we could be required to restate our financial results, which could lead to substantial additional costs for accounting and legal fees and shareholder litigation. Moreover, any future disclosures of additional weaknesses, or errors as a result of those weaknesses, could result in could result in investors losing confidence in our reported financial information and may lead to a decline in the stock price. For more information about this material weakness, see Item 9A, “Controls and Procedures”.

As of December 31, 2019, we became 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, 2019, we are an “accelerated filer” as defined by SEC rule. 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 and going forward, the auditor’s attestation report on 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 neverbecome 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 collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize one or more of our drug or biologic 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 drug or biologic candidates;
- obtaining regulatory and marketing approvals for one or more of our drug or biologic candidates;
- manufacturing one or more drug or biologic candidates and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible;
- marketing, launching and commercializing one or more drug or biologic 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 drug or biologic candidates as treatment options;
- meeting our supply needs in sufficient quantities to meet market demand for our drug or biologic 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 drug or biologic candidates that supports profitability; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the drug or biologic candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with launching and commercializing any approved drug or biologic 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 drug or biologic 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 drug or biologic 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 drug or biologic 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 drug or biologic 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 drug or biologic 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 drug or biologic 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 drug or biologic candidates.

We also have historically received, and may receive in the future, funds from state or 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 Drug or biologic 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 drug or biologic 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 drug or biologic 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 Drug or Biologic Candidates

Manufacturing difficulties, disruptions or delays could limit supply of our drug or biologic 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 drug or biologic candidates for use in the conduct of our clinical trials. We may not be able to manufacture drug or biologic candidates or there may be substantial technical or logistical challenges to supporting manufacturing demand for drug or biologic 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 drug or biologic candidates for our clinical trials and future 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 drug or biologic candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our drug or biologic 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 drug or biologic candidate to complete the trial, any significant delay or discontinuity in the supply of a drug or biologic candidate, or the raw materials or other material components in the manufacture of the drug or biologic candidate, could delay completion of our clinical trials and potential timing for regulatory approval of our drug or biologic 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 drug or biologic candidates and our current costs to manufacture our drug products may not be commercially feasible, and the actual cost to manufacture our drug or biologic candidates could materially and adversely affect the commercial viability of our drug or biologic candidates. As a result, we may never be able to develop a commercially viable product.

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

- limited capacity of manufacturing facilities;
- contamination of drug or biologic candidates in the manufacturing process;

- natural or other disasters, including hurricanes, earthquakes, volcanoes, fires or pandemics;
- labor disputes or shortages, including the effects of health emergencies, epidemics, pandemics 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 New Drug Application, or NDA, or 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; and
- as a drug or biologic 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.

For example, in December 2019, a novel strain of coronavirus was first identified in Wuhan, Hubei Province, China. Any outbreak of contagious diseases such as coronavirus, or other adverse public health developments, could have a material and adverse effect on our business operations. Such adverse effects could include disruptions or restrictions on the ability of our, our collaborators', or our suppliers' personnel to travel, and could result in temporary closures of our facilities or the facilities of our collaborators or suppliers. Any disruption to our operations or the operations of our collaborators or suppliers would likely impact our drug development efforts, operating results, and our financial condition. The extent to which the coronavirus may impact our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus.

Each of these risks could delay our clinical trials, the marketing approval, if any, of our drug or biologic candidates, or the commercialization of our drug or biologic 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 drug or biologic 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 drug or biologic 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 volunteers or 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;
- subjects or 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 drug or biologic candidates;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical trials of our drug or biologic 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 drug or biologic candidate; and
- delays in reaching agreement on acceptable terms with third-party manufacturers or an inability to manufacture sufficient quantities of our drug or biologic candidates for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for one or more of our drug or biologic 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 drug or biologic 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 drug or biologic 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 drug or biologic candidates and may harm our business and results of operations.

Additionally, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for our drug or biologic candidates which would materially harm our business.

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 drug or biologic candidates are relatively recent. To date, neither we nor any other company has received regulatory approval to market products 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 drug or biologic 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 drug or biologic candidates that we develop may not demonstrate in patients the biological or 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 drug or biologic 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 drug or biologic 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 drug or biologic candidates, whether appropriate or not.

We are heavily dependent on the success of our drug or biologic candidates, the most advanced of which is in the early stages of clinical development. Our ETB therapeutic drug or biologic 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 drug or biologic candidates have produced results in preclinical settings to date and we cannot give any assurance that we will generate data for any of our drug or biologic candidates sufficient to receive regulatory approval in our planned indications, which will be required before they can be commercialized. To date, no ETB products 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 drug or biologic 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 drug or biologic candidates. Our future success is dependent on our ability to successfully further develop, obtain regulatory approval for, and commercialize one or more drug or biologic candidates. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a drug or biologic candidate. We currently have one ETB drug or biologic 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 drug or biologic candidate, MT-5111, has one Phase I study, which began dosing patients in the fourth quarter of 2019. Our CD38-targeted SLT-A fusion protein, TAK-169, developed in collaboration with Takeda, has one Phase I study, which began dosing patients in the 1st quarter of 2020, and the remainder of our drug or biologic 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 drug or biologic candidate. There can be no assurance that we will not experience problems or delays in developing our drug or biologic 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 drug or biologic candidates in our planned indications will be sufficient to obtain regulatory approval.

None of our ETB drug or biologic 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 drug or biologic 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 drug or biologic candidates. We cannot be certain that any of our drug or biologic candidates will be successful in clinical trials or receive regulatory approval. Further, our drug or biologic candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our drug or biologic candidates, we may not be able to continue our operations.

Additionally, the FDA and comparable foreign regulatory authorities have relatively limited experience with ETB products. No regulatory authority has granted approval to any person or entity, including us, to market or commercialize ETB drug or biologic candidates, which may increase the complexity, uncertainty and length of the regulatory approval process for our drug or biologic candidates. If our ETB drug or biologic candidates fail to prove to be safe, effective or commercially viable, our drug or biologic 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 EMA, and other regulatory authorities, and the criteria these regulators use to determine the safety and efficacy of a drug or biologic candidate, vary substantially according to the type, complexity, novelty and intended use and market of the drug or biologic candidate. The regulatory approval process for novel drug or biologic candidates such as ETB drug or biologic candidates could be more expensive and take longer than for other, better known or more extensively studied drug or biologic candidates. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our drug or biologic candidates in either the United States or the European Union or elsewhere or how long it will take to commercialize our drug or biologic 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 drug or biologic 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.

During the global response to the COVID-19 pandemic, moreover, FDA and EMA resources may be redeployed to priority projects, which could have an impact on the timeline for review and approval of new marketing applications. Although the FDA has recently communicated that its new drug and biologic review programs are continuing to meet key performance goals involving communicating with applicants and approving new products, the agency also noted that the uncertainty of the COVID-19 situation may make it difficult to sustain its current level of performance indefinitely. The FDA has told industry that it intends to be as transparent as possible as the situation evolves.

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 drug or biologic candidates are being studied, which could delay or prevent clinical trials of our drug or biologic candidates.

Identifying and enrolling patients to participate in clinical trials of our ETB drug or biologic 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 drug or biologic 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 for 2020 is 77,240 new cases and approximately 19,940 deaths are estimated to be attributable to non-Hodgkin's B-cell lymphomas in 2020. Patients must be diagnosed with relapsed or refractory B cell non-Hodgkin lymphoma to be considered as an eligible trial participant for our Phase II combination study of MT-3724 with GEMOX. 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 drug or biologic 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 drug or biologic candidates may be delayed.

If we experience delays in the completion of, or termination of, any clinical trials of our drug or biologic candidates, the commercial prospects of our drug or biologic candidates could be harmed, and our ability to generate product revenue from any of these drug or biologic candidates could be delayed or prevented. In addition, any delays in completing our clinical trials would likely increase our overall costs, impair drug or biologic 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 drug or biologic 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 drug or biologic 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 drug or biologic candidate has been studied in only a limited number of patients with a confirmed diagnosis of non-Hodgkin's lymphoma, and the adverse events which occurred in >15% of patients were anemia, diarrhea, nausea, stomatitis, asthenia, fatigue, peripheral edema, pyrexia, pneumonia, hypoalbuminemia, hypokalemia, arthralgia, myalgia, headache, insomnia, cough, dyspnea, rash or hypotension.

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 adverse events, orAEs, previously unknown side effects, or side effects having 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 drug or biologic candidates for current and other indications. Undesirable side effects and negative results for any of our drug or biologic candidates may negatively impact the development and potential for approval of our drug or biologic candidates for their proposed indications.

Additionally, even if one or more of our drug or biologic 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 may be required to change the way such drug or biologic candidates are distributed or administered, or change the labeling of the drug or biologic candidates;
- we may be subject to regulatory investigations and government enforcement actions;

- the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the product;
- we may decide to recall such drug or biologic candidates from the marketplace after they are approved;
- 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 drug or biologic candidate, even if approved, and could significantly harm our business, results of operations, and prospects.

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 drug or biologic candidates and adversely affect our ability to conduct our business or obtain regulatory approvals for our drug or biologic 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 drug or biologic candidates prescribing treatments that involve the use of one or more of our approved drug or biologic 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 drug or biologic candidates 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 drug or biologic 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 drug or biologic candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our drug or biologic candidates, stricter labeling requirements for those drug or biologic candidates that are approved and a decrease in demand for any such drug or biologic 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.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products.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 development process. Clinical trials may produce negative or inconclusive results, and we or any future collaboration partners may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our drug or biologic candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. The results of preclinical studies and early clinical trials of our drug or biologic candidates may not be predictive of the results of larger, later-stage controlled clinical trials. Drug or biologic 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. In particular, no ETB-based drug or biologic candidates have been approved or commercialized in any jurisdiction, and the outcome of our preclinical studies and early-stage clinical trials may not be predictive of the success of later-stage clinical trials.

From time to time, we may publish or report interim or preliminary data from our clinical trials. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same drug or biologic candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We therefore do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our drug or biologic candidates.

We may use our financial and human resources to pursue a particular research program or drug or biologic candidate and fail to capitalize on programs or drug or biologic 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 drug or biologic 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 drug or biologic 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 drug or biologic candidates in indications with potentially large commercial markets. If we do not accurately evaluate the commercial potential or target market for a particular drug or biologic candidate, we may relinquish valuable rights to that drug or biologic 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 drug or biologic candidate, or we may allocate internal resources to a drug or biologic 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 drug or biologic candidates harms patients or is perceived to harm patients even when such harm is unrelated to our drug or biologic candidates, 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 drug or biologic 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 drug or biologic candidates and approved products, if any. There is a risk that our drug or biologic 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 drug or biologic candidates have shown in clinical trials to induce adverse events, including anemia, diarrhea, nausea, stomatitis, asthenia, fatigue, peripheral edema, pyrexia, pneumonia, hypoalbuminemia, hypokalemia, arthralgia, myalgia, headache, insomnia, cough, dyspnea, rash, and hypotension, among others. There is a risk that our future drug or biologic candidates may induce similar or more severe adverse events. Patients with the diseases targeted by our drug or biologic 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 drug or biologic 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 drug or biologic 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 drug or biologic 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 $7.0 million per occurrence up to an aggregate limit of $7.0 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 drug or biologic 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 drug or biologic 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 drug or biologic 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.

Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations.

The successful discovery, development, manufacturing and sale of biologics is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically. Failure to successfully discover, develop, manufacture and sell our biological drug or biologic candidates would adversely impact our business and future 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, pandemics, 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.

Fluctuations in foreign currency exchange rates could result in changes in our reported financial results.

We currently incur significant expenses denominated in foreign currencies, specifically in connection with our clinical trial sites, several of which are located in various countries outside of the United States. These clinical trial sites invoice us in the local currency of the site. As we expand internationally, our exposure to currency risks will increase. We do not manage our foreign currency exposure in a manner that would eliminate the effects of changes in foreign exchange rates. Therefore, changes in exchange rates between these foreign currencies and the U.S. dollar will affect our revenues and expenses and could result in exchange losses in any given reporting period. We incur currency transaction risks whenever we enter into either a purchase or a sale transaction using a currency other than the dollar, our functional currency, particularly in our arrangements for the purchase of supplies or licensing and collaboration agreements with partners outside of the United States. We do not engage in foreign currency hedging arrangements for our accounts payable, and, consequently, foreign currency fluctuations may adversely affect our earnings. We may decide to manage this risk by hedging our foreign currency exposure, principally through derivative contracts. Even if we decide to enter into such hedging transactions, we cannot be sure that such hedges will be effective or that the costs of such hedges will not exceed their benefits. Given the volatility of exchange rates, we can give no assurance that we will be able to effectively manage our currency transaction risks or that any volatility in currency exchange rates will not have an adverse effect on our results of operations.

Our business activities may be subject to the Foreign Corrupt Practices Act and similar anti-bribery and anti-corruption laws of other countries in which we operate.

We have conducted and have ongoing studies in international locations, and may in the future initiate additional studies in countries other than the United States. Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their governments, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products, if approved, in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

Risks Related to Regulatory Approval of Our Drug or biologic candidates and Other Legal Compliance Matters

A potential breakthrough therapy designation by the FDA for our drug or biologic candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our drug or biologic candidates will receive marketing approval.

We may seek a breakthrough therapy designation from the FDA for one or more of our drug or biologic 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 drug or biologic 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 drug or biologic candidate may not result in a faster development process, review or approval, compared to drugs or biologics considered for approval under conventional or other accelerated FDA procedures and does not ensure ultimate approval by the FDA. In addition, even if one or more of our drug or biologic candidates qualify and are designated as a breakthrough therapy, 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 drug or biologic 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 drug or biologic 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 drug or biologic 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 drug or biologic 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, NDA or other marketing authorization application.

Any regulatory approvals that we receive for our drug or biologic candidates may be subject to limitations on the approved indicated uses for which the drug or biologic 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 drug or biologic candidate. In addition, if the FDA, EMA or a comparable foreign regulatory authority approves any of our drug or biologic 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 drug or biologic 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.

We must also comply with requirements concerning advertising and promotion for any of our drug or biologic candidates for which we hope to obtain marketing approval. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. If we are not able to comply with post-approval regulatory requirements, we could have marketing approval for any of our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

In addition, later discovery of 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 failure to comply with applicable regulatory requirements may result in a variety of risks. For example, 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 requirements to conduct post-marketing studies or clinical trials;
- issue warning or untitled letters if the regulator is the FDA, or comparable notice of violations from foreign regulatory authorities;
- issue consent decrees, injunctions or impose civil or criminal penalties;
- require the payment of fines, restitution or disgorgement of profits or revenues;
- 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 or biologic 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.

Our commercial success will depend upon attaining significant market acceptance of our drug or biologic candidates, if approved, among physicians, patients, third-party payors and other members of the medical community.

Even if we obtain regulatory approval for our drug or biologic candidates, the approved products may nonetheless fail to gain sufficient market acceptance among physicians, third-party payors, patients and other members of the medical community, which is critical to commercial success. If an approved product does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any drug or biologic candidate for which we receive approval depends on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments or competitive products;
- perceptions by the medical community, physicians, and patients, regarding the safety and effectiveness of our products and the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the size of the market for such drug or biologic candidate, based on the size of the patient subsets that we are targeting, in the territories for which we gain regulatory approval and have commercial rights;
- the safety of the drug or biologic candidate as demonstrated through broad commercial distribution;
- the ability to offer our drug or biologic candidates for sale at competitive prices;
- the availability of adequate reimbursement and pricing for our products from governmental health programs and other third-party payors;
- relative convenience and ease of administration compared to alternative treatments;
- cost-effectiveness of our product relative to competing products;
- the prevalence and severity of any side effects;
- the adequacy of supply of our drug or biologic candidates;
- the timing of any such marketing approval in relation to other product approvals;
- any restrictions on concomitant use of other medications;
- support from patient advocacy groups; and
- the effectiveness of sales, marketing and distribution efforts by us and our licensees and distributors, if any.

If our drug or biologic candidates are approved but fail to achieve an adequate level of acceptance by key market participants, we will not be able to generate significant revenues, and we may not become or remain profitable, which may require us to seek additional financing.

Our ability to negotiate, secure and maintain third-party coverage and reimbursement for our drug or biologic candidates may be affected by political, economic and regulatory developments in the United States, the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of any drug or biologic candidate of ours that receives marketing approval in the future.

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 Patient Protection and Affordable Care Act, or the ACA, was passed. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Both members of Congress and President Trump have expressed an intention to repeal or repeal and replace the ACA, and as a result certain sections of the ACA have not been fully implemented or have been effectively repealed through Executive Orders and/or executive agency actions. In addition, the Fifth Circuit Court of Appeals recently upheld a federal district court decision finding the individual insurance mandate in the ACA to be unconstitutional. The Fifth Circuit also reversed and remanded the case to the district court to determine if other reforms enacted as part of the ACA, but not specifically related to the individual mandate or health insurance, could be severed from the rest of the ACA so that the entire law would not be declared invalid. It is unclear how this decision, subsequent appeals including potentially to the U.S. Supreme Court, and other efforts to repeal and replace the ACA will affect the implementation of that law and our business. The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels, may lead to uncertainty or delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. If there are not adequate reimbursement levels, our business and results of operations could be adversely affected.

In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our drug or biologic candidates, restrict or regulate post-approval activities, or affect our ability to profitably sell any drug or biologic candidates for which we obtain marketing approval, if any. Further, increased scrutiny by the US Congress of the FDA's approval process for drugs and biological products may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. There also are a number of state and local legislative and regulatory efforts related to drug or biologic pricing, including drug or biologic price transparency laws that apply to pharmaceutical manufacturers, that may have an impact on our business.

In addition, the Drug Supply Chain Security Act enacted in 2013 imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing, and that law is expected to be fully implemented over a ten-year period. Most recently, on December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94) that includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 or the "CREATES Act." The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. The CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown. Other legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical or biological 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 drug or biologic candidates, may be or whether such changes will have any other impacts on our business. 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.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or EU member state level may result in significant additional requirements or obstacles that may increase our operating costs.

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, lower reimbursement and additional downward pressure on the price that we will receive for any approved product. Any reduction in payments from Medicare or other government-funded 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.

Our relationships with prescribers, purchasers, third-party payors and patients will be subject to applicable anti-kickback, fraud and abuse and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

If we obtain FDA approval for any of our drug or biologic candidates and begin commercializing those products in the United States, our operations will be subject to additional health care statutory and regulatory requirements and oversight by federal and state governments in the United States as well as foreign governments in the jurisdictions in which we conduct our business. Physicians, other health care providers and third-party payors will play a primary role in the recommendation, prescription and use of any drug or biologic candidates for which we obtain marketing approval. In the U.S., our future arrangements with such third parties may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain our business or financial arrangements and relationships through which we market, sell and distribute any products for which we may obtain marketing approval. Restrictions under applicable domestic and foreign health care laws and regulations include but are not limited to the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase order or recommendation of a good or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the U.S. False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; actions may be brought by the government or a whistleblower and may include an assertion that a claim for payment by federal health care programs for items and services which results from a violation of the federal Anti-Kickback Statue constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, that imposes criminal and civil liability for executing a scheme to defraud any health care benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- analogous state and foreign laws and regulations relating to health care fraud and abuse, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers;
- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act," enacted as part of the ACA, which requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals (and, beginning in 2021, for transfers of value to other health care providers), as well as the ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations;
- analogous state and foreign laws that require pharmaceutical companies to track, report and disclose to the government and/or the public information related to payments, gifts, and other transfers of value or remuneration to physicians and other health care providers, marketing activities or expenditures, or product pricing or transparency information, or that require pharmaceutical companies to implement compliance programs that meet certain standards or to restrict or limit interactions between pharmaceutical manufacturers and members of the health care industry;
- the U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal health care programs;
- HIPAA, which imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable health care lawsand regulations will involve substantial costs. If the FDA or a comparable foreign regulatory authority approves any of our drug or biologic candidates, we will be subject to an expanded number of these laws and regulations and will need to expend resources to develop and implement policies and processes to promote ongoing compliance. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations, resulting in government enforcement actions. 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, criminal and administrative 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.

We may be subject to, or may in the future become subject to, U.S. federal and state, and foreign laws and regulations imposing obligations on how we collect, use, disclose, store and process personal information. Our actual or perceived failure to comply with such obligations could result in liability or reputational harm and could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In many activities, including the conduct of clinical trials, we may be subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data.

The privacy and security of personally identifiable information stored, maintained, received or transmitted, including electronically, is subject to significant regulation in the United States and abroad. While we strive to comply with all applicable privacy and security laws and regulations, legal standards for privacy continue to evolve and any failure or perceived failure to comply may result in proceedings or actions against us by government entities or others, or could cause reputational harm, which could have a material adverse effect on our business.

Numerous foreign, federal and state laws and regulations govern collection, dissemination, use and confidentiality of personally identifiable health information, including state privacy and confidentiality laws (including state laws requiring disclosure of breaches), federal and state consumer protection and employment laws, HIPAA and European and other foreign data protection laws. These laws and regulations are increasing in complexity and number, and may change frequently and sometimes conflict. The European Union's omnibus data protection law, the General Data Protection Regulation, or GDPR, took effect on May 25, 2018. The GDPR imposes numerous requirements on entities that process personal data in the context of an establishment in the European Economic Area, or EEA, or that process the personal data of data subjects who are located in the EEA. These requirements include, for example, establishing a basis for processing, providing notice to data subjects, developing procedures to vindicate expanded data subject rights, implementing appropriate technical and organizational measures to safeguard personal data, and complying with restrictions on the cross-border transfer of personal data from the EEA to countries that the European Union does not consider to have in place adequate data protection legislation, such as the United States. The GDPR additionally establishes heightened obligations for entities that process "special categories" of personal data, such as health data. Nearly all clinical trials involve the processing of these "special categories" of personal data, and thus processing of personal data collected during the course of clinical trials is subject to heightened protections under the GDPR. Violations of the GDPR can lead to penalties of up to $20 million or 4% of an entity's annual turnover.

As a means to transfer personal data from the EEA to the US, US-based companies may certify compliance with the privacy principles of the EU-US Privacy Shield, or the Privacy Shield. Certification to the Privacy Shield, however, is not mandatory. If a US-based company does not certify compliance with the Privacy Shield, it may rely on other authorized mechanisms to transfer personal data. Notably, the Privacy Shield is currently subject to challenge in the EU courts, and it is possible that it will be invalidated, which was the fate of its predecessor, the EU-US Safe Harbor. In the event of invalidation of the Privacy Shield, US companies that currently rely on the Privacy Shield as the basis for cross-border transfer of personal data will need to establish another basis for cross-border transfer of personal data.

HIPAA establishes a set of national privacy and security standards for the protection of individually identifiable health information, including protected health information, or PHI, by health plans, certain health care clearinghouses and health care providers that submit certain covered transactions electronically, or covered entities, and their "business associates," which are persons or entities that perform certain services for, or on behalf of, a covered entity that involve creating, receiving, maintaining or transmitting PHI. While we are not currently a covered entity or business associate under HIPAA, we may receive identifiable information from these entities. Failure to receive this information properly could subject us to HIPAA's criminal penalties, which may include fines up to $250,000 per violation and/or imprisonment. In addition, responding to government investigations regarding alleged violations of these and other laws and regulations, even if ultimately concluded with no findings of violations or no penalties imposed, can consume company resources and impact our business and, if public, harm our reputation.

In addition, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. In addition to the California Confidentiality of Medical Information Act, California also recently enacted the California Consumer Privacy Act of 2018, or CCPA, which became effective January 1, 2020. The CCPA has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States because it mirrors a number of the key provisions of the EU General Data Protection Regulation. The CCPA establishes a new privacy framework for covered businesses in the State of California, by creating an expanded definition of personal information, establishing new data privacy rights for consumers, imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches.

The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing focus on privacy and data security issues which may affect our business. Failure to comply with current and future laws and regulations could result in government enforcement actions (including the imposition of significant penalties), criminal and/or civil liability for us and our officers and directors, private litigation and/or adverse publicity that negatively affects our business.

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 drug or biologic 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 drug or biologic 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 & Researc h Institute of Texas, or CPRIT. We entered our first CPRIT award grant contract, or the 2011 CPRIT Agreement, on December 1, 2011. On September 18, 2018, we entered into a second CPRIT award grant contract for our CD38 targeted ETB program, or the 2018 CPRIT CD38 Agreement, which was extended in November 2019. 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 march-in and other 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 CD38 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 drug or biologic 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 changes and cannot be certain of our future compli ance. 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 drug or biologic 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. Moreover, recent shutdowns or slowdowns caused by COVID-19 can retard rate or agency review or approval. If a prolonged government shutdown or slowdown 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 drug or biologic 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 drug or biologic candidates. Our commercial success and viability depend in large part on our and any current and potential future licensors or collaboration partners' 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 drug or biologic candidates. If we or our current or future licensors or 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 drug or biologic 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 licensors or collaboration partners or licensees will best be able to protect our proprietary ETB technologies, drug or biologic 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 in the United States and elsewhere patent applications related to our proprietary ETB technologies, drug or biologic 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, drug or biologic 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 disclosed in or covered by pending patent applications or issued patents;
- we or our current or future licensors or collaboration partners may not have been the first to file patent applications covering our ETB technology, drug or biologic candidates, compositions or their uses;
- others may independently develop identical, similar or alternative methods, products, drug or biologic candidates or compositions and uses thereof;
- we or our current or future licensors or 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 licensors or collaboration partners' pending patent applications may not result in issued patents;
- we or our current or future licensors or collaboration partners may not seek or obtain patent protection in jurisdictions or countries that may provide us with a significant business opportunity;
- we or our current or future licensors or collaboration partners might seek or obtain patent protection in jurisdictions or countries that might not provide us with a significant business opportunity;
- any patents issued to us or to our current or future licensors or collaboration partners, or to us and to our current or future licensors or collaboration partners, may not provide a basis for commercially viable products, may not provide any competitive advantages or may be successfully challenged by one or more third parties;
- we or our current or future licensors' or collaboration partners' products, drug or biologic candidates, compositions, methods or uses thereof may not be patentable;
- we or our current or future licensors or collaboration partners might fail to maintain our or their patents, resulting in their abandonment;
- we or our current or future licensors or collaboration partners might fail to obtain patent term extensions available in the United States or in foreign jurisdictions or countries;
- others may design around our or our current or future licensors' or collaboration partners' patent claims to produce competitive technologies, 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 render unpatentable our or our current or future licensors' or collaboration partners' patent applications, or invalidate our or our current or future licensors or 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 licensors or 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 licensors or 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 or our competitors' drug or biologic 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 technologies, drug or biologic candidates, compositions 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 drug or biologic 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 collaboration partners, have filed patent applications covering various aspects of our ETB technology, drug or biologic 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 one or more third parties. Any successful opposition or challenge to these patents or to any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any drug or biologic candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a drug or biologic 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 technology, drug or biologic candidates, compositions 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 drug or biologic 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 or state laws in the United States. Competitors may use our technologies to develop our own products in jurisdictions where we have not obtained patent protection and may also export infringing products to territories where we do not have patent protection, to territories where we have patent protection, but where 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 resources, 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 term or regulatory exclusivity protections for our drug or biologic 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, drug or biologic candidates and associated uses are obtained, once the patent's life has expired, including for failure to pay maintenance fees or annuities, 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 drug or biologic candidates depending on the timing and duration of the regulatory review process relative to patent term. In addition, upon issuance of a United States patent, 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. Although we will likely seek patent term extensions in the U.S. and in one or more foreign jurisdictions where available, 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 drug or biologic 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 term or regulatory exclusivity to protect our drug or biologic 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 technologies and 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 benefit or priority of a patent application filed 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 AIA was signed into law. The AIA includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, effect the scope of prior art and may also affect patent litigation. The USPTO has

promulgated regulations and developed procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA, and in particular, the first inventor to file a provisional patent application, did not come into effect until March 16, 2013. The AIA 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 AIA 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 granted 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 drug or biologic candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the AIA are 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 used by many third parties to challenge and invalidate patents. The IPR process is not limited to patents filed after the AIA 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, e.g., an IPR, to invalidate our patent claims that would not have been invalidated if first challenged by the third party 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 drug or biologic 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 research, development or commercialization activities before they are publicly disclosed, making it in many cases too late to obtain patent protection on them. Further, given the amount of time required for the development, testing and regulatory review of new drug or biologic 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 comparable 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, our collaboration partners or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we, our collaboration partners or our licensors were the first to file for patent protection of such inventions.

Issued patents covering our ETB technologies, drug or biologic candidates, compositions or uses could be found invalid or unenforceable if challenged in a patent office or court.

Even if our or our current or future collaboration partners' or licensors' patents do successfully issue and even if such patents cover our technologies, drug or biologic candidates, compositions or 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, scope or term of such patents in other patent

administrative or court proceedings worldwide, which may result in patent claims being narrowed or invalidated. Such proceedings could result in revocation or amendmentof our patents in such a way that they no longer cover competitive technologies, drug or biologic candidates, compositions or methods of use. Further, if we initiate legal proceedings against a third party to enforce a patent covering our technologies, drug or biologic candidates, compositions 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 novelty, nonobviousness (or inventive step), clarity, adequate written description and enablement of the claimed invention. Grounds for unenforceability assertions include allegations that someone associated with the filing or prosecution of the patent withheld material 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 or 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 part, and perhaps all, of the patent protection on our ETB technology, drug or biologic candidates, compositions 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 collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our drug or biologic candidates, the defendant could counterclaim that the patent covering our drug or biologic candidate is invalid and/or unenforceable. In addition, a third party might initiate legal proceedings against us alleging that our patent covering one or more of our drug or biologic candidates is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including 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, for example, such that they don't cover our drug or biologic candidates, 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, pursue or maintain 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 drug or biologic candidates to market.

If we are unable to protect the confidentiality of our trade secrets and know-how for our drug or biologic candidates or any future drug or biologic 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 drug or biologic 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 although 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 research and development activities and commercial success depends in part on our ability to develop, manufacture, market and sell our drug or biologic candidates and use our proprietary technology without infringing the patent rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. We are currently not aware of U.S. or foreign patents or pending patent applications that are owned solely by one or more third parties and that cover our ETB drug or biologic candidates or therapeutic uses of those ETB drug or biologic 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 drug or biologic candidates or technologies or a requisite manufacturing process, we may not be free to manufacture or market our drug or biologic 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, patent applications filed before November 29, 2000 and patent applications filed after that date, but that will not be filed outside the United States, remain confidential until the patent applications issue as patents. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to drug or biologic 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 drug or biologic candidate, or we may incorrectly conclude that a patent office or court would determine 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 drug or biologic candidates or the use of our drug or biologic 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 drug or biologic candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our drug or biologic 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 drug or biologic 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. Further, if we were to seek a license from the third-party holder of any applicable intellectual property rights, we may not be able to obtain the applicable license rights when needed or on reasonable terms, or at all. Some of our competitors may be able to sustain the costs of complex patent litigation or proceeding more effectively than us due to their substantially greater resources. The occurrence of any of the above events could prevent us from continuing to develop and commercialize one or more of our drug or biologic candidates and our business could materially suffer.

We may be unsuccessful in obtaining or maintaining third-party intellectual property rights necessary to develop our ETB technologies or to commercialize our drug or biologic 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 agreements. 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 drug or biologic candidates may require specific formulations or manufacturing technologies to be safe, work effectively or be manufactured efficiently, and these rights may be held by others. We may be unable to acquire or in-license on reasonable terms 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 collaborated, 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 retain 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 us, and vice versa. 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 drug or biologic 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 drug or biologic 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 drug or biologic candidates, there may be times when certain patents or patent applications relating to our drug or biologic candidates, their compositions, uses or their manufacture may be controlled by our collaboration partners or licensors. If any of our collaboration partners fail to appropriately or broadly prosecute patent applications or maintain patent protection of claims covering any of our drug or biologic candidates, their compositions, uses or their manufacture, our ability to develop and commercialize those drug or biologic candidates may be adversely affected and we may not be able to prevent competitors from making, using, importing, offering to sell or 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, presently or 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 if 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 wrongfully used or disclosed alleged confidential information of third parties or that our employees 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 with these individuals, and although we 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 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 at 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 or to foreign patent agencies in several stages over the lifetime of the patent, and periodic annuities are due to be paid for foreign patent applications in some foreign patent offices. 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 drug or biologic 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, which went 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 drug or biologic 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 drug or biologic 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 drug or biologic candidates in clinical development. If we, or any of our CROs or vendors, fail to comply with applicable laws, regulations or 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 or 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 or 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 drug or biologic 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 drug or biologic candidates for use in the conduct of our clinical trials. We may not be able to manufacture drug or biologic candidates or there may be substantial technical or logistical challenges to supporting manufacturing demand for drug or biologic 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 at least in part on third-party manufacturers, and their responsibilities often include purchasing from third-party suppliers the materials necessary to produce our drug or biologic 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 drug or biologic candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our drug or biologic 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 drug or biologic candidate to complete the trial, any significant delay or discontinuity in the supply of a drug or biologic candidate, or the raw materials or other material components in the manufacture of the drug or biologic candidate, could delay completion of our clinical trials and potential timing for regulatory approval of our drug or biologic 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 drug or biologic candidates and our current costs to manufacture our drug or biologic candidates may not be commercially feasible, and the actual cost to manufacture our drug or biologic candidates could materially and adversely affect the commercial viability of our drug or biologic 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 drug or biologic candidates on acceptable terms or at all, because the number of qualified potential manufacturers is limited. Following NDA or 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 drug or biologic candidates;
- drug or biologic 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 be able to license, or we may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug or biologic 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 drug or biologic candidates, or the commercialization of our drug or biologic 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 drug or biologic 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 drug or biologic 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 Takeda Development and 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 Takeda Development and 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. We exercised our co-development option in July 2019 and can elect to end our co-development by providing Takeda with written notice of termination of the co-development. In the event we elect to end the co-development, we will be subject to reduced payments and royalty rates as set forth more specifically in the Takeda Development and License Agreement.

Pursuant to the terms of the Takeda Development and 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 manner different 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 Takeda Development and 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 Takeda Development and 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. Following the exercise of our option to co-develop the Licensed Products, we have 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 Takeda Development and License Agreement for convenience upon 90 days prior written notice. Takeda also maintains the right to terminate the Takeda Development and 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 Takeda Development and 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 drug or biologic 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 Takeda Development and License Agreement prior to regulatory approval of any drug or biologic candidates under the Takeda Development and 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 have entered into a Master Collaboration Agreement (" Vertex Collaboration Agreement") with Vertex Pharmaceuticals Incorporated ("Vertex") and, pursuant to the terms of that agreement, could become dependent on Vertex for development, manufacturing, regulatory and commercialization activities with respect to certain of our ETB products for novel targeted biologic therapies.

In November 2019, we entered into the Vertex Collaboration Agreement, pursuant to which we agreed to leverage our ETB technology platform to discover and develop novel targeted biologic therapies for applications outside of oncology. Pursuant to the terms of the Vertex Collaboration Agreement, we granted Vertex an exclusive option to obtain an exclusive license to exploit one or more ETB drug or biologic candidates that are discovered by us against up to two designated targets. Vertex has selected an initial target and has the option to designate one additional target within specified time limits.

Under the Vertex Collaboration Agreement, Vertex paid us an upfront payment of $38 million, consisting of $23 million in cash and a $15 million equity investment pursuant to a Share Purchase Agreement. In addition to the upfront payments, we may also receive an additional $22 million through the exercise of the options to license ETB drug or biologic candidates or to add an additional target. We are required to provide, and Vertex will reimburse us for, certain mutually agreed manufacturing technology transfer activities. Vertex may never choose to exercise its option and we cannot predict whether Vertex will, if ever, exercise its option.

We may, for each target under the Vertex Collaboration Agreement, receive up to an additional $180 million in milestone payments upon the achievement of certain development and regulatory milestone events and up to an additional $70 million in milestone payments upon the achievement of certain sales milestone events. We will also be entitled to receive, subject to certain reductions, tiered mid-single digit royalties as percentages of calendar year net sales, if any, on any licensed ETB product. The milestones that trigger a payment or royalties under the Vertex Collaboration Agreement may never be reached and failure to do so could harm our business and financial condition.

We will be responsible for conducting the research activities through the designation, if any, of one or more development candidates. Upon the exercise by Vertex of its option for a development candidate, Vertex will be responsible for all development, manufacturing, regulatory and commercialization activities with respect to that development candidate. We cannot control whether Vertex will devote sufficient attention or resources to this collaboration or will proceed in an expeditious manner. Even if the FDA or other regulatory agencies approve any of the licensed ETB drug or biologic candidates, Vertex may elect not to proceed with the commercialization of the resulting product in one or more countries.

Unless earlier terminated, the Vertex Collaboration Agreement will expire (i) on a country-by-country basis and licensed product-by-licensed product basis on the date of expiration of all payment obligations under the Vertex Collaboration Agreement with respect to such licensed product in such country and (ii) in its entirety upon the expiration of all payment obligations thereunder with respect to all licensed products in all countries or upon Vertex's decision not to exercise any option on or prior to the applicable deadlines. Vertex has the right to terminate the Vertex Collaboration Agreement for convenience upon prior written notice to Company. Either party has the right to terminate the Vertex Collaboration Agreement (a) for the insolvency of the other party or (b) subject to specified cure periods, in the event of the other party's uncured material breach. If Vertex terminates the Vertex Collaboration Agreement, it will result in a delay in or could prevent us from further developing or commercializing products directed to these targets, and will delay and could prevent us from obtaining revenues for such product. Further, disputes may arise between us and Vertex, which may delay or cause the termination of this collaboration, result in significant litigation, cause Vertex to act in a manner that is not in our best interest, or cause us to seek another collaborator or proceed with development, commercialization and funding on our own. If we seek a new collaborator 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 product directed to these new targets ourselves, we may have to curtail or abandon that development or commercialization, which could harm our business.

We depend on third parties and intend to continue to license or collaboratewith third parties and may be unable to realize the potential benefits of any collaboration.

Our business strategy, along with our short- and long-term operating results depend in part on our ability to execute on existing strategic collaborations and to license or partner with new strategic partners. In addition to the Takeda Development and License Agreement and the Vertex Collaboration 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 at entering into one or more additional collaborations with respect to the development and/or commercialization of one or more drug or biologic candidates, there is no guarantee that any of these collaborations will be successful. We believe collaborations allow us to leverage our resources and technologies and we anticipate deriving some revenues from research and development fees, license fees, milestone payments, and royalties from our collaborative partner. Collaborations may pose a number of risks, including the following:

- collaboration partners 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;
- collaboration partners may not perform their obligations as expected or may breach or terminate their agreements with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner;
- 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 drug or biologic candidates, potential products or proprietary technologies or grant licenses on terms that are not favorable to us;
- collaboration partners may cease to devote resources to the development or commercialization of our drug or biologic candidates if the collaboration partners view our drug or biologic candidates as competitive with their own products or drug or biologic candidates;
- disagreements with collaboration partners, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of drug or biologic candidates, and might result in legal proceedings, which would be time consuming, distracting and expensive;
- collaboration partners 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;
- collaboration partners 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;
- by entering into certain collaborations, we may forego opportunities to collaborate with other third parties who do not wish to be associated with our existing third-party strategic partners; 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 drug or biologic candidate.

There can be no assurance that we will be successful at establishing collaborative arrangements on acceptable terms or at all, that collaborative partners will not terminate funding before the completion of projects, that our collaborative arrangements will result in successful product commercialization, or that we will derive any revenues from such arrangements. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position and our internal capabilities. Additionally, the negotiation, documentation and implementation of collaborative arrangements are complex and time-consuming. Our discussions with potential collaborators may not lead to new collaborations on favorable terms and may have the potential to provide collaborators with access to our key intellectual property rights.

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 drug or biologic 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 collaboration partners from any third-party product liability claims that could result from the production or use of the drug or biologic 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 Drug 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 drug or biologic 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 drug or biologic 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 collaboration partners 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 collaboration partners do not commit sufficient resources to commercialize our future drugs or biologics, and if 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 drug or biologic candidates are intended to address. Without appropriate capabilities, whether directly or through third-party collaboration partners, 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 drug or biologic 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 collaboration partners, 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 drug or biologic candidates and programs on terms that are acceptable, or at all. This may be because our drug or biologic 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 drug or biologic candidates and programs as having sufficient potential for commercialization, including the likelihood of an adequate safety and efficacy profile.

Any delays in identifying suitable collaboration partners and entering into agreements to develop and/or commercialize our drug or biologic candidates could delay the development or commercialization of our drug or biologic 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 drug or biologic candidates or bring them to market and our business may be materially and adversely affected.

If the market opportunities for our drug or biologic candidates are smaller than we believe they are, we may not meet our revenue expectations and, even if a drug or biologic candidate receives marketing approval, our business may suffer. Because the patient populations in the market for our drug or biologic 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 drug or biologic candidates may differ significantly from the actual market addressable by our drug or biologic 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 lymphoma in the United States for 2020 is 77,240 new cases and approximately 19,940 deaths are estimated to be attributable to non-Hodgkin's B-cell lymphomas in 2020., 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 drug or biologic 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 drug or biologic candidates may be limited or may not be amenable to treatment with ourdrug or biologic 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 drugs 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, MT-5111, TAK-169 and the other drug or biologic candidates that we may seek to develop or commercialize in the future. We are aware that companies including the following have products marketed or in development that could compete directly or indirectly with ETBs: Genentech, Bayer, Takeda, AbbVie, 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, ADC Therapeutics, Bluebird Bio, Gilead, ZymeWorks, Forty Seven, GlaxoSmithKline, and F-Star. Our competitors may succeed in developing, acquiring or licensing technologies or drug or biological products that are more effective or less costly than MT-3724, MT-5111, TAK-169 or any other drug or biologic candidates that we are currently developing or that we may develop, which could render our drug or biologic 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 drug or biologic 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. In addition, third-party payors, including governmental and private insurers, also may encourage the use of generic products. For example, if MT-3724, MT-5111, or TAK-169 is ultimately approved, it may be priced at a significant premium over other competitive products. This may make it difficult for MT-3724, MT-5111, TAK-169 or any other future drugs or biologics to compete with these products. Failure of MT-3724, MT-5111, TAK-169 or other drug or biologic 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 drug or biologic 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 drugs will depend in part on the health care providers, patients and third-party payors accepting our drug or biologic candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients or third-party payors. The degree of market acceptance of any of our drugs 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 drugs or biologics 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 drugs may require significant investment and resources and may never be successful. If our drugs or biologics 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 drug or biologic candidates.

Although a substantial amount of our effort has focused on the continued clinical testing, potential approval and commercialization of our existing drug or biologic candidates, the success of our business is also expected to depend in part upon our ability to identify, license, discover, develop or commercialize additional drug or biologic candidates. Research programs to identify new drug or biologic candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or drug or biologic candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to yield additional drug or biologic 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 drug or biologic candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional drug or biologic candidates;
- our drug or biologic candidates may not succeed in preclinical or clinical testing;
- our drug or biologic 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 drug or biologic candidates obsolete or less attractive;
- drug or biologic candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a drug or biologic candidate may change during our program so that such a drug or biologic candidate may become unreasonable or infeasible to continue to develop;
- a drug or biologic candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a drug or biologic 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 drug or biologic 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 drugs, if any, could limit our ability to market those drugs and decrease our ability to generate revenue.

The pricing, coverage, and reimbursement of our approved drugs, 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 drugs, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of our approved drugs, 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 drugs for free or we may not be able to successfully commercialize our drugs.

In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved drugs. 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 drug or biologic candidates such as ours and what reimbursement codes our drug or biologic 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 drugs. In many countries, the prices of drugs 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 drugs, 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 drugs and, as a result, they may not cover or provide adequate payment for our drugs, if any. We expect to experience pricing pressures in connection with drugs 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 or biologics in particular, has and is expected to continue to increase in the future. As a result, profitability of our drugs, if any, may be more difficult to achieve even if any 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 drug or biologic candidates, and delays or failures to obtain such approvals;
- failure of any of our drug or biologic 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 drug or biologic candidates;
- any inability to obtain adequate supply of our drug or biologic 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;
- the issuance of additional shares of our preferred stock or common stock, or the perception that such issuances may occur, including through our "at-the-market" offering program or any sales of our preferred stock or common stock by our stockholders in the future;
- 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 drugs generally, including with respect to other drugs and potential drugs in such markets;
- the introduction of technological innovations or new therapies that compete with our potential drugs;
- 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 March 31, 2020, a total of 45,703,934 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, securities convertible into 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 shares of our common stock reserved for issuance pursuant to the 2018 Plan which includes potential forfeitures and cancellations of outstanding stock options from the 2004 Equity Incentive Plan, the 2009 Stock Plan, and 2014 Equity Incentive Plan. Any future grantsof 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 effect 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.

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, including from the sale of shares of common stock under the Sales Agreement and from our public offering in November 2019. 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 drug or biologic candidates. Pending their use, we may invest our cash reserves in a manner that does not produce income or that loses value. 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 collaboration partners 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.

We can issue and have issued shares of preferred stock, which may adversely affect the rights of holders of our common stock.

Our amended and restated Certificate of Incorporation authorizes us to issue up to 2,000,000 shares of preferred stock with designations, rights, and preferences determined from time-to-time by our Board of Directors. Accordingly, our Board of Directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting or other rights superior to those of holders of our common stock. For example, an issuance of shares of preferred stock could:

- adversely affect the voting power of the holders of our common stock;
- make it more difficult for a third party to gain control of us;
- discourage bids for our common stock at a premium;
- limit or eliminate any payments that the holders of our common stock could expect to receive upon our liquidation; or
- otherwise adversely affect the market price or our common stock.

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 significantlyincreased 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 a "smaller reporting company", and/or an 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 executive officers, directors and principal stockholders have the ability to significantly influence all matters submitted to our stockholders for approval.

As of March 31, 2020, our directors, executive officers, and stockholders beneficially owning 5% or more of our shares or that may be affiliated with our board members, beneficially owned, in the aggregate, approximately 54% of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence almost all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

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.

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.

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 drug or biologic 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 March 31, 2020, we had 183 full-time employees and 20 part-time and temporary 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 drug or biologic 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 drug or biologic 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.

Our financial condition, clinical development efforts, and results of operations could be adversely affected by the ongoing coronavirus outbreak.

Any outbreak of contagious diseases or other adverse public health developments, could have a material and adverse effect on our business operations. Such adverse effects could include disruptions or restrictions on the ability of our, our collaborators', or our suppliers' personnel to travel, and could result in temporary closures of our facilities or the facilities of our collaborators or suppliers. In December 2019, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) ("coronavirus"), which causes coronavirus disease 2019 ("COVID-19"), surfaced in Wuhan, China and has reached multiple other regions and countries, including Texas and New Jersey where our primary offices are located. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures, as well as reported adverse impacts on healthcare resources, facilities and providers, in Texas and New Jersey, across the United States and in other countries. The extent to which COVID-19 will impact our operations or those of our third-party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and the actions to contain COVID-19 or address its impact in the short and long-term, among others.

In response to the pandemic and in accordance with direction from state and local government authorities, we have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring most employees to work remotely (which in turn increases the threat to our cyber security and data accessibility, and communication matters) and suspending all non-essential travel worldwide for our employees. In addition, industry events and in-person work-related meetings have been cancelled, the continuation of which could negatively affect our business.

As COVID-19 continues to affect individuals and businesses around the globe, we will likely experience disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials, or drop-outs from our clinical trials, including those resulting from an inability to travel to our clinical trial sites as a result of quarantines or other restrictions resulting from COVID-19;
- delays or difficulties in obtaining the financing necessary to undertake our clinical trials;
- interruptions or delays in the operations of the FDA and comparable foreign regulatory agencies, which may impact review, inspection, clearance and approval timelines with respect to our drug and biologic candidates;
- limitations on travel that could interrupt key clinical activities and trial activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our research, manufacturing and clinical trial sites or secure visas or entry permissions, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;
- diversion or prioritization of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations, cyber security and data accessibility, or communication or mass transit disruptions;
- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or requirements imposed on employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;
- continued volatility in our and other biotechnology companies' shares of equity which may result in difficulties raising capital through sales of our common stock or equity linked to our common stock, to the extent needed, and the terms of sales may be on unfavorable terms or unavailable, which may impact our short-term and long-term liquidity;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether; and
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

In addition, the continued spread of COVID-19 globally could adversely affect our manufacturing and supply chain. Parts of our direct and indirect supply chain could be subject to disruption or product contamination. Additionally, our results of operations could be adversely affected to the extent that COVID-19 or any other epidemic harms our business or the economy in general either domestically or in any other region in which we do business. A prolonged disruption or any further unforeseen delay in our operations could continue to result in increased costs and reduced revenue. If the outbreak of COVID-19 is not effectively and timely controlled, our business operations and financial condition may be materially and adversely affected as a result of the deteriorating market outlook, the slowdown in regional and national economic growth, and other factors that we cannot foresee. The extent to which COVID-19 affects our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others, which could have an adverse effect on our business and financial condition.

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 and we also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party vendors who may or could have access to our confidential information. 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, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, require us to comply with federal and/or state breach notification laws and foreign law equivalents, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. In addition, the loss of data from clinical trials for our drug or biologic 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

None.

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
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.

* 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: May 11, 2020

/s/ Eric E. Poma
Eric E. Poma, Ph.D.
Chief Executive Officer and Chief Scientific Officer

Date: May 11, 2020

/s/ Adam Cutler
Adam Cutler
Chief Financial Officer

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: May 11, 2020

/s/ Eric E. Poma, Ph.D.
Eric E. Poma, Ph.D.
Chief 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: May 11, 2020

/s/ Adam Cutler
Adam Cutler
Chief Financial 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 March 31, 2020 (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, 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: May 11, 2020

/s/ Eric E. Poma, Ph.D.
Eric E. Poma, Ph.D.
Chief Executive Officer

Dated: May 11, 2020

/s/ Adam Cutler
Adam Cutler
Chief Financial Officer