

**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, 2018

or

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

For the transition period from _____ to _____

Commission File Number: 001-32979

Molecular Templates, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

94-3409596
(I.R.S. Employer
Identification No.)

9301 Amberglen Blvd, Suite 100, Austin TX 78729
(Address of principal executive offices, including zip code)

(512) 869-1555
(Registrant's telephone number, including area code)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities 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 10, 2018, there were 27,060,603 shares of common stock, par value \$0.001 per share, of Molecular Templates, Inc. outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained herein 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. These forward-looking statements include, but are not limited to, statements about the implementation of our business strategies, including our ability to pursue development pathways and regulatory strategies for MT-3724 and other engineered toxin body, or ETB, product candidates; our ability to advance the development of our product candidates; our plans to pursue discussions with regulatory authorities, and the anticipated timing, scope and outcome of related regulatory actions or guidance; our ability to establish and maintain potential new partnering or collaboration arrangements for the development and commercialization of ETB product candidates; our financial condition, including our ability to obtain the funding necessary to advance the development of our product candidates; the anticipated progress of our product candidate development programs, including whether our ongoing and potential future clinical trials will achieve clinically relevant results; our ability to generate data and conduct analyses to support the regulatory approval of our product candidates; our ability to establish and maintain intellectual property rights for our product candidates; whether any product candidates that we are able to commercialize are safer or more effective than other marketed products, treatments or therapies; our ability to discover and develop additional product candidates suitable for clinical testing; our ability to identify, in-license or otherwise acquire additional product candidates and development programs; our anticipated research and development activities and projected expenditures; our ability to complete preclinical and clinical testing successfully for new product candidates that we may develop or license; our ability to have manufactured active pharmaceutical ingredient, or API, and drug product that meet required release and stability specifications; our ability to have manufactured sufficient supplies of drug product for clinical testing and commercialization; our ability to obtain licenses to any necessary third-party intellectual property; our ability to retain and hire necessary employees and appropriately staff our development programs; the sufficiency of our cash resources; and other risks and uncertainties, including those listed under Part II, Item 1A. “Risk Factors”.

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

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

Molecular Templates, Inc.

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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)
(unaudited)

	March 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 49,275	\$ 58,910
Prepaid expenses	1,477	1,485
Accounts receivable from related party	4,000	—
Other current assets	144	19
Total current assets	54,896	60,414
Property and equipment, net	4,294	1,952
In-process research and development	26,623	26,623
Other assets	1,402	1,402
Total assets	<u>\$ 87,215</u>	<u>\$ 90,391</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,859	\$ 2,517
Accrued liabilities	2,800	2,690
Current portion of long-term debt	—	2,400
Deferred revenue	6,350	2,765
Other current liabilities	98	70
Total current liabilities	12,107	10,442
Warrant liabilities	340	954
Long-term debt, net	2,999	1,078
Other liabilities	828	628
Total liabilities	16,274	13,102
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock, \$0.001 par value, shares authorized: 150,000,000 shares; issued and outstanding: 27,060,035 shares at March 31, 2018 and 26,898,330 shares at December 31, 2017	27	27
Additional paid-in capital	144,044	141,733
Accumulated other comprehensive loss	—	—
Accumulated deficit	(73,130)	(64,471)
Total stockholders' equity	70,941	77,289
Total liabilities and stockholders' equity	<u>\$ 87,215</u>	<u>\$ 90,391</u>

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

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

	Three Months Ended	
	March 31,	
	2018	2017
Research and development revenue	\$ 231	\$ 1,760
Grant revenue	251	125
Total revenue	<u>482</u>	<u>1,885</u>
Operating expenses:		
Research and development	6,687	1,067
General and administrative	2,910	1,791
Total operating expenses	<u>9,597</u>	<u>2,858</u>
Loss from operations	9,115	973
Interest and other income, net	82	—
Interest expense	(295)	(223)
Change in fair value of warrant liabilities	614	1
Net loss	<u>8,714</u>	<u>1,195</u>
Deemed dividends on preferred stock	—	427
Net loss attributable to common shareholders	<u>\$ 8,714</u>	<u>\$ 1,622</u>
Net loss per share attributable to common shareholders:		
Basic and diluted	<u>\$ 0.32</u>	<u>\$ 7.56</u>
Weighted average number of shares used in net loss per share calculations:		
Basic and diluted	<u>26,989,693</u>	<u>214,641</u>
Other comprehensive loss:		
Unrealized gain (loss) on available-for-sale securities	—	—
Comprehensive loss	<u>\$ 8,714</u>	<u>\$ 1,622</u>

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,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ 8,714	\$ 1,195
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	72	18
Stock-based compensation expense	643	26
Amortization of debt discount and accretion related to long-term liabilities	63	38
Change in common stock warrant fair value	(615)	2
Accretion of asset retirement obligations	8	—
Loss on extinguishment of debt	115	—
Loss on disposal of equipment	2	—
Changes in operating assets and liabilities:		
Prepaid expenses	(58)	8
Accounts receivable from related party	(4,000)	(750)
Other current assets	(71)	—
Accounts payable	(355)	(139)
Accrued liabilities	110	473
Other current liabilities	34	—
Other liabilities	198	—
Deferred revenue	3,585	(1,135)
Net cash used in operating activities	<u>(8,983)</u>	<u>(2,654)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(1,719)	(8)
Increase in other assets	—	(188)
Net cash used in investing activities	<u>(1,719)</u>	<u>(196)</u>
Cash flows from financing activities:		
Payments of capital lease obligations	(13)	(11)
Proceeds from issuance of long-term debt and warrants, net	4,537	—
Repayment of long-term debt	(3,605)	(600)
Proceeds from issuance of related party debt	—	2,685
Proceeds from stock option exercise	148	—
Proceeds from promissory note	—	2,000
Net cash provided by financing activities	<u>1,067</u>	<u>4,074</u>
Net increase (decrease) in cash and cash equivalents	<u>(9,635)</u>	<u>1,224</u>
Cash and cash equivalents, beginning of period	58,910	1,716
Cash and cash equivalents, end of period	<u>\$ 49,275</u>	<u>\$ 2,940</u>
Supplemental Cash Flow Information		
Cash paid for interest	<u>\$ 51</u>	<u>\$ 68</u>
Non-Cash Investing and Financing Activities		
Deemed dividends on preferred stock	<u>\$ —</u>	<u>\$ 428</u>

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

Molecular Templates, Inc.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of the Business

Molecular Templates, Inc. (the “Company” or “Molecular”), 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. Molecular 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 the entity then known as Molecular Templates, Inc., a private Delaware Corporation (“Private Molecular”), in accordance with the terms of an Agreement and Plan of Merger and Reorganization, (the “Merger Agreement”), dated as of March 16, 2017, by and among Threshold, Trojan Merger Sub, Inc., a wholly owned subsidiary of Threshold (“Merger Sub”), 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”). Also on August 1, 2017, in connection with, and prior to the completion of, the Merger, Threshold effected an 11-for-1 reverse stock split of its common stock (the “Reverse Stock Split”) and changed its name to “Molecular Templates, Inc.” Following the completion of the Merger, the business conducted by the Company became primarily the business conducted by Private Molecular as described in the paragraph above.

Basis of Presentation

These unaudited interim condensed consolidated financial statements reflect the historical results of Private Molecular prior to the completion of the Merger, and do not include the historical results of the Company prior to the completion of the Merger. All share and per share disclosures have been adjusted to reflect the exchange of shares in the Merger, and the 11-for-1 reverse stock split of the common stock effected on August 1, 2017. Under U.S. GAAP, the Merger is treated as a “reverse merger” under the purchase method of accounting. For accounting purposes, Private Molecular is considered to have acquired Threshold. See Note 3, “Merger with Private Molecular”, for further details on the Merger and the U.S. GAAP accounting treatment.

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

The 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 estimate 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, 2017 included in the Company’s Annual Report on Form 10-K filed with the SEC on March 30, 2018.

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

Reclassifications

Certain amounts in prior year’s presentations have been reclassified to conform to the current presentation. These classifications had no effect on previously reported net loss.

Significant Accounting Policies

Except as detailed below, there have been no material changes to the Company's significant accounting policies during the three months ended March 31, 2018, 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, 2017.

Revenue Recognition

Effective January 1, 2018, the Company adopted the Financial Accounting Standards Board's ("FASB") provisions of ASC 606, *Revenue from Contracts with Customers* (ASC 606), using the modified retrospective method for all contracts not completed as of the date of adoption. For contracts that were modified before the effective date, the Company reflected the aggregate effect of all modifications when identifying performance obligations and allocating transaction price in accordance with available practical expedients. The reported results for 2018 reflect the application of ASC 606 guidance, while the reported results for 2017 were prepared under the guidance of ASC 605, *Revenue Recognition*, which is also referred to herein as "previous guidance."

Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer.

The Company identifies the goods or services promised within each collaboration agreement and assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. In assessing whether a promised good or service is distinct, the Company considers factors such as the research, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. If a promised good or service is not distinct, an entity is required to combine that promised good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The allocation of the transaction price to the performance obligations in proportion to their standalone selling prices is determined at contract inception. If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if there is a significant benefit of financing. The Company assessed its collaboration agreements and concluded that no significant financing components were present.

If an arrangement contains customer options that allow the customer to acquire additional goods or services, including an exclusive license to the Company's intellectual property, the goods and services underlying the customer options are evaluated to determine whether they are deemed to represent a material right. In determining whether the customer option has a material right, the Company assesses whether there is an option to acquire additional goods or services at a discount. If the customer option is determined not to represent a material right, the option is not considered to be performance obligations at the outset of the arrangement. If the customer option is determined to represent a material right, the material right is recognized as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the relative standalone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until the option is exercised.

The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation as each performance obligation is satisfied over time, based on the use of an input method. Performance obligations may include research and development services to be performed by the Company on behalf of the collaboration partner. Revenue is recognized on research and development efforts as the services are performed and presented on a gross basis, since the Company is the principal.

Refer to Note 4, "Research and Development Agreements", for further details about the impact of the adoption of ASC 606.

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, cash equivalents are with two major financial institutions in the United States.

The Company performs an ongoing credit evaluation of its strategic partners' financial conditions and generally does not require collateral to secure accounts receivable from its strategic partners. The Company's exposure to credit risk associated with non-payment will be affected principally by conditions or occurrences within Takeda Pharmaceutical Company Ltd. ("Takeda"). Approximately 34% of total revenues for the three months ended March 31, 2018, were derived from Takeda. There was \$4.0 million in accounts receivable due from Takeda at March 31, 2018 that was received in April 2018. See also Note 4, "Research and Development Agreements", regarding the collaboration agreements with Takeda.

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

Recently Issued Accounting Pronouncements

Effective January 1, 2018, the Company adopted ASC 606, which provides principles for recognizing revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The Company adopted ASC 606 on a modified retrospective basis through a cumulative adjustment to equity. The impact of the adoption of the standard to prior period amounts is discussed below in Note 4, "Research and Development Agreements".

In February 2016, the FASB issued ASU 2016-02, "Leases (Topic 842)." ASU 2016-02 requires management to record right-to-use asset and lease liability on the statement of financial position for operating leases. ASU 2016-02 is effective for annual and interim reporting periods beginning on or after December 15, 2018 and the modified retrospective approach is required. The Company is in the process of evaluating the impact the adoption of this standard would have on its consolidated financial statements and disclosures and expects the new standard to significantly increase the reported assets and liabilities on its consolidated balance sheets.

In May 2017, the FASB issued ASU 2017-09, "Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting" to clarify when to account for a change to the terms or conditions of a share-based payment award as a modification. Under this new guidance, modification accounting is required if the fair value, vesting conditions, or classification of the award changes as a result of the change in terms or conditions. ASU 2017-09 is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within each annual reporting period. The Company adopted the standard in the first quarter of 2018 and it did not have a material impact to its consolidated financial statements.

In December 2017, the SEC issued Staff Accounting Bulletin ("SAB") 118 to address the application of GAAP in situations in which a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Cuts and Jobs Act, or the Tax Act, which was signed into law on December 22, 2017. In March 2018, the FASB issued ASU No. 2018-05, "Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 (SEC Update)," which amended ASC 740 to incorporate the requirements of SAB 118. There were no changes in the provisional amounts recorded by the Company at December 31, 2017 related to the Tax Act. The Company continues to evaluate the impact of the Tax Act.

NOTE 2 — NET LOSS PER COMMON SHARE

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by giving effect to all potential dilutive common shares, including outstanding options and warrants. The following is the calculation of basic and diluted net loss per share (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2018	2017
Numerator:		
Net loss attributable to common shareholders	\$ 8,714	\$ 1,622
Denominator:		
Weighted average common shares outstanding - basic and diluted	26,989,693	214,641
Net loss per share:		
Basic and diluted	\$ 0.32	\$ 7.56

The following outstanding warrants and options were excluded from the computation of diluted net loss per share for the periods presented because including them would have had an antidilutive effect (in thousands):

	Three Months Ended March 31,	
	2018	2017
Shares issuable upon exercise of warrants	3,522	35
Shares issuable upon exercise of stock options	2,880	458

NOTE 3 — MERGER WITH PRIVATE MOLECULAR

On August 1, 2017, the Company, formerly known as Threshold, completed the Merger with Private Molecular, in accordance with the terms of the Merger Agreement. Immediately upon completion of the Merger, the former stockholders of Private Molecular held a majority of the voting interest of the combined company.

Also on August 1, 2017, in connection with, and prior to the completion of, the Merger, Threshold effected a Reverse Stock Split and changed its name from Threshold Pharmaceuticals, Inc. to Molecular Templates, Inc. Under the terms of the Merger, at the effective time of the Merger, the Company issued shares of its common stock to Private Molecular stockholders, at an exchange ratio of 7.7844 shares of common stock (the "Exchange Ratio"), after taking into account the Reverse Stock Split, in exchange for each share of Private Molecular common stock outstanding immediately prior to the Merger. Immediately following the closing of the Merger on August 1, 2017, the former Threshold stockholders owned approximately 34.4% of the aggregate number of shares of common stock of the Company and the former Private Molecular stockholders owned approximately 65.6% of the shares of common stock of the Company, subject to adjustments in accordance with the merger agreement.

All Private Molecular stock options granted under the Private Molecular stock option plan (whether or not then exercisable) outstanding prior to the effective time of the Merger were exchanged for options to purchase the Company's common stock. All outstanding and unexercised Private Molecular stock options assumed by the Company may be exercised solely for shares of the Company's common stock. The number of shares of the Company's common stock subject to each Private Molecular stock option assumed by the Company was determined by multiplying (a) the number of shares of Private Molecular common stock that were subject to such Private Molecular stock option, as in effect immediately prior to the effective time of the merger by (b) the Exchange Ratio and dividing by 11 (to account for the Reverse Stock Split); rounding the resulting number down to the nearest whole number of shares of the Company's common stock. The per share exercise price for the Company's common stock issuable upon exercise of each Private Molecular stock option assumed by the Company is determined by dividing (a) the per share exercise price of Private Molecular common stock subject to such Private Molecular stock option, as in effect immediately prior to the effective time of the merger, by (b) the Exchange Ratio, and multiplying by 11 (to account for the Reverse Stock Split); rounding the resulting exercise price up to the nearest whole cent. The exchange of the Private Molecular stock options for the Company's stock options was treated as a modification of the awards.

Threshold equity awards issued and outstanding at the time of the Merger will remain issued and outstanding. However, for accounting purposes, Threshold equity awards will be assumed to have been exchanged for equity awards of Private Molecular, the accounting acquirer. As of August 1, 2017, Threshold had outstanding stock options to purchase 963,681 shares of common stock, of

which stock options to purchase 963,681 shares were vested and exercisable at a weighted average exercise price of \$3.62 per share, after giving effect to the Reverse Stock Split.

Allocation of Purchase Consideration

Pursuant to business combination accounting, the Company applied the acquisition method, which requires the assets acquired and liabilities assumed be recorded at fair value with limited exceptions.

The purchase price for Threshold on August 1, 2017, the closing date of the Merger, was as follows (in thousands, except per share amounts):

	<u>August 1, 2017</u>	
Number of share of the combined company owned by Threshold stockholders	6,508	(1)
Multiplied by the price per share of Threshold common stock	\$ 5.94	(2)
Purchase price before options	\$ 38,658	
Threshold options assumed	1,006	(3)
Settlement of preexisting bridge note with Threshold	(4,010)	(4)
Total purchase price	<u>\$ 35,654</u>	

1. Represents the number of shares of common stock of the combined company that Threshold stockholders owned as of the closing of the Merger pursuant to the Merger Agreement. This amount is calculated as 6,508,356 shares of Threshold common stock outstanding as of August 1, 2017, adjusted for the 11-for-1 reverse stock split.
2. The fair value of Threshold common stock used in determining the purchase price was \$5.94, which was derived from the \$0.54 per share closing price of Threshold on August 1, 2017, the current price at the time of closing, adjusted for the 11-for-1 reverse stock split.
3. Because the Company is considered to be the acquirer for accounting purposes, the pre-Merger vested stock options granted by Threshold under the 2014 Equity Incentive Plan are deemed to have been exchanged for equity awards of the Company and as such the portion of the acquisition date fair value of these equity awards attributable to pre-Merger service to Threshold were accounted for as a component of the consideration transferred.
4. Represents the bridge loan as of the closing date of the Merger. As the receivable on Threshold's balance sheet was settled as part of the merger, it is deemed to be a reduction in the purchase price.

Under the acquisition method of accounting, the total purchase price was allocated to tangible and identifiable intangible assets acquired and liabilities assumed of Threshold on the basis of their estimated fair values as of the transaction closing date on August 1, 2017.

The following table summarizes the allocation of the purchase consideration to the assets acquired and liabilities assumed based on their fair values as of August 1, 2017 (in thousands):

	<u>August 1, 2017</u>
Cash and cash equivalents	\$ 11,216
Prepaid expenses and other current assets	945
In-process research and development (IPR&D)	26,623
Accounts payable, accrued expenses	(2,009)
Warrant liability	(1,121)
Net assets acquired	<u>\$ 35,654</u>

The Company believes that the historical values of Threshold's current assets and current liabilities approximate fair value based on the short-term nature of such items. The allocation of the purchase price is dependent on the valuation of the fair value of assets acquired and liabilities assumed. The Company does not expect any further revisions to the allocation of the purchase price.

In Process Research and Development

The Company used the risk adjusted discounted cash flow method to value the in-process research and development intangible asset. Under the valuation method, the present value of future cash flows expected to be generated from the in-process research and development of the acquired product candidate, evofosfamide, was determined using a discount rate of 12%, and identified projected cash flows from evofosfamide were risk adjusted to take into consideration the probabilities of moving through the various clinical stages.

Goodwill

The excess of the purchase price over the assets acquired and liabilities assumed represents goodwill. The goodwill is primarily attributable to the synergies expected to arise after the acquisition and is not expected to be deductible for tax purposes.

Transaction Costs

Transaction costs associated with the Merger of approximately \$2.0 million are included in general and administrative expense.

Threshold Promissory Note

On March 24, 2017, the Company received \$2.0 million from Threshold in the form of a promissory note at an interest rate of 1% per annum. The Company received an additional \$2.0 million on June 1, 2017. The note was settled as part of the Merger.

Share Based Awards

The exchange of Private Molecular stock options to purchase Threshold common stock, as renamed Molecular, was accounted for as a modification of the awards because the legal exchange of the awards is considered a modification of Private Molecular stock options. The modification of the stock options did not result in any incremental compensation expense as the modification did not increase the fair value of the stock options.

Additionally, pursuant to the terms of the Merger Agreement, participants in the 2014 Equity Incentive Plan received accelerated vesting for all or a portion of their pre-merger awards as well as a modification of the exercise period. The Company recorded \$1.2 million in stock compensation associated with the transaction. See Note 11, "Stock Based Compensation", for further details about stock based compensation recorded.

NOTE 4 — RESEARCH AND DEVELOPMENT AGREEMENTS

Disaggregated Research and Development Revenue

Research and Development revenues disaggregated by location were as follows (in thousands):

	March 31, 2018	March 31, 2017
Japan	\$ 163	\$ 1,260
United States	68	500
Total Research and Development Revenue	\$ 231	\$ 1,760

(1) Collaboration revenue is attributable to regions based on the location of our collaboration partner's parent company headquarters.

Impact of Adoption of ASC 606

Effective January 1, 2018, the Company adopted ASC 606, which provides principles for recognizing revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The Company adopted ASC 606 on a modified retrospective basis through a cumulative adjustment to stockholders' equity.

The cumulative effect of applying the new guidance of ASC 606 to all contracts with customers that were not completed as of January 1, 2018 was recorded as an adjustment to accumulated deficit as of the adoption date. As a result of applying the modified retrospective method to adopt the new revenue guidance, the following adjustments were made to accounts on the Condensed Consolidated Balance Sheet as of January 1, 2018 (in thousands):

Balance Sheet	December 31, 2017	Effect of adoption of ASC 606 (1)	January 1, 2018
Assets			
Other current assets	\$ 19	\$ 54	\$ 73
Total assets	<u>90,391</u>	<u>54</u>	<u>90,445</u>
Stockholder's equity			
Accumulated deficit	(64,471)	54	(64,417)
Total liabilities and stockholder's equity	<u>\$ 90,391</u>	<u>\$ 54</u>	<u>\$ 90,445</u>

- (1) This impact represents the amount of revenue that would have been recognized and accounted for as unbilled revenue, during the year ended December 31, 2017.

The impact of adoption on the Company's Condensed Consolidated Statement of Operations and Comprehensive Loss for the three months ended March 31, 2018 was as follows (in thousands):

Statement of operations and comprehensive loss	As reported March 31, 2018	Effect of adoption of ASC 606 (1)	Balance without adoption of ASC 606 March 31, 2018
Research and development revenue	\$ 231	\$ (68)	\$ 163
Total revenue	<u>482</u>	<u>(68)</u>	<u>414</u>
Net loss	<u>\$ 8,714</u>	<u>\$ 68</u>	<u>\$ 8,782</u>
Net loss per share	<u>\$ 0.32</u>	<u>\$ 0.01</u>	<u>\$ 0.33</u>

- (1) The adoption of ASC 606 resulted in additional revenues recognized in the first quarter of 2018. This impact represents the amount of aggregate revenue that would not have been recognized during the quarter ended March 31, 2018 under Previous Guidance.

The impact of adoption on the Company's Condensed Consolidated Statement of Cash Flows for the three months ended March 31, 2018 was as follows (in thousands):

Statement of cash flows	As reported March 31, 2018	Effect of adoption of ASC 606 (1)	Balance without adoption of ASC 606 March 31, 2018
Net loss	\$ 8,714	\$ 68	\$ 8,782
Changes in operating assets and liabilities:			
Other current assets	(71)	(68)	(3)
Net cash used in operating activities	<u>\$ (8,983)</u>	<u>\$ —</u>	<u>\$ (8,983)</u>

- (1) The adoption of ASC 606 resulted in a decrease of net loss and an increase in unbilled revenue that is included in other current assets.

Contract Assets and Liabilities

Changes in our contract assets and liabilities under Topic 606 were as follows (in thousands):

	March 31, 2018	December 31, 2017 (1)
Contract Assets		
Unbilled revenue	\$ 54	\$ —
Contract Liabilities		
Deferred revenue	\$ 4,929	\$ 1,092

- (1) December 31, 2017 balances prior to the impact related to the modified retrospective adoption of ASC 606. During the three months ended March 31, 2018, the Company recorded \$163,000 in research and development revenue that was previously included in deferred revenue at December 31, 2017.

The performance obligations are expected to be fulfilled, and revenue fully recognized through June 30, 2019. The aggregate amount of the contract price of the Company's collaborative agreements, allocated to performance obligations not yet satisfied is \$5.1 million.

Related Party Collaboration Agreement - Takeda Pharmaceuticals, Inc.

Takeda Collaboration Agreement

In October 2016, Private Molecular entered into a collaboration and option agreement (the "Takeda Collaboration Agreement") with Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda, to discover and develop CD38-targeting engineered toxin bodies ("ETBs"), which includes MT-4019 for evaluation by Takeda. Under the terms of the Takeda Collaboration Agreement, Molecular is responsible for providing to Takeda (i) new ETBs generated using Takeda's proprietary fully human antibodies targeting CD38 and (ii) MT-4019 for in vitro and in vivo pharmacological and anti-tumor efficacy evaluations. Molecular granted Takeda (1) a background IP license during the term of the Takeda Collaboration Agreement, and (2) an exclusive option during the term of the Takeda Collaboration Agreement and for a period of thirty days thereafter, to negotiate and obtain an exclusive worldwide license to develop and commercialize any ETB that may result from this collaboration, including MT-4019.

Molecular has received payments of \$2.0 million in technology access fees and cost reimbursement associated with the Company's performance obligations under the agreement.

The Company determined that the promised goods and services under the Takeda Collaboration Agreement were the background IP license, as well as the research and development services. The Company determined that there was one performance obligation, since the background IP and manufacturing were not distinct from the research and development services. 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 that the option does not provide the customer with a material right, and should be accounted for if and when the option is exercised.

During the three months ended March 31, 2018 and 2017, the Company recorded research and development revenue from Takeda of \$11,000 and \$1.3 million, respectively, under the Takeda Collaboration Agreement. This revenue is deemed to be revenue from a related party.

Takeda Multi-Target Agreement

In June 2017, Molecular entered into a Multi-Target Collaboration and License Agreement with Takeda ("Takeda Multi-Target Agreement") in which Molecular will 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 grants to the other nonexclusive rights in its intellectual property for purposes of the conduct of the research, and Molecular agrees 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 Molecular'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. Under the Takeda Multi-Target Agreement, both parties have the right to cancel the agreement, with a specified notice period.

Molecular received an upfront fee of \$1.0 million and was entitled to receive an additional \$2.0 million with the designation of each of the two targets. These two targets were designated in December 2017, and as of March 31, 2018, Molecular had a receivable of \$4.0 million from Takeda. Molecular may also receive an additional \$25.0 million, in aggregate through the exercise of the option to license ETBs. Additionally, Molecular is entitled to receive up to approximately \$547.0 million in additional milestone payments through preclinical and clinical development and commercialization. Molecular is 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, Molecular is 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 may be sooner terminated by Takeda for convenience or upon a Molecular change of control, or by either party for an uncured material breach of the agreement.

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

The Company determined that the promised goods and services under the Takeda Multi-Target Agreement were the background IP license, the research and development services, and 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 obligation; 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 obligation 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 that the option does not provide the customer with a material right, and should be accounted for if and when the option is exercised.

In connection with the execution of the Takeda Multi-Target Agreement. Takeda also entered into a stock purchase agreement with the Company (“Takeda Stock Purchase Agreement”), pursuant to which Takeda purchased approximately \$20.0 million of shares of the Company’s common stock following the reverse-merger in the third quarter of 2017. See Note 10, “Stockholders’ Equity” for further details. Since the Takeda Stock Purchase Agreement was dependent on contingent events, the Company determined that the transaction was constraint, and not a performance obligation under the Takeda Multi-Target Agreement. The Company accounted for the stock purchase agreement in August 2017, once the constraints were removed, and recorded the \$20.0 million in equity upon the settlement of the stock purchase transaction.

During the three months ended March 31, 2018, the Company recorded \$152,000 research and development revenue under the Multi-Target Takeda Agreement. During the three months ended March 31, 2017, the Company recorded no research and development revenue under the Multi-Target Takeda Agreement, since the agreement had not been entered into.

Other Collaboration Agreements

In September 2016, Private Molecular entered into a collaboration agreement with an undisclosed pharmaceutical company (“Other Collaboration Agreement”) to generate ETBs, for evaluation for consideration of \$500,000. Under the terms of the Other Collaboration Agreement, Molecular was responsible for providing to the customer (i) new ETBs generated using the customer’s materials and (ii) ETB study molecules for testing and evaluation.

The customer also received an option under the Other Collaboration Agreement for the manufacture of additional quantities of ETB molecules, for additional consideration of \$250,000, upon delivery and acceptance of the additional materials.

The Company determined that at the inception of the agreement, the promised goods and services under the Other Collaboration Agreement were, the research and development services, and manufacturing. The Company determined that there was one performance obligation, since the manufacturing was not distinct from the research and development services. Revenues are recognized over the period that the research and development services occur using an input method to measure progress towards satisfaction of the performance obligation. The option for additional ETB molecules was determined to be at fair value and was accounted for once the option was exercised.

The option for additional materials was exercised in November 2017, and revenues are recognized over the period that the research and development services occur.

During the three months ended March 31, 2018 and 2017, the Company recorded \$68,000 and \$500,000 in research and development revenue under the Other Collaboration Agreement, respectively.

Grant Agreements

The Company receives funds from a state grant funding program, which is a conditional cost reimbursement grant and revenue is recognized as allowable costs are paid. In November 2011, Private Molecular was awarded a \$10.6 million product development grant from the Cancer Prevention Research Institute of Texas (“CPRIT”) for its CD20-targeting ETB MT-3724. To date, Molecular has received \$9.5 million in grant funds.

The Company recognized \$251,000 and \$125,000 in grant revenue under these awards during the three months ended March 31, 2018 and 2017, respectively. Amounts collected in excess of revenue recognized are recorded as deferred revenue.

NOTE 5 — RELATED PARTY TRANSACTIONS

Takeda Collaboration and Stock Purchase

In connection with the Takeda Stock Purchase Agreement described in Note 4, “Research and Development Agreements”, Takeda became a related party, following the stock purchase. Refer to Note 4, “Research and Development Agreements” for more details about the Takeda Collaboration Agreement and the Takeda Multi-Target Agreement. Refer to Note 10, “Stockholders’ Equity”, for more detail about the Takeda Stock Purchase Agreement.

Concurrent Financing

Following the Concurrent Financing described in Note 10, “Stockholders’ Equity” below, Longitude Venture Partner III, L.P. (“Longitude”) and CDK Associates, L.L.C. (“CDK”) became related parties, with Longitude and CDK beneficially owning 15.3% and 4.99% of the Company, respectively, following investments of \$20.0 million and \$7.0 million, respectively. The ownership of CDK is subject to a 4.99% ownership blocker, pursuant to which shares of the Company’s common stock may not be issued pursuant to the warrant held by CDK to the extent such issuance would cause CDK to beneficially own more than 4.99% of the Company’s outstanding common stock. Scott Morenstein, a director of the Company is a Managing Director of Caxton Alternative Management LP, the investment manager of CDK. David Hirsch, a director of the Company, is a member of Longitude Capital Partners III, LLC, the general partner of Longitude. Furthermore, Kevin Lalande, a director of the Company is affiliated with Sante Health Ventures I, L.P. and Sante Health Ventures Annex Fund, L.P., which are stockholders of the Company and were investors in the Concurrent Financing. Finally, Excel Venture Fund II, L.P., a stockholder of the Company beneficially owning greater than 5% of the Company invested approximately \$333,000 in the Concurrent Financing.

NOTE 6 — MARKETABLE SECURITIES AND FAIR VALUE MEASUREMENTS

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

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

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

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

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

The following table sets forth the Company's financial assets (cash equivalents and marketable securities) at fair value on a recurring basis as of March 31, 2018 and December 31, 2017 (in thousands):

	Fair Value as of March 31, 2018	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	\$ 48,830	\$ 48,830	\$ —	\$ —

	Fair Value as of December 31, 2017	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	\$ 51,751	\$ 51,751	\$ —	\$ —

The Company invests in highly-liquid, investment-grade securities. The following is a summary of the Company's available-for-sale securities at March 31, 2018 and December 31, 2017 (in thousands):

As of March 31, 2018	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	\$ 48,830	\$ —	\$ —	\$ 48,830
Less cash equivalents	(48,830)	—	—	(48,830)
Total marketable securities	\$ —	\$ —	\$ —	\$ —

As of December 31, 2017 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	\$ 51,751	\$ —	\$ —	\$ 51,751
Less cash equivalents	(51,751)	—	—	(51,751)
Total marketable securities	\$ —	\$ —	\$ —	\$ —

There were no realized gains or losses in the three months ended March 31, 2018 and 2017, respectively.

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

	Fair Value as of March 31, 2018	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
2017 Warrants	340	—	—	340

	Fair Value as of December 31, 2017	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
2017 Warrants	954	—	—	954

The Company determined the fair value of the liability associated with its 2017 Warrants to purchase in aggregate 377,273 shares of outstanding common stock using a Black-Scholes Model. See detailed discussion in Note 10, "Stockholders' Equity".

As of March 31, 2018 and December 31, 2017, the fair value of the long-term debt, payable in installments through year ended 2022 and 2019, respectively, approximated its carrying value of \$3.0 million and \$3.5 million because it is carried at a market observable interest rate, which are considered Level 2.

NOTE 7 — BALANCE SHEET COMPONENTS

Accrued liabilities were comprised of the following (in thousands):

	March 31, 2018	December 31, 2017
Accrued liabilities:		
General and administrative	\$ 670	\$ 374
Clinical costs	734	702
Non-clinical research	868	435
Payroll related	491	1,149
Other accrued expenses	37	30
Total accrued liabilities	<u>\$ 2,800</u>	<u>\$ 2,690</u>

Deferred revenue was comprised of the following:

	March 31, 2018	December 31, 2017
Deferred revenue:		
Grant agreements	\$ 1,421	\$ 1,673
Research and development agreements	4,929	1,092
Total deferred revenue	<u>\$ 6,350</u>	<u>\$ 2,765</u>

NOTE 8 — BORROWING ARRANGEMENTS***SVB Growth Capital Loan***

In April 2014, the Company entered into a loan and security agreement with Silicon Valley Bank (“SVB”) that was subsequently amended, to provide for (1) growth capital advances to the Company of up to \$6.0 million over three tranches based on corporate milestones (2) term loans of up to \$6.0 million in the aggregate (the “Growth Capital Loan”); (3) warrants to purchase 48,874 shares of the Company’s common stock at an exercise price of \$3.07 per share under the amended loan and security agreement; and (4) a final fee of \$375,000 due at the loan maturity date in addition to the principal and interest payments.

The Company drew down \$0.8 million and \$2.3 million in May and June 2015 and issued warrants to purchase 14,254 and 17,310 shares of the Company’s common stock at an exercise price of \$3.07 per share under the second and amended loan and security agreement. The Company drew down \$3.0 million in April 2016 and issued warrants to purchase 17,310 shares of the Company’s common stock at an exercise price of \$3.07 per share under the second term loan. The warrants issued in the Loan Agreement became exercisable upon issuance and were converted into common stock upon the closing of the Merger.

As of December 31, 2017, the Company had received \$6 million in the aggregate from the Growth Capital Loan. The Company was required to repay the outstanding principal in 30 equal installments beginning November 1, 2016 and was due in full on April 30, 2019. Interest accrued at a rate of 1.19% above prime, or 5.44% per annum as of December 31, 2017. Interest only payments were made monthly and beginning November 1, 2016, the Company paid the first of thirty consecutive equal monthly payments of principal plus interest.

The Company paid down the Growth Capital Loan on February 27, 2018, from the proceeds of the Perceptive Credit Facility, discussed below. Until the termination of the Growth Capital Loan on February 27, 2018, the Company paid \$3.2 million in principal, \$375,000 in a final fee, and \$42,000 in interest during the three months ended March 31, 2018 and \$0.6 million in principal and \$66,000 in interest in the three months ended March 31, 2017.

As of March 31, 2018 and December 31, 2017 the Growth Capital Loan principal balance was zero and \$3.5 million, respectively. As of December 31, 2017, the Company was in compliance with the non-financial covenants of the Growth Capital Loan.

Perceptive Credit Facility

On February 27, 2018, the Company entered into a term loan facility with Perceptive Credit Holdings II, LP (“Perceptive”) in the amount of \$10.0 million (the “Perceptive Credit Facility”). The Perceptive Credit Facility consists of a \$5.0 million term loan, which was drawn on the effective date of the Perceptive Credit Facility and an additional \$5.0 million term loan to be drawn six

months following the effective date of the Perceptive Credit Facility. The Company used a portion of the proceeds from the Perceptive Credit Facility to pay off the existing debt facility with SVB. Borrowings under the Perceptive Credit Facility are secured by all of the property and assets of the Company. 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, 2018 was 12.96%. Payments for the first twenty-four months are interest only and are paid quarterly. After the second anniversary of the closing date of the Perceptive Credit Facility, principal payments of \$200,000 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.

For the three months ended March 31, 2018, the Company recorded \$59,000 of interest expense and \$54,000 of amortization of debt discount in interest expense, related to the Perceptive Credit Facility. For the three months ended March 31, 2017, the Company did not incur any interest expense related to the Perceptive Credit Facility, since the facility was not in place at that time.

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 will be exercisable for a period of seven years from the date of issuance at an exercise price of \$9.5792, subject to certain adjustments as specified in the Warrant. See Note 10, "Stockholders' Equity" for further discussion of the warrant.

As of March 31, 2018 and December 31, 2017 the Perceptive Credit Facility principal balance was \$5.0 million and zero, respectively. As of March 31, 2018, the Company was in compliance with the non-financial covenants of the Perceptive Credit Facility.

Future required principal and final payments on the Perceptive Credit Facility were as follows as of March 31, 2018:

2018 (remaining)	\$	—
2019		—
2020		800
2021		800
2022		<u>3,500</u>
Total debt		5,100
Debt discount and deferred finance costs		<u>(2,101)</u>
Total debt, net	\$	<u><u>2,999</u></u>

NOTE 9 — COMMITMENTS AND CONTINGENCIES

The Company is obligated under operating lease agreements covering the Company's office facilities in Austin, Texas and Jersey City, New Jersey, respectively. Facilities expense under the operating leases was approximately \$340,000 and \$77,000 three months ended March 31, 2018 and 2017, respectively.

Future minimum payments due under the operating lease agreements at March 31, 2018 were as follows (in thousands):

2018 (remaining)	\$	832
2019		1,135
2020		1,048
2021		1,074
2022		1,096
Thereafter		486
Total	\$	<u><u>5,671</u></u>

The Company leases laboratory equipment under non-cancelable capital lease agreements. As of March 31, 2018 and December 31, 2017, laboratory equipment under capital leases included in property and equipment totaled approximately \$237,000 and \$162,000, respectively, net of accumulated amortization of approximately \$83,000 and \$75,000, respectively. Future minimum capital lease payments consisted of the following at March 31, 2018 (in thousands):

2018 (remaining)	\$	41
2019		33
2020		19
Total future minimum capital lease payments		93
Less: amount representing interest		(7)
Total capital lease obligations		86
Current portion of lease obligations		(45)
Capital lease obligations, non-current portion	\$	41

Contingencies

In the ordinary course of business, the Company may provide indemnifications of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters, including, but not limited to, losses arising out of the Company's breach of such agreements, services to be provided by or on behalf of the Company, or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with its directors and certain of its officers and employees that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors, officers or employees. The Company maintains director and officer insurance, which may cover certain liabilities arising from its obligation to indemnify its directors and certain of its officers and employees, and former officers and directors in certain circumstances. The Company maintains product liability insurance and comprehensive general liability insurance, which may cover certain liabilities arising from its indemnification obligations. It is not possible to determine the maximum potential amount of exposure under these indemnification obligations due to the limited history of prior indemnification claims and the unique facts and circumstances involved in each particular indemnification obligation. Such indemnification obligations may not be subject to maximum loss clauses. Management is not currently aware of any matters that could have a material adverse effect on the financial position, results of operations or cash flows of the Company.

NOTE 10 — STOCKHOLDERS' EQUITY

Concurrent Financing

On August 1, 2017, the Company entered into the a securities purchase agreement with Longitude Venture Partners III, L.P. and certain other accredited investors (the Longitude Securities Purchase Agreement"), pursuant to which the Company sold an aggregate of 5,793,063 units (the "Units") accredited investors having an aggregate purchase price of \$40.0 million, each such Unit consisting of (i) one (1) share (the "Shares") of our common stock and (ii) a warrant (the "Private Placement Warrants") to purchase 0.5 shares of our common stock (the "Private Placement"). The Private Placement was pursuant to equity commitment letter agreements entered into by and between the Company and investors in March and June 2017. The purchase price per Unit was \$6.9048. The Warrants will be exercisable for a period of seven years from the date of their issuance at a per-share exercise price of \$6.8423 (which exercise price shall be payable in cash or through a cashless exercise mechanic), subject to certain adjustments as specified in the Warrants. At March 31, 2018, there were warrants outstanding under the Longitude Securities Purchase Agreement to purchase 2,896,532 shares of common stock. The warrants met the requirements for equity classification under ASC 815, "Derivatives and Hedging" (ASC 815), and the value of these warrants is included in additional paid-in capital on the balance sheet. The Private Placement Warrants are exercisable upon issuance and expire August 1, 2024. The Company will continue to evaluate equity classification on a quarterly basis.

In December 2015, the Company entered into an agreement (the "Wedbush Agreement") with Wedbush Securities Inc., which was subsequently amended in December of 2017, related to their services associated with the equity financing under the Longitude Securities Purchase Agreement. As part of the Wedbush Agreement, the Company issued to Wedbush Securities, Inc, warrants to purchase 57,930 shares of our common stock (the "Wedbush Warrants"). The Wedbush Warrants will be exercisable for a period of seven years from the date of their issuance at a per-share exercise price of \$6.8423 (which exercise price shall be payable in cash or through a cashless exercise mechanic), subject to certain adjustments as specified in the Wedbush Warrants. At March 31, 2018, there were warrants outstanding under the Wedbush Agreement to purchase 57,930 shares of common stock. The warrants met the requirements for equity classification under ASC 815, and the value of these warrants is included in additional paid-in capital on the balance sheet. The Wedbush Warrants are exercisable upon issuance and expire December 1, 2024. The Company will continue to evaluate equity classification on a quarterly basis.

The total warrants outstanding under this amended agreement are 2,954,462 and are listed in the summary table below under “2017 Private Placement Warrants”.

Subsequent Financing

In connection with the execution of the Takeda Multi-Target Agreement, Threshold and Private Molecular entered into the Takeda Stock Purchase Agreement. Pursuant to the Takeda Stock Purchase Agreement, following the consummation of the Merger and Private Placement, Takeda purchased 2,922,993 shares of the Company’s common stock, at a price per share of \$6.84, for an aggregate purchase price of \$20 million.

Common Stock Warrants

As of March 31, 2018, the Company had warrants outstanding to purchase 3.5 million shares of the Company’s stock. The Company accounts for certain of its common stock warrants under guidance in ASC 480 that clarifies the determination of whether an instrument is classified as a liability or equity. The following table summarizes the Company’s outstanding warrants as of March 31, 2018 and December 31, 2017 and the warrant activity during the three months ended March 31, 2018:

	Warrants Outstanding			Warrants Outstanding	
	December 31, 2017	Issued	Exercised	March 31, 2018	Weighted Average Exercise Price
2017 Warrants	377,273	—	—	377,273	\$ 39.82
2017 Private Placement Warrants	2,954,462	—	—	2,954,462	\$ 6.84
2018 Warrants	—	190,000	—	190,000	\$ 9.58
	<u>3,331,735</u>	<u>190,000</u>	<u>—</u>	<u>3,521,735</u>	

On August 1, 2017, as part of the Merger, the Company assumed the warrant liability of the predecessor Threshold, related to issued warrants to purchase 377,273 shares of our common stock (“2017 Warrants”), with an exercise price of \$39.82 per share. Refer to Note 3, “Merger with Private Molecular”, for further detail about the Merger.

Due to change in control provisions outside of the Company’s control in the 2017 Warrants, the guidance requires the Company’s outstanding warrants to be classified as liabilities and to be fair valued at each reporting period, with the changes in fair value recognized as change in fair value of warrant liabilities in the Company’s consolidated statements of operations and comprehensive loss.

The following table is a reconciliation of the 2017 Warrant liability measured at fair value using level 3 inputs (in thousands):

	Warrant Liability
Balance at December 31, 2017	\$ 954
Change in fair value during the three months ended March 31, 2018	(614)
Balance at March 31, 2018	<u>\$ 340</u>

The fair value of the 2017 Warrants on March 31, 2018 and December 31, 2017 was determined using a Black-Scholes model with the following key level 3 inputs:

	March 31, 2018	December 31, 2017
Risk-free interest rate	2.27 %	1.89 %
Expected life (in years)	1.89	2.13
Dividend yield	—	—
Volatility	89 %	103 %
Stock price	\$ 8.00	\$ 10.02

During the three months ended March 31, 2018 the change in fair value of \$614,000 of noncash income related to the 2017 Warrants was recorded as change in fair value of warrant liabilities in the Company’s consolidated statement of operations and comprehensive loss. Significant changes in the level 3 inputs of volatility, stock price and expected life, used in the fair value measurement of the 2017 Warrants in isolation could result in a material change in the fair value measurement.

On August 1, 2017, in conjunction with the Private Placement, the Company issued warrants to purchase 2,896,532 shares of the Company's common stock with an exercise price of \$6.84, the Private Placement Warrants as described above. The Private Placement warrants are classified as equity and were valued at \$16.3 million using the Black-Scholes model, and recorded in additional paid-in capital. The Black-Scholes inputs used were: expected dividend rate of 0%, expected volatility of 147%, risk free interest rate of 2.07%, and expected term of 7.0 years.

In December 2017 the Company issued warrants to purchase 57,930 shares of the Company's common stock with an exercise price of \$6.84, the Wedbush Warrants as described above. The Wedbush Warrants are classified as equity and recorded in additional paid-in capital; and were valued at \$0.4 million using the Black-Scholes model. The Black-Scholes inputs used were: expected dividend rate of 0%, expected volatility of 108%, risk free interest rate of 2.33%, and expected term of 7.0 years. The Wedbush Warrants together with the Private Placement Warrants are combined as "2017 Private Placement Warrants" in the table above.

On February 28, 2018, in connection with the Perceptive Credit Facility, the Company issued warrants to purchase 190,000 shares of the Company's common stock with an exercise price of \$9.58, the 2018 Warrants in the table above. The 2018 Warrants are exercisable for a period of seven years from the date of issuance, subject to certain adjustments as specified in the Warrants. The 2018 Warrants were classified as equity and recorded in additional paid-in capital; and were valued at \$1.5 million using the Black-Scholes model. The Black-Scholes inputs used were: expected dividend rate of 0%, expected volatility of 105%, risk free interest rate of 2.83%, and expected term of 7.0 years. See Note 8, "Borrowing Arrangements", for further detail about the Perceptive Credit Facility.

NOTE 11 — STOCK BASED COMPENSATION

The Company recognizes stock-based compensation in accordance with ASC 718, "Compensation—Stock Compensation." Stock-based compensation expense, which consists of the compensation cost for employee stock options granted under the 2009 Stock Plan, as amended (the "2009 Stock Plan") and under the Company's 2014 Equity Incentive Plan, as amended (the "2014 Equity Incentive Plan") and the value of options issued to non-employees for services rendered, was allocated to research and development and general and administrative expenses in the unaudited consolidated statements of operations. Stock-based compensation for the three months ended March 31, 2018 and 2017 were (in thousands):

	Three Months Ended March 31,	
	2018	2017
Research and development	\$ 180	\$ —
General and administrative	463	26
Total stock-based compensation	\$ 643	\$ 26

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 for the three months ended March 31, 2018 and 2017:

	Three Months Ended March 31,	
	2018	2017
Employee Stock Options:		
Risk-free interest rate	2.68 %	1.95 %
Expected term (in years)	6.02	5.00
Dividend yield	—	—
Volatility	108 %	76 %
Weighted-average fair value of stock options granted	\$ 8.85	\$ 0.82

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

Employee Stock-based Compensation Expense

As required by ASC 718, the Company recognized \$643,000 and \$26,000 of stock-based compensation expense related to stock options under the Company's equity incentive plans for the three months ended March 31, 2018 and 2017, respectively.

As of March 31, 2018, the total unrecognized compensation cost related to unvested stock-based awards granted to employees under the Company's equity incentive plans was approximately \$9.2 million. This cost will be recorded as compensation expense on a ratable basis over the remaining weighted average requisite service period of approximately 3.4 years.

Equity Incentive Plans

The Company's equity incentive plans include the 2009 Stock Plan and the 2014 Equity Incentive Plan. The Company does not intend to issue any shares under the 2009 Stock Plan.

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

Options	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value (in millions)
Outstanding at December 31, 2017	2,768,711	\$ 12.07	5.6	\$ 11.0
Granted	297,750	\$ 10.69	—	—
Exercised	(161,705)	\$ 0.91	—	—
Forfeitures	(24,995)	\$ 31.47	—	—
Outstanding at March 31, 2018	<u>2,879,761</u>	\$ 12.38	6.2	\$ 7.7
Exercisable at March 31, 2018	<u>1,470,533</u>	\$ 15.89	2.9	\$ 6.6

The total intrinsic value of stock options exercised during the three months ended March 31, 2018, was \$1.6 million, as determined at the date of the option exercise. Cash received from stock option exercises was \$148,000 for the three months ended March 31, 2018. No stock options were exercised during the three months ended March 31, 2017. 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.

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, 2017.

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 Item 1A of the Annual Report.

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

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

Overview

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

Recent Developments

On February 27, 2018, we entered into a term loan facility with Perceptive Credit Holdings II, LP ("Perceptive") in the amount of \$10.0 million (the "Perceptive Credit Facility"). The Perceptive Credit Facility consists of a \$5.0 million term loan, which was drawn on the effective date of the Perceptive Credit Facility and an additional \$5.0 million term loan to be drawn six months following the effective date of the Perceptive Credit Facility. We used a portion of the proceeds from the Perceptive Credit Facility to pay off the existing debt facility with Silicon Valley Bank. Borrowings under the Perceptive Credit Facility are secured by all of our property and assets. 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, 2018 was 12.96%. Payments for the first twenty-four months are interest only and are paid quarterly. After the second anniversary of the closing date of the Perceptive Credit Facility, principal payments of \$200,000 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. We were in compliance with financials and non-financial covenants at March 31, 2018. We are 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. For the three months ended March 31, 2018, we recorded \$59,000 of interest expense and \$54,000 of amortization of debt discount in interest expense, related to the Perceptive Credit Facility. For the three months ended March 31, 2017, the Company did not incur any interest expense related to the Perceptive Credit Facility, since the facility was not in place at that time.

In connection with the Perceptive Credit Facility, on February 27, 2018 we issued Perceptive a warrant to purchase 190,000 shares of our common stock (the “Perceptive Warrant”). The Perceptive Warrant will be exercisable for a period of seven years from the date of issuance at an exercise price of \$9.5792, subject to certain adjustments as specified in the warrant. Refer to Note 8, “Borrowing Arrangement” to the consolidated financial statement in this document for further details on the Credit Facility.

Business

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

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

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

Our initial approach to drug development in oncology involves the selection of lead compounds to validated targets in cancer. We have developed ETBs for various targets, including CD20, CD38, HER2, and PD-L1. CD20 is central to B cell malignancies and is clinically validated as a target for the treatment of lymphomas and autoimmune disease. CD38 has been validated as a meaningful clinical target in the treatment of multiple myeloma. PD-L1 is central to immune checkpoint pathways and is a target expressed in a variety of solid tumor cancers. Our lead compound, MT-3724, is an ETB that recognizes CD20, a B cell marker and is currently in phase I study. The dose escalation portion of its first Phase I clinical trial has been completed for MT-3724 and was followed by the initiation of a Phase Ib expansion cohort, which was initiated in the quarter ended December 31, 2017. We anticipate initiating combination studies with MT-3724 and advancing one or more additional ETBs into clinical trials in 2018. We anticipate filing IND applications for MT-4019 in the third quarter of 2018, for our HER2 ETB in the fourth quarter of 2018, and for our PD-L1 ETB in the first quarter of 2019.

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

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

We are a clinical-stage company and have not generated revenue from product sales. Our ability to generate revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our ETB candidates. Since inception, we have incurred significant operating losses. For the three months ended March 31, 2018 and 2017, we incurred net losses of \$8.7 million and \$1.2 million, respectively. As of March 31, 2018, we had an accumulated deficit of \$73.1 million.

We expect to incur significant expenses and operating losses for the foreseeable future as we advance our lead ETB candidates through clinical trials, progress our pipeline ETB candidates from discovery through pre-clinical development, and seek regulatory approval and pursue commercialization of our ETB candidates. In addition, if we obtain regulatory approval for any of our ETB

candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In addition, we may incur expenses in connection with the in-license or acquisition of additional technology to augment or enable development of future ETB candidates. Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

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

We expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into late 2019.

Collaboration Agreements

Takeda Pharmaceuticals

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 may result from this collaboration, including MT-4019. We are 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 agreement. As of March 31, 2018, we have received \$2.0 million under the Takeda Collaboration Agreement.

In June 2017, we entered into a multi-target collaboration and license agreement with Takeda (the “Takeda Multi-Target Agreement”), pursuant to which we will collaborate with Takeda to identify, generate and evaluate ETBs, against certain targets designated by Takeda. Takeda will designate certain targets of interest as the focus of the research. Takeda will provide to us targeting moieties against the designated targets. We will create and characterize ETBs against those targets and provide them to Takeda for further evaluation. Each party grants to the other nonexclusive rights in its intellectual property for purposes of the conduct of the research, and we agree to work exclusively with Takeda with respect to the designated targets. We are entitled to receive up to \$5.0 million in technology access fees and research and development fees associated with our performance and completion of our obligations under the agreement. As of March 31, 2018, we have received \$1.0 million under the Takeda Multi-Target Agreement.

In December 2017, Takeda nominated both targets under the Takeda Multi-Target Agreement. We received \$4.0 million, in the aggregate, in April 2018, following the approval of the project plans for these two targets under the Takeda Multi-Target Agreement.

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

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

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

Financial Operations Overview

Revenue

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

Grant revenue relates to our Cancer Prevention Research Institute of Texas, or CPRIT grant for MT-3724. CPRIT grant funds are provided to us in advance as conditional cost reimbursement where revenue is recognized as allowable costs are paid. Amounts collected in excess of revenue recognized are recorded as deferred revenue. For the three months ended March 31, 2018 and 2017, we recognized \$251,000 and \$125,000 in CPRIT grant revenues related to the pre-clinical and clinical development of MT-3724.

Research and Development revenue primarily relates to our collaboration with Takeda. We have an ongoing research collaboration with Takeda Pharmaceuticals related to the evaluation of our ETB technology that was initiated in the fourth quarter 2016. The Takeda Collaboration Agreement and Takeda Multi-Target Agreement provide for upfront technology access fees, milestone payments and reimbursement payments. Under ASC 606, *Revenue from Contracts with Customers*, we recognize revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of ASC 606, we perform the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer. Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in our balance sheet. For the three months ended March 31, 2018, we recognized \$231,000 in research and development revenue related to research collaboration agreements. For the three months ended March 31, 2017, we recognized \$1.8 million in research and development revenue related to research collaboration agreements.

We have no products approved for sale. Other than the sources of revenue described above, we do not expect to receive any revenue from any ETB candidates that we develop, including MT-3724, MT-4019 and other pre-clinical ETB candidates, until we obtain regulatory approval and commercialize such products, or until we potentially enter into collaborative agreements with third parties for the development and commercialization of such candidates.

Research and Development Expenses

Research and development expenses consist principally of:

- salaries for research and development staff and related expenses, including stock-based compensation expenses;
- costs for current good manufacturing practices, or cGMP, manufacturing of drug substances and drug products by contract manufacturers;
- fees and other costs paid to clinical trials sites and clinical research organizations, or 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.

For the three months ended March 31, 2018 and 2017, we incurred research and development costs of \$6.7 million and \$1.1 million, respectively. Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including the initiation and enrollment of patients in clinical trials and manufacture of drug materials for clinical trials.

We expect research and development expenses to increase as we advance the clinical development of MT-3724 and further advance the research and development of our pre-clinical ETB candidates, including MT-4019, and other earlier stage products. The successful development of our ETB candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our ETB candidates. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- clinical trials and early-stage results;
- the terms and timing of regulatory approvals; and
- the ability to market, commercialize and achieve market acceptance for MT-3724, MT-4019 or any other ETB candidate that we may develop in the future.

Any of these variables with respect to the development of MT-3724, MT-4019 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, MT-4019 or such other ETB candidates. For example, if the U.S. Food and Drug Administration (“FDA”), the European Medical Association (“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 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

The table below summarizes our results of operations for the three months ended March 31, 2018 and 2017 (in thousands).

	Three Months Ended March 31,	
	2018	2017
Research and development revenue	\$ 231	\$ 1,760
Grant revenue	251	125
Total revenue	482	1,885
Research and development expenses	6,687	1,067
General and administrative expenses	2,910	1,791
Total operating expenses	9,597	2,858
Loss from operations	9,115	973
Interest and other income, net	82	—
Interest expense	(295)	(223)
Change in fair value of warrant liabilities	614	1
Net loss	\$ 8,714	\$ 1,195

Grant Revenue

Grant revenue increased \$126,000 during the three months ended March 31, 2018 compared to three months ended March 31, 2017. The increase was primarily attributable to the CPRIT phase II program expenses increasing during the first quarter of 2018, and minimal activity in the first quarter of 2017 due to Phase I having been completed.

Research and Development Revenue

Research and development revenue decreased \$1.5 million during the three months ended March 31, 2018 compared to the three months ended March 31, 2017.

Research and development revenues for the three months ended March 31, 2018 were comprised of research and development revenues from our collaboration with Takeda of \$163,000, and research and development revenues from our collaboration with an undisclosed pharmaceutical company of \$68,000.

Research and development revenues for the three months ended March 31, 2017 were comprised of research and development revenues from our collaboration with Takeda of \$1.3 million, and research and development revenues from our collaboration with an undisclosed pharmaceutical company of \$0.5 million.

For more information about our collaboration agreements, please see Note 4, "Research and Development Agreements" to our unaudited condensed financial statements for the three months ended March 31, 2018, included in this Quarterly Report on form 10-Q.

Research and Development Expenses

The table below summarizes our research and development expenses for the three months ended March 31, 2018 and 2017 (in thousands).

Research and development expenses by cost type:	Three Months Ended March 31,	
	2018	2017
Employee compensation	\$ 1,694	\$ 382
Program costs	3,771	565
Laboratory costs	375	107
Other research and development costs	847	13
Total research and development expenses	\$ 6,687	\$ 1,067

Research and development costs increased \$5.6 million during the three months ended March 31, 2018 as compared to the three months ended three months ended March 31, 2017. The increase was primarily due to costs related to increased outsourced program costs, along with increased payroll related costs due to increased headcount.

From a program perspective, all of our research and development expenses relate primarily to the discovery and development of ETBs. The increase in outsourced program costs in the first quarter of 2018 compared to the same period in 2017 is primarily due to a \$1.7 million increase in costs related to CD-38; a \$0.6 million increase in costs related to MT-3724; and a \$0.4 million increase in costs related to HER2.

The risks and uncertainties associated with our research and development projects are discussed more fully in the “Risk Factors” section in Part II, Item 1A of this Quarterly Report on Form 10-Q. As a result of the risks and uncertainties discussed in the “Risk Factors” section and above, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, anticipated completion dates or when and to what extent we will receive cash inflows from the commercialization and sale of a product candidate. To date, we have not commercialized any of our product candidates and in fact may never do so.

General and Administrative

General and administrative expenses increased \$1.1 million during the three months ended March 31, 2018 compared to the three months ended March 31, 2017, primarily due to increased costs associated with being a publicly traded company, along with increased payroll related costs due to increased headcount.

Interest Expense

Interest expense increased \$72,000 during the three months ended March 31, 2018 as compared to the three months ended March 31, 2017, primarily due to the write off of the remaining debt discount in the SVB Growth Capital Loan, as well as the increase in interest expense under the Perceptive Credit Facility.

Change in fair value of warrant liability

The change in fair value of warrant liability relate to the revised fair value of the 2016 warrants categorized as liabilities.

Liquidity and Capital Resources

Sources of Funds

We have devoted substantially all of our resources to developing our ETB candidates and platform technology, building our intellectual property portfolio, developing our supply chain, conducting business planning, raising capital and providing for general and administrative support for these operations. We plan to increase our research and development expenses for the foreseeable future as we continue to advance MT-3724, MT-4019 and our earlier-stage pre-clinical programs. At this time, due to the inherently unpredictable nature of preclinical and clinical development and given the early stage of our programs and product candidates, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval and commercialize our products, if and when approved. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. In addition, we cannot forecast which products, if and when approved, may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We have incurred an accumulated deficit of \$73.1 million through March 31, 2018. We expect to incur substantial additional losses in the future as we expand our research and development activities. Based on our current research and development plans, we expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into late 2019.

Our financial statements as of March 31, 2018 have been prepared under the assumption that we will continue as a going concern for the next 12 months. To date, we have financed our operations through private placements of equity securities, a reverse merger, and upfront and milestone payments received from our collaborators under our research evaluation agreements, as well as funding from governmental bodies and bank and bridge loans. Since 2009, we raised gross proceeds of \$78.2 million from private placements of equity securities, including \$40 million from the Private Placement in August 2017, \$20 million from the Takeda Financing in August 2017. Since 2009, we have also received aggregate gross proceeds of \$3.5 million from our collaborators, received \$10.0 million in proceeds from related-party convertible promissory notes, received \$6.0 million in proceeds from bank loan from Silicon Valley Bank (“SVB”); and assumed \$15.2 million of cash balances of Threshold upon the closing of the Merger.

On February 27, 2018, we entered into the Perceptive Credit Facility, which allows for aggregate borrowings of up to \$10.0 million, subject to our achievement of certain milestones. We drew down an aggregate of \$5.0 million under the Perceptive Credit Facility through March 31, 2018. Payments for the first twenty-four months are interest only and are paid quarterly, commencing April 2018. After the second anniversary of the closing date of the Perceptive Credit Facility, principal payments of

\$200,000 are due each calendar quarter, with a final payment of \$3.4 million due on February 27, 2022. The loan matures on February 27, 2022 and is secured by substantially all our assets.

In November 2016, we received notice that we have been awarded a second CPRIT product development grant totaling \$15.2 million to fund development of our CD38-targeting ETB MT-4019, and we are currently in the process of negotiating the terms of the contract with CPRIT.

In April 2014, we entered into a loan and security agreement with SVB that was subsequently amended in April 2015 (the "Growth Capital Loan"), and we borrowed an aggregate of \$6.0 million under the Growth Capital Loan through March 31, 2018. We used the proceeds from the Perceptive Credit Facility to pay off the Growth Capital Loan on February 27, 2018. We paid \$3.2 million in principal, \$375,000 in a final fee, and \$42,000 in interest during the three months ended March 31, 2018.

As of March 31, 2018, we had cash and cash equivalents of \$49.3 million. As of December 31, 2017, we had cash and cash equivalents of \$58.9 million.

Cash Flows

(in thousands)	Three Months Ended March 31,	
	2018	2017
Net cash used in operating activities	\$ (8,983)	\$ (2,654)
Net cash used in investing activities	(1,719)	(196)
Net cash provided by financing activities	1,067	4,074
Net increase (decrease) in cash and cash equivalents	\$ (9,635)	\$ 1,224

The increase in net cash used in operating activities to \$9.0 million for the three months ended March 31, 2018 from \$2.7 million for the three months ended March 31, 2017 was primarily due to an increase in operating cash disbursements as result of an increase in operating activities.

The increase in net cash used in investing activities to \$1.7 million for the three months ended March 31, 2018 from \$196,000 for the three months ended March 31, 2017 was primarily due to increased leasehold improvements and increased purchases of equipment related to our GMP manufacturing facility build-out in our Austin, Texas facility.

The decrease in net cash provided by financing activities to \$1.1 million for the three months ended March 31, 2018 from \$4.1 million for the three months ended March 31, 2017 was primarily due to the proceeds from issuance in related party debt of \$2.6 million in 2017 and the proceeds from promissory note of \$2.0 million in 2017, that did not reoccur this year.

Operating and Capital Expenditure Requirements

Other than for one year, we have not achieved profitability since our inception and had an accumulated deficit of \$73.1 million as of March 31, 2018. 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, MT-4019, 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:

- complete the ongoing Phase I expansion clinical trial of MT-3724, our lead ETB candidate;
- support the ongoing Phase Ib and initiate Phase II clinical trials of MT-3724;
- conduct the Phase I clinical trial of MT-4019, our second ETB candidate;
- continue the research and development of our other ETB candidates, including completing pre-clinical studies and commencing clinical trials;
- seek to enhance our technology platform using our antigen-seeding technology approach to immuno-oncology;
- seek regulatory approvals for any ETB candidates that successfully complete clinical trials;
- complete the build-out of our in-house GMP manufacturing facility;

- potentially establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our increased operations; and
- 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.

We expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into late 2019. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with the development of MT-3724, MT-4019 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-4019 or our other pre-clinical programs will depend on many factors, including:

- the progress, timing and completion of pre-clinical testing and clinical trials for our current or any future ETB candidates;
- the number of potential new ETB candidates we identify and decide to develop;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or any future ETB candidates;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties;
- the time and costs involved in obtaining regulatory approval for our ETB candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these ETB candidates;
- any licensing or milestone fees we might have to pay during future development of our current or any future ETB candidates;
- selling and marketing activities undertaken in connection with the anticipated commercialization of our current or any future ETB candidates and costs involved in the creation of an effective sales and marketing organization; and
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our ETB candidates, if approved.

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

Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as stockholders. Additional debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute stockholders' ownership interest.

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

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses based on historical experience and on various assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. For further information on our critical accounting policies, see the discussion of critical accounting policies in our Annual Report on Form 10-K for the year ended December 31, 2017, which we filed with the SEC on March 30, 2018.

Recent Accounting Pronouncements Not Yet Adopted

For a discussion of recently issued accounting pronouncements and interpretations not yet adopted by us, please see Note 1, “Organization and Summary of Significant Accounting Policies” to our unaudited condensed financial statements for the three months ended March 31, 2018, included in this Quarterly Report on Form 10-Q.

Contractual Commitments and Obligations

As of March 31, 2018, we had no material commitments other than the liabilities reflected and commitments disclosed in our condensed consolidated financial statements.

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

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

Credit Risk

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

Liquidity Risk

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

Market Risk

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2018. 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 as of March 31, 2018, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level.

Material Weakness and Remediation of Material Weakness

The management of the company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. As previously disclosed in the Form S-4/A Registration Statement (File No. 333-217993) relating to the Merger, in connection with the audits of Private Molecular’s consolidated financial statements for the years ended December 31, 2015 and 2016 and preparation of interim financial statements for the first quarter of 2017, Private Molecular and its independent registered public accounting firm identified a material weakness in Private Molecular’s internal control over financial reporting. This material weakness continues to be in place as of March 31, 2018. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity’s financial statements will not be prevented or detected and corrected on a timely basis.

Prior to the completion of the Merger, Private Molecular was a private company and had limited accounting and financial reporting personnel and other resources with which to address its internal controls and procedures. Private Molecular’s lack of adequate accounting personnel resulted in the identification of a material weakness in its internal control over financial reporting, which has continued through March 31, 2018. Specifically, Private Molecular did not timely and appropriately account for and disclose the impact of complex, non-routine transactions in accordance with U.S. GAAP.

We have begun our remediation plan and have hired and intend to hire additional accounting and finance personnel. For example, in November 2017, we hired a new Chief Financial Officer and a Senior Vice President, Finance and Corporate Controller, each with extensive accounting and public company experience. Additionally, we are in the process of implementation of more robust review, supervision and monitoring of the non-routine transactions and the financial reporting process intended to remediate the identified material weakness.

Changes in internal controls over financial reporting.

Other than as described above, 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 three months ended March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. If any of the possible adverse events described below actually occurs, we may be unable to conduct our business as currently planned and our financial condition and operating results could be harmed. 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 Ownership of our Common Stock

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

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

- our ability to obtain regulatory approvals for MT-3724 or other product candidates, and delays or failures to obtain such approvals;
- failure of any of our product candidates, if approved, to achieve commercial success;
- failure to maintain our existing third-party license and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue any adverse or misleading opinions regarding our business and 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;
- trading volume of our common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to ETB therapeutics generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with our potential products;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in our financial results.

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

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

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. As of May 10, 2018, we had outstanding a total of approximately 27,060,603 shares of common stock.

Future sales of shares by existing stockholders could cause our stock price to decline.

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. The perception in the market that these sales may occur could also cause the trading price of our common stock to decline. As of May 10, 2018, we had outstanding a total of approximately 27,060,603 shares of common stock.

Our certificate of incorporation, 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 certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your 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 the issuance of "blank check" preferred stock without any need for action by stockholders;
- providing for a classified board of directors with staggered terms;
- requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;
- eliminating the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

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

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

- We will indemnify our directors and officers for serving us in those capacities or for serving other 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 costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We incur significant legal, accounting and other expenses that Private Molecular did not incur as a private company, including costs associated with public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as new implemented by the SEC and Nasdaq. These rules and regulations are expected to increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, our management team includes certain executive officers of Private Molecular prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These rules and regulations also may make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers, which may adversely affect investor confidence in us and could cause our business or stock price to suffer.

Our 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 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 certificate of incorporation or our 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 the bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

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

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

Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval.

As of March 31, 2018, our principal stockholders beneficially own, in the aggregate, approximately 64% of our outstanding shares of common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence 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 control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. Within this group, Santé Health Ventures I, L.P. and its affiliates own approximately 32% of our shares, and Longitude Venture Partners III, L.P. and its affiliates and Millennium Pharmaceuticals, Inc. own approximately 15% and 10%, respectively. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

We have broad discretion in the use of our cash reserves and may not use them effectively.

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

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

Under Section 12b-2 of the Exchange Act, a "smaller reporting company" is a company that is not an investment company, an asset backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company, and has a public float of less than \$75 million and annual revenues of less than \$50 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. Being a smaller reporting company, we are permitted to avail ourselves of the scaled disclosure requirements available to smaller reporting companies in this Annual Report on Form 10-K. 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 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 \$8.7 million for three months ended March 31, 2018. As of March 31, 2018, we had an accumulated deficit of \$73.1 million.

As of March 31, 2018, we had cash and cash equivalents of \$49.3 million. In August 2017, we raised approximately \$60 million through private placements of our common stock and warrants to purchase our common stock. We will continue to require substantial additional capital to continue our clinical development and potential commercialization activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will

depend on many factors, including the pace and results of our clinical development efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop our product candidates.

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

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

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

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

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

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

In general, under Section 382 of the Code, a corporation that undergoes an “ownership change” (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period) is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. If we undergo additional ownership changes (some of which changes may be outside our control), our ability to utilize our NOLs could be further limited by Section 382 of the Code. The Merger resulted in an ownership change under Section 382 of the Code for us, and our pre-Merger net operating loss carryforwards and certain other tax attributes will be subject to limitation or elimination. The net operating loss carryforwards and certain other tax attributes of ours may also be subject to limitations as a result of ownership changes. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. federal taxable income.

Other than for 2015, 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 a material weakness in our internal control over financial reporting. If one or more material weaknesses persist or if we fail to establish and maintain effective internal control over financial reporting, our ability to accurately report our financial results could be adversely affected.

Prior to the Merger, Private Molecular had limited accounting and financial reporting personnel and other resources with which to address its internal control over financial reporting. In connection with the audits of our consolidated financial statements for the years ended December 31, 2015 and 2016 and preparation of interim financial statements for the first quarter of 2017, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control, such that there is a reasonable possibility that a material misstatement of the entity's financial statements will not be prevented or detected and corrected on a timely basis.

Prior to the completion of the Merger, Private Molecular was a private company and had limited accounting and financial reporting personnel and other resources with which to address its internal controls and procedures. Private Molecular's lack of adequate accounting personnel resulted in the identification of a material weakness in its internal control over financial reporting, which has continued through March 31, 2018. Specifically, Private Molecular did not timely and appropriately account for and disclose the impact of complex, non-routine transactions in accordance with U.S. GAAP. We have begun our remediation plan and have hired and intend to hire additional accounting and finance personnel. Additionally, we are in the process of implementation of more robust review, supervision and monitoring of the non-routine transactions and the financial reporting process intended to remediate the identified material weakness. There can be no assurance that these efforts will remediate the material weakness or avoid future weaknesses or deficiencies. Any failure to remediate the material weakness and any future weaknesses or deficiencies or any failure to implement required new or improved controls or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Following the closing of the Merger, our management has been assessing the effectiveness of its disclosure controls and procedures and internal control over financial reporting and will be required to provide an annual report on internal control over financial reporting as of December 31, 2018. If we are unable to remediate our material weakness, our management may not be able to conclude that its disclosure controls and procedures or internal control over financial reporting are effective, which could result in investors losing confidence in our reported financial information and may lead to a decline in the stock price. Failure to comply with Section 404 of Sarbanes-Oxley could potentially subject us to sanctions or investigations by the SEC, the Financial Industry Regulatory Authority or other regulatory authorities, as well as increasing the risk of liability arising from litigation based on securities law.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our stock price.

Section 404 of the Sarbanes-Oxley Act of 2002 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 of 2002 and the related rules and regulations of the SEC. If we cannot favorably assess, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on, the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

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

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

- completing research and development of one or more of our product candidates;
- obtaining regulatory and marketing approvals for one or more of our product candidates;
- manufacturing one or more product candidates and establishing and maintaining supply and manufacturing relationships with third parties that are commercially feasible;

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

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

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights.

To 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 dividends. For instance, our loan and security agreement with Silicon Valley Bank limits our ability to enter into an asset sale, enter into any change of control, incur additional indebtedness, pay any dividends or enter into specified transactions with our affiliates. If we raise additional funds through strategic collaborations or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We cannot be assured that we will be able to obtain additional funding if and when necessary to fund our entire portfolio of product candidates to meet our projected plans. If we are unable to obtain funding on a timely basis, we may be required to delay or discontinue one or more of our development programs or the commercialization of any product candidates or be unable to expand our operations or otherwise capitalize on potential business opportunities, which could materially harm our business, financial condition, and results of operations.

We also have historically received funds from state and federal government grants for research and development. The grants have been, and any future government grants and contracts we may receive may be, subject to the risks and contingencies set forth below under the section titled “—Risks Related to the Development of Our Product Candidates—Reliance on government funding for our programs may add uncertainty to our research and commercialization efforts with respect to those programs that are tied to such funding and may impose requirements that limit our ability to take certain actions, increase the costs of commercialization and production of product candidates developed under those programs and subject us to potential financial penalties, which could materially and adversely affect our business, financial condition and results of operations.” Although we might apply for government contracts and grants in the future, we cannot assure you that we will be successful in obtaining additional grants for any product candidates or programs.

Risks Related to the Development of Our Product Candidates

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.

Clinical development is expensive, time consuming and involves significant risk. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include but are not limited to:

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

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

The approach we are taking to discover and develop next generation immunotoxin therapies (called ETBs) is unproven and may never lead to marketable products.

The scientific discoveries that form the basis for our efforts to discover and develop our product candidates are relatively recent. To date, neither we nor any other company has received regulatory approval to market therapeutics utilizing ETBs. The scientific evidence to support the feasibility of developing drugs based on these discoveries is both preliminary and limited. Successful development of ETB therapeutic products by us will require solving a number of issues, including identifying appropriate receptor targets, screening for and selecting potent and safe ETB drug 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 may be commercialized and commercializing an ETB successfully in a competitive product landscape. In addition, any product candidates that we develop may not demonstrate in patients the biological and pharmacological properties ascribed to them in laboratory and preclinical testing, and they may interact with human biological systems in unforeseen, ineffective or even harmful ways. If we do not successfully develop and commercialize one or more product candidates based upon this technological approach, we may not become profitable and the value of our capital stock may decline.

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

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

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

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

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

The clinical trial and manufacturing requirements of the FDA, the European Medicines Agency, or the EMA, and other regulatory authorities, and the criteria these regulators use to determine the safety and efficacy of a product candidate, vary substantially according to the type, complexity, novelty and intended use and market of the product candidate. The regulatory approval process for novel product candidates such as ETB therapeutics can be more expensive and take longer than for other, better known or more extensively studied product candidates. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the United States or the European Union or how long it will take to commercialize our product candidates, even if approved for marketing. Approvals by the European Commission 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 potential product candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be harmed.

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

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

The eligibility criteria of our planned clinical trials may further limit the available eligible trial participants as we expect to 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, our Phase I clinical trial of MT-3724 includes patients with non-Hodgkin's lymphoma. The estimated incidence of non-Hodgkin's lymphoma in the United States is 72,580 new cases and approximately 20,150 deaths were attributable to non-Hodgkin's B-cell lymphomas in 2016. We may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical trials in a timely manner because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, and the willingness of physicians to participate in our planned clinical trials. If patients are unwilling to participate in our clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of our product candidates may be delayed.

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

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

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

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

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

- regulatory authorities may withdraw approvals of such products;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, even if approved, and could significantly harm its business, results of operations, and prospects.

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

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

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

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

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

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

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

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

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

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

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

Although we have product liability insurance covering our clinical trials in the United States for up to \$4.0 million per occurrence up to an aggregate limit of \$4.0 million, our insurance may be insufficient to reimburse us for any expenses or losses we may suffer. We also will likely be required to increase our product liability insurance coverage for the advanced clinical trials that we plan to initiate. If we obtain marketing approval for any of our product candidates, we will need to expand our insurance coverage to include the sale of commercial products. There is no way to know if we will be able to continue to obtain product liability coverage and obtain expanded coverage if we require it, in sufficient amounts to protect us against losses due to liability, on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limits of, our insurance coverage. Where we have provided indemnities in favor of third parties under our agreements with them, there is also a risk that these third parties could incur liability and bring a claim under such indemnities. An individual may bring a product liability claim against us alleging that one of our product candidates causes, or is claimed to have caused, an injury or is found to be unsuitable for consumer use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and breach of warranties. Claims also could be asserted under state consumer protection acts. Any product liability claim brought against us, with or without merit, could result in:

- withdrawal of clinical trial volunteers, investigators, patients or trial sites or limitations on approved indications;
- the inability to commercialize, or if commercialized, decreased demand for, our product candidates;
- if commercialized, product recalls, withdrawals of labeling, marketing or promotional restrictions or the need for product modification;
- initiation of investigations by regulators;
- loss of revenues;
- substantial costs of litigation, including monetary awards to patients or other claimants;
- liabilities that substantially exceed our product liability insurance, which we would then be required to pay ourselves;
- 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.

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

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

We may seek a breakthrough therapy designation from the FDA for some of our product candidates. A breakthrough therapy is defined as a drug or biological product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug or biological product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs or biological products that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of a clinical trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA could also be eligible for accelerated approval.

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

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

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

Even if we obtain regulatory approval for a product, we will remain subject to ongoing regulatory requirements.

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

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

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product candidate may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. We will be required to report adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. If our original marketing approval for a product candidate was obtained through an accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial in order to confirm the clinical benefit for our products. An unsuccessful post-marketing clinical trial or failure to complete such a trial could result in the withdrawal of marketing approval.

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

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- require a product recall.

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.

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 ACA was passed. The ACA was intended to substantially change the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of specified branded prescription drugs, and promotes a new Medicare Part D coverage gap discount program. However, the ACA has been under threat of repeal since its passage and in May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act, or the AHCA, which, if enacted, would amend and repeal significant portions of the ACA. While the AHCA was passed by the U.S. House of Representatives, it is unclear whether and in what form this legislation might be passed by the U.S. Senate and, if so, what form any final legislation might take. In any event, it is not clear what the impact of this legislation or other healthcare reform measures that may be adopted in the future will have on any of our product candidates if they are approved.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted, and we expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand or lower pricing for our product candidates or additional pricing pressures.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal physician sunshine requirements under the Health Care Reform Laws requires manufacturers of drugs, devices, biologics and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including governmental and private payors, to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

During the course of our development of our lead product candidate, we have been funded in significant part through state grants, including but not limited to the substantial funding we have received from the Cancer Prevention & Research Institute of Texas, or CPRIT. 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. We have been awarded a second CPRIT grant for our MT-4019 program where contract negotiations and amendments are still ongoing and may or may not be successful. Contracts and grants funded by the U.S. government, state governments and their related agencies, including our contracts with the State of Texas pertaining to funds we have already received, include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- require repayment of all or a portion of the grant proceeds, in certain cases with interest, in the event we violate certain covenants pertaining to various matters that include any potential relocation outside of the State of Texas, failure to achieve certain milestones or to comply with terms relating to use of grant proceeds, or failure to comply with certain laws;
- terminate agreements, in whole or in part, for any reason or no reason;
- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including certain intellectual property rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;

- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose State of Texas or U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- impose 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 award from CPRIT, we are required to pay CPRIT a portion of its revenues from sales of products directly funded by CPRIT, or received from our licensees or sublicensees, at a percentage in the mid-single digits until the aggregate amount of such payments equals a specified multiple of the grant amount, and thereafter at a rate of less than or equal to three percent, subject to our right, under certain circumstances, to make a one-time payment in a specified amount to CPRIT to buy out such payment obligations.

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 terms and conditions. These requirements include, for example:

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

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

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

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations; environmental damage resulting in costly clean-up; and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and

regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of specified materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

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

On December 22, 2017, President Trump signed into law the “Tax Cuts and Jobs Act,” or TCJA, that significantly reforms the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards, allows for the expensing of capital expenditures, and puts into effect the migration from a “worldwide” system of taxation to a territorial system. Our net deferred tax assets and liabilities will be revalued at the newly enacted U.S. corporate rate, and the impact, if any, will be recognized in our tax expense in the year of enactment. We continue to examine the impact this tax reform legislation may have on our business. The impact of this tax reform is uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

Risks Related to Our Intellectual Property

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

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

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

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

- we or our current or future collaboration partners may not have been the first to make the inventions covered by pending patent applications or issued patents;
- we or our current or future collaboration partners may not have been the first to file patent applications covering our ETB technology, product candidates, compositions or their uses;
- others may independently develop identical, similar or alternative methods, products, product candidates or compositions and uses thereof;
- we or our current or future collaboration partners’ disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our or our current or future collaboration partners’ pending patent applications may not result in issued patents;

- we or our current or future collaboration partners may not seek or obtain patent protection in countries that may eventually provide us with a significant business opportunity;
- any patents issued to us or our current or future collaboration partners may not provide a basis for commercially viable products, may not provide any competitive advantages or may be successfully challenged by third parties;
- we or our current or future collaboration partners' products, product candidates, compositions, methods or uses thereof may not be patentable;
- others may design around our or our current or future collaboration partners' patent claims to produce competitive products or uses which fall outside of the scope of our patents or other intellectual property rights;
- others may identify prior art or other bases which could invalidate our or our current or future collaboration partners' patents;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we or our current or future collaboration partners do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in major commercial markets; or
- we or our current or future collaboration partners may not develop additional proprietary technologies or products that are patentable.

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

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

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

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop our own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries, particularly some developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to healthcare, medicine, or biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims

against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

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

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

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

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

For our U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO has promulgated regulations and developed procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first inventor to file provisions, did not come into effect until March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition or results of operations.

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

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

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

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

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

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

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

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

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

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

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

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

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

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

It is also possible that we have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to product candidates and technologies because patent searching is imperfect due to differences in terminology among patents,

incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to specified limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates.

There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding foreign patent offices. Third parties own numerous U.S. and foreign issued patents and pending patent applications in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Parties making patent infringement claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, may involve substantial litigation expense and may require a substantial diversion of employee resources from our business. In the event of a successful claim of patent infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may be unsuccessful in obtaining or maintaining third-party rights necessary to develop our ETB technologies or to commercialize our product candidates and associated methods of use through acquisitions and in-licenses.

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

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

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to it. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

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

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

While we normally have or seek and gain the right to fully prosecute the patent applications relating to our product candidates, there may be times when certain patents or patent applications relating to our product candidates, their uses or their manufacture may be controlled by our future licensors. If any of our future licensors fail to appropriately and broadly prosecute patent applications and maintain patent protection of claims covering any of our product candidates, their uses or their manufacture, our ability to develop and

commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, importing and selling competing products. In addition, even where we now have the right to control patent prosecution of patent applications or the maintenance of patents we have licensed from third parties in the future, we may still be adversely affected or prejudiced by actions or inactions of our licensors in effect from actions prior to us assuming control over patent prosecution.

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

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

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

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

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct our clinical trials, manufacture our product candidates and perform other services. If these third parties do not successfully perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates, and our business could be substantially harmed.

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

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

We currently do not have the capability to manufacture product candidates for use in the conduct of our clinical trials, and we currently lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale without the use of third-party manufacturers. Until the completion of our cGMP manufacturing facility, we plan to rely in part on third-party manufacturers, and their responsibilities will include purchasing from third-party suppliers the materials necessary to produce our product candidates for our clinical trials and regulatory approval. We expect there to be a limited number of suppliers for some of the raw materials that we expect to use to manufacture our product candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our product candidates for our clinical trials, and, if approved, ultimately for commercial sale. Even after the completion of our cGMP manufacturing facility, we may not be able to manufacture product candidates or there may be substantial technical or logistical challenges to supporting manufacturing demand for products candidates. We may also fail to comply with cGMP requirements and standards which would not enable us to utilize the manufacturing facility to make clinical trial supply.

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

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

- we may be unable to identify manufacturers on acceptable terms or at all;
- 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;
- contract manufacturers may not be able to execute our manufacturing procedures appropriately;
- 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 products;
- 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;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates; and
- our third-party manufacturers could breach or terminate their agreement with us.

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

The manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical products often encounter difficulties in production, particularly in scaling up and validating initial production and absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot be assured that any stability or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

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

We have multi-target research and development collaborations ongoing with Millennium Pharmaceuticals, Inc. (a wholly owned subsidiary of Takeda Pharmaceutical Company Ltd) and seek to collaborate with other partners in the future. Even if we are successful in entering into one or more additional collaborations with respect to the development and/or commercialization of one or more product candidates, there is no guarantee that any of these collaborations will be successful. Collaborations may pose a number of risks, including:

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

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

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

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

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

Risks Related to Commercialization of Our Product Candidates

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

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

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

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

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

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

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

Our estimates for the addressable patient population and our estimates for the prices we can charge for our product candidates may differ significantly from the actual market addressable by our product candidates. For instance, our Phase I clinical trial of MT-3724 is focused on non-Hodgkin's lymphoma. The estimated incidence of non-Hodgkin's B-cell lymphoma is 72,240 new cases and approximately 20,140 deaths were attributable to the disease in the United States in 2017, only a subset of which may benefit from treatment with MT-3724. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, while we believe that the data in our Phase I clinical trials for MT-3724 are supportive of application to other indications, there can be no assurance that our clinical trials will successfully address any additional indications. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our business, financial condition, results of operations and prospects.

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

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

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

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

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

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

- the efficacy of the product as demonstrated in clinical trials and potential advantages over competing treatments;
- the prevalence and severity of the disease and any side effects;
- 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;
- the cost of treatment;
- the willingness of the patients and physicians to accept these therapies;
- the perceived ratio of risk and benefit of these therapies by physicians and the willingness of physicians to recommend these therapies to patients based on such risks and benefits;
- the marketing, sales and distribution support for the product;
- the publicity concerning our products or competing products and treatments; and
- the pricing and availability of third-party insurance coverage and reimbursement.

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Business Operations

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

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

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

As of March 31, 2018, we had 44 full-time employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Failure in our information technology and storage systems could significantly disrupt the operation of our business.

Our ability to execute our business plan and maintain operations depends on the continued and uninterrupted performance of our information technology, or IT, systems. IT systems are vulnerable to risks and damages from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. 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. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. 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. For example, the loss of data from completed clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs. 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

The Company will hold its annual meeting of stockholders on May 31, 2018. Because the date of the annual meeting is more than 30 days from the date of the anniversary of the Company's previous annual meeting, in accordance with Rule 14a-5(f) under the Exchange Act, the Company is informing stockholders of the change.

ITEM 6. EXHIBITS**EXHIBIT INDEX**

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

Exhibit Number	Description
10.1	<u>Credit Agreement and Guaranty, dated as of February 27, 2018, among the Molecular Templates OpCo, Inc., a Delaware corporation, as borrower, Molecular Templates, Inc., a Delaware corporation, as guarantor, Perceptive Credit Holdings II, LP, as Lender, and certain of Lender's successors and assigns party thereto from time to time (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on March 2, 2018).</u>
10.2	<u>Warrant to Purchase Common Stock issued to Perceptive Credit Holdings II, LP (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on March 2, 2018).</u>
10.3	<u>Registration Rights Agreement, dated February 27, 2018, by and between Molecular Templates, Inc. and Perceptive Credit Holdings II, LP (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on March 2, 2018).</u>
31.1	<u>Certification of Principal Executive Officer required by Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934 as amended.</u>
31.2	<u>Certification of Principal Financial Officer required by Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934 as amended.</u>
32.1*	<u>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).</u>
32.2*	<u>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).</u>
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 14, 2018

/s/ Eric E. Poma

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

Date: May 14, 2018

/s/ Adam Cutler

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

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Eric E. Poma, 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 14, 2018

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

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

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 14, 2018

/s/ Adam Cutler

Adam Cutler
Chief Financial Officer

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

In connection with the Quarterly Report of Molecular Templates, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Eric E. Poma, Ph.D., Chief Executive Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2018

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

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

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

In connection with the Quarterly Report of Molecular Templates, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Adam Cutler, Chief Financial Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 14, 2018

/s/ Adam Cutler
Adam Cutler
Chief Financial Officer