

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

---

**FORM 10-Q**

---

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

For the quarterly period ended September 30, 2017

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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting 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 November 8, 2017, there were 26,895,230 shares of common stock, par value \$0.001 per share, of Molecular Templates, Inc. outstanding.

---

**Molecular Templates, Inc.**

**TABLE OF CONTENTS**

	<u>Page</u>
PART I.	
Item 1.	
	<a href="#"><u>FINANCIAL INFORMATION</u></a>
	<a href="#"><u>Condensed Consolidated Financial Statements (Unaudited)</u></a>
	3
	<a href="#"><u>Condensed Consolidated Balance Sheets (Unaudited)</u></a>
	3
	<a href="#"><u>Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)</u></a>
	4
	<a href="#"><u>Condensed Consolidated Statements of Cash Flows (Unaudited)</u></a>
	5
	<a href="#"><u>Notes to Condensed Consolidated Financial Statements (Unaudited)</u></a>
	6
Item 2.	<a href="#"><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></a>
	21
Item 3.	<a href="#"><u>Quantitative and Qualitative Disclosures About Market Risk</u></a>
	31
Item 4.	<a href="#"><u>Controls and Procedures</u></a>
	31
PART II.	
	<a href="#"><u>OTHER INFORMATION</u></a>
Item 1	<a href="#"><u>Legal Proceedings</u></a>
	33
Item 1A.	<a href="#"><u>Risk Factors</u></a>
	33
Item 2.	<a href="#"><u>Unregistered Sales of Equity Securities and Use of Proceeds</u></a>
	61
Item 3.	<a href="#"><u>Defaults Upon Senior Securities</u></a>
	61
Item 4.	<a href="#"><u>Mine Safety Disclosures</u></a>
	61
Item 5.	<a href="#"><u>Other Information</u></a>
	61
Item 6.	<a href="#"><u>Exhibits</u></a>
	62
	<a href="#"><u>EXHIBIT INDEX</u></a>
	64
	<a href="#"><u>SIGNATURES</u></a>
	66

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2017	December 31, 2016
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 68,181	\$ 1,716
Accounts receivable	38	—
Prepaid expenses and other current assets	1,363	127
Total current assets	69,582	1,843
Property and equipment, net	963	334
In-process research and development	27,300	—
Goodwill	3,314	—
Intangible assets	1,321	921
Other assets	57	—
Total assets	<u>\$ 102,537</u>	<u>\$ 3,098</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,823	\$ 934
Accrued liabilities	1,500	1,210
Current portion of long-term debt	2,348	2,400
Current portion of capital lease obligations	51	36
Related party debt (Note 5)	—	7,315
Deferred revenue	3,585	1,870
Total current liabilities	11,307	13,765
Capital lease obligations, net of current portion	60	53
Warrant liabilities	1,392	49
Deferred rent	145	—
Long-term debt, net of current portion	1,734	3,165
Total liabilities	14,638	17,032
Commitments and contingencies (Note 9)		
Redeemable convertible preferred stock	—	25,871
Stockholders' deficit:		
Common stock, \$0.001 par value, shares authorized: 150,000,000 shares; issued and outstanding: 26,884,192 shares at September 30, 2017 and 303,303 shares at December 31, 2016	27	—
Additional paid-in capital	145,428	568
Accumulated other comprehensive loss	—	—
Accumulated deficit	(57,556)	(40,373)
Total stockholders' equity (deficit)	87,899	(39,805)
Total liabilities and stockholders' equity (deficit)	<u>\$ 102,537</u>	<u>\$ 3,098</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 per share data)  
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Collaboration revenue	\$ 648	\$ —	\$ 2,408	\$ —
Grant revenue	—	—	167	1,526
Total revenue	648	0	2,575	1,526
Operating expenses:				
Research and development	2,522	2,271	4,829	7,178
General and administrative	3,996	810	8,233	2,553
Total operating expenses	6,518	3,081	13,062	9,731
Loss from operations	(5,870)	(3,081)	(10,487)	(8,205)
Interest and other income, net	1	6	2	18
Other expense, net	(107)	(118)	(752)	(279)
Change in fair value of warrant liabilities	(272)	1	(269)	2
Loss on conversion of notes	(4,719)	—	(4,719)	—
Net loss	(10,967)	(3,192)	(16,225)	(8,464)
Deemed dividends on preferred stock	(138)	(393)	(958)	(1,179)
Net loss attributable to common shareholders	\$ (11,105)	\$ (3,585)	\$ (17,183)	\$ (9,643)
Net loss per share attributable to common shareholders:				
Basic and diluted	\$ (0.62)	\$ (11.89)	\$ (2.75)	\$ (32.01)
Weighted average number of shares used in net loss per share calculations:				
Basic and diluted	17,926	301	6,242	301
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities	—	—	—	—
Comprehensive loss	\$ (11,105)	\$ (3,585)	\$ (17,183)	\$ (9,643)

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

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

	Nine Months Ended September 30,	
	2017	2016
<b>Cash flows from operating activities:</b>		
Net loss	\$ (16,225)	\$ (8,464)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	71	48
Stock-based compensation expense	1,430	85
Amortization of debt discount	282	9
Change in common stock warrant fair value	269	(2)
Loss on conversion of notes	4,719	—
Loss on disposal of equipment	—	2
Changes in operating assets and liabilities:		
Accounts receivable	(38)	(250)
Prepaid expenses and other assets	(280)	101
Long term deposits	(57)	—
Accounts payable	2,618	(26)
Accrued liabilities	(1,003)	576
Deferred rent	145	—
Deferred revenue	1,715	(276)
Net cash used in operating activities	<u>(6,354)</u>	<u>(8,197)</u>
<b>Cash flows from investing activities:</b>		
Cash received from merger transaction	11,216	—
Purchases of property and equipment	(287)	(25)
Increase in leasehold improvements	(82)	—
Increase in intangible assets	(400)	(371)
Net cash provided by (used in) investing activities	<u>10,447</u>	<u>(396)</u>
<b>Cash flows from financing activities:</b>		
Payments of capital lease obligations	(35)	(21)
Proceeds from issuance of long-term debt	—	3,000
Repayment of long-term debt	(1,800)	—
Retirement of stock warrants	(208)	—
Proceeds from issuance of related party debt	2,685	3,000
Proceeds from stock option exercise	14	—
Proceeds from promissory note	4,000	—
Proceeds from issuance of common stock and warrants, net of offering expenses	57,716	1
Net cash provided by financing activities	<u>62,372</u>	<u>5,980</u>
Net increase (decrease) in cash and cash equivalents	<u>66,465</u>	<u>(2,613)</u>
Cash and cash equivalents, beginning of period	1,716	4,245
Cash and cash equivalents, end of period	<u>\$ 68,181</u>	<u>\$ 1,632</u>
<b>Supplemental Cash Flow Information</b>		
Cash paid for interest	<u>\$ 194</u>	<u>\$ 159</u>
<b>Non-Cash Investing and Financing Activities</b>		
Deemed dividends on preferred stock	<u>\$ 958</u>	<u>\$ 1,179</u>
Conversion of preferred stock	<u>\$ 26,830</u>	<u>\$ —</u>
Conversion of related party debt	<u>\$ 10,486</u>	<u>\$ —</u>
Capital lease additions to fixed assets	<u>\$ 57</u>	<u>\$ 50</u>
Fixed asset additions in accounts payable	<u>\$ 274</u>	<u>\$ —</u>
Warrants issued with debt	<u>\$ —</u>	<u>\$ 18</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 clinical stage a 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 initial 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 accounting principles generally accepted in the United States of America for 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 accounting principles generally accepted in the United States of America 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, 2016 included in the Company’s Amended Registration Statement on Form S-4/A filed with the SEC on June 27, 2017.

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.

***Prior Year’s Presentations***

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

### ***Revenue Recognition***

The accounting guidance for revenue recognition requires that the following criteria must be met before revenue can be recognized: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured. Determination of whether persuasive evidence of an arrangement exists and whether delivery has occurred or services have been rendered are based on management's judgments regarding the fixed nature of the fee charged for research performed and milestones met, and the collectability of those fees. Should changes in conditions cause management to determine these criteria are not met for certain future transactions, revenue recognized for any reporting period could be adversely affected.

Revenue under the Company's license and collaboration arrangements is recognized based on the performance requirements of the contract. Collaboration agreements may include non-refundable license fees, research and development funding, cost reimbursements and contingent milestones and royalties. Under ASC 605-25, in multiple-element arrangement; fixed or determinable contract consideration is allocated to the deliverables with stand-alone value and revenue is recognized for each such deliverable according to the method appropriate for each deliverable. Revenue is allocated to each element using a selling price hierarchy, using the selling price for an element based on vendor specific objective evidence ("VSOE"); third-party evidence ("TPE"); or the best estimate of selling price, if neither VSOE nor TPE is available.

Upfront, non-refundable licensing payments are assessed to determine whether or not the licensee is able to obtain stand-alone value from the license. Where the license does not have stand-alone value, non-refundable license fees are recognized as revenue as the Company performs under the applicable agreement. Where the license has stand-alone value, the Company recognizes total license revenue at the time all revenue recognition criteria have been met.

The Company receives funds from a state financial assistance program, which is a conditional cost reimbursement grant and revenue is recognized as allowable costs are paid. The Company recognized approximately \$0 million and \$0.2 million in grant revenue under these awards during the three and nine months ended September 30, 2017 compared to \$0 and \$1.5 million for the three and nine months ended September 30, 2016, respectively. Amounts collected in excess of revenue recognized are recorded as deferred revenue.

### ***Accounts Receivable***

Accounts receivable represent valid claims against customers. Management reviews accounts receivable regularly to determine if any receivable amounts are potentially uncollectible and then estimates the amount of allowance for doubtful accounts necessary to reduce the accounts receivable to estimate its net realizable value. As of September 30, 2017, management believes there were no receivable amounts requiring an allowance for doubtful accounts.

### ***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 and investments are invested in deposits with two major financial institutions in the United States. Deposits in these banks may exceed the amount of insurance provided on such deposits. The Company has not experienced any realized losses on its deposits of cash, cash equivalents or investments.

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 100% and 74% of total revenues for the three and nine months ended September 30, 2017, were derived from Takeda. There were no accounts receivable due from Takeda at December 31, 2016. See also Note 4, Research and Development Collaboration Agreement, 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.

### ***Intangible Assets (Patents)***

Intangible assets consist of patents in application statuses which are not yet subject to amortization, and which management has deemed to have an alternative future use.

### ***In-process Research & Development***

In-process research and development, or IPR&D, represents the fair value assigned to research and development assets that were not fully developed as of the completion of the Merger. IPR&D acquired in a business combination is capitalized on the Company's balance sheet at its acquisition-date fair value. Until the project is completed, the asset is accounted for as an indefinite-lived intangible asset subject to impairment testing. Upon completion of a project, the carrying value of the related IPR&D is reclassified to intangible assets and is amortized over the estimated useful life of the asset. The Company evaluates the potential impairment of its intangible assets if events or changes in circumstances indicate that the carrying amount of the asset may not be fully recoverable.

### ***Recently Issued Accounting Pronouncements***

In November 2015, the Financial Accounting Standards Board (FASB) issued an accounting standard update for the presentation of deferred income taxes. Under this new guidance, deferred tax liabilities and assets should be classified as noncurrent in a classified balance sheet. The update is effective for the Company beginning in the first quarter of fiscal year 2017 with early adoption permitted as of the beginning of an interim or annual reporting period. Additionally, this guidance may be applied either prospectively or retrospectively to all periods presented. We adopted the standard in the first quarter of 2017 and it did not have a material impact to our consolidated financial statements.

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606), or ASU 2014-09, which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. In March 2016, the FASB amended the principal-versus-agent implementation guidance and illustrations in the new standard. In April 2016, the FASB amended the guidance on identifying performance obligations and the implementation guidance on licensing in the new standard. In May 2016, the FASB amended the guidance on collectability, noncash consideration, presentation of sales tax and transition in the new standard. In December 2016, the FASB issued ASU No. 2016-20, "Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers," which amends certain narrow aspects of the guidance issued in ASU 2014-09. The new standard will become effective starting on January 1, 2018. Early application is permitted to the original effective date of January 1, 2017. The Company will adopt the standard on January 1, 2018. The standard permits the use of either the modified retrospective method or full retrospective approach for all periods presented. While the Company is continuing to assess all potential impacts of the standard, the Company believes the most significant accounting impact will relate to the timing of the recognition of our license, collaboration, and milestone revenues.

In March 2016, the FASB issued ASU No. 2016-09, "Improvements to Employee – Share Based Payment Accounting," or ASU 2016-09," which amends ASC Topic 718, "Compensation – Stock Compensation." ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years and early adoption is permitted. The Company adopted the standard effective January 1, 2017 and the adoption did not have a material effect on its condensed consolidated financial statement.

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 financial statements and disclosures.

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 does not expect the adoption of this guidance to have a material impact on its financial statements or disclosures.



## NOTE 2 — NET LOSS PER 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.

Potential dilutive common shares also include the dilutive effect of the common stock underlying in-the-money stock options and warrants that were calculated based on the average share price for each period using the treasury stock method. Under the treasury stock method, the exercise price of an option or warrant is assumed to be used to repurchase shares in the current period. In addition, the average amount of compensation cost for in-the-money options, if any, for future service that the Company has not yet recognized when the option is exercised, is also assumed to repurchase shares in the current period. A reconciliation of the numerator and denominator used in the calculation is as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
<b>Numerator:</b>				
Net loss attributable to common shareholders	\$ (11,105)	\$ (3,585)	\$ (17,183)	\$ (9,643)
<b>Denominator:</b>				
Weighted average common shares outstanding - basic and diluted	17,925,585	301,494	6,241,947	301,275
<b>Net loss per share:</b>				
Basic and diluted	\$ (0.62)	\$ (11.89)	\$ (2.75)	\$ (32.01)

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 September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Shares issuable upon exercise of warrants	3,274	49	3,274	49
Shares issuable upon exercise of stock options	1,870	856	1,870	856

## NOTE 3 — MERGER WITH PRIVATE MOLECULAR

On August 1, 2017, the Company, formerly known as Threshold, completed its business combination with Private Molecular, in accordance with the terms of the Merger Agreement, dated as of March 16, 2017, by and among Threshold, the Merger Sub, a wholly owned subsidiary of Threshold, and Private Molecular, pursuant to which Merger Sub merged with and into Private Molecular, with Private Molecular, surviving as a wholly-owned subsidiary of Threshold (the "Merger"). Immediately upon completion of the Merger, the former stockholders of Private Molecular stockholders 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 an 11-for-1 reverse stock split of its common stock (the "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 shall be 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 \$33.62 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)
Total purchase price	<u>\$ 39,664</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.

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)	27,300
Goodwill	3,314
Accounts payable, accrued expenses	(1,990)
Warrant liability	(1,121)
Net assets acquired	<u>\$ 39,664</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 final allocation of the purchase price is dependent on the finalization of the valuation of the fair value of assets acquired and liabilities assumed and may differ from the amounts included in these financial statements. The Company expects to complete the final allocation as soon as practical but no later than one year from the acquisition date.

### *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 \$1.9 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 12, Stock Based Compensation, for further details about stock based compensation recorded.

### *Pro Forma Results in connection with the Merger*

The Company's operating results include \$142,000 of operating expenses attributable to the former Threshold business activities for the period of August 1, 2017 to September 30, 2017.

The unaudited financial information in the following table summarizes the combined results of operations of the Company and Threshold, on a pro forma basis, as if the Merger occurred at the beginning of the periods presented (in thousands, except per share data).

	<u>Nine Months Ended September 30,</u>	
	<u>2017</u>	<u>2016</u>
Revenue	<u>\$ 5,575</u>	<u>\$ 1,526</u>
Net loss	<u>\$ (14,201)</u>	<u>\$ (28,226)</u>

The above unaudited pro forma information was determined based on historical GAAP results of Molecular and Threshold. The unaudited pro forma combined results do not necessarily reflect what the Company's combined results of operations would have been, if the acquisition was completed on January 1, 2016. The unaudited pro forma combined net loss includes pro forma adjustments primarily related to the following non-recurring items directly attributable to the business combinations:

- Elimination of combined transaction costs of \$3.3 million for the nine-months ended September 30, 2017. No such costs were incurred in 2016.
- Elimination of the loss on conversion of notes of \$4.7 million for the nine-months ended September 30, 2017. No such loss was incurred in 2016.

- Elimination of stock-based compensation expenses of \$1.2 million related to the acceleration of vesting and modification of post-termination exercise periods of Threshold stock options awards in connection with the Merger for the nine-months ended September 30, 2017. No such costs were incurred in 2016.
- Elimination of interest expense of \$0.3 million for the nine months ended September 30, 2017, related to the Threshold bridge loan to Private Molecular that was paid down with the Merger. No such interest was incurred in 2016.
- Elimination of the change in the fair value of the Threshold warrant liabilities of \$0.3 million and \$0.5 million of loss for the nine months ended September 30, 2017 and September 30, 2016, respective.

#### **NOTE 4 — RESEARCH AND DEVELOPMENT COLLABORATION AGREEMENTS**

##### ***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 received an upfront payment of \$2.0 million in technology access fees and cost reimbursement associated with the Company’s performance and completion of the Company’s obligations under the agreement.

The Company determined that the deliverables under the Takeda Collaboration Agreement were the background IP license, as well as the research and development services. The option to license ETBs is a substantive option, and not deemed a deliverable. The Company determined that there was one unit of accounting, since the background IP license did not have standalone value. Revenues are recognized over the period that the research and development services occur using the proportional performance model.

During the three and nine months ended September 30, 2017, the Company recorded collaboration revenue from Takeda of \$0.6 and \$1.9 million, respectively, under the Takeda Collaboration Agreement. During the three and nine months ended September 30, 2016, the Company recorded no collaboration revenue from Takeda since the agreement was not yet in place.

###### *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 will designate 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.

Molecular received an upfront fee of \$1.0 million and is entitled to receive an additional \$2 million upon the designation of each of the two targets. 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 \$545.0 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.

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. 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 determined that the deliverables under the Takeda Multi-Target Agreement were the background IP license, the research and development services, and manufacturing know-how. The option to license ETBs is a substantive option, considered to be at fair value, and not deemed a deliverable. The Company determined that there was one unit of accounting, since the background IP license, and the manufacturing know-how did not have standalone value. Revenues are recognized over the period that the research and development services occur using the proportional performance model.

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 11. Stockholders’ Equity, for further details. Since the Takeda Stock Purchase Agreement was contingent, it was not a deliverable under the Takeda Multi-Target Agreement.

During the three and nine months ended September 30, 2017, the Company recorded no collaboration revenue under the Multi-Target Takeda Agreement, since no services had been performed under the project.

#### ***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 CPRIT for its CD20-targeting ETB MT-3724. To date, Molecular has received \$9.5 million in grant funds. The Company did not recognize any grant revenue under these awards during the three months ended September 30, 2017 and 2016, respectively. The Company recognized approximately \$0.2 million and \$1.5 million in grant revenue under these awards during the nine months ended September 30, 2017 and 2016, respectively. Amounts collected in excess of revenue recognized are recorded as deferred revenue.

#### **NOTE 5 — RELATED PARTY TRANSACTIONS**

##### *Convertible Notes*

As of September 30, 2017 and December 31, 2016, the Company had received an aggregate of approximately \$10,000,000 and \$7,315,038, respectively, from stockholders under secured convertible promissory notes (the “Notes”). All of the Notes issued in 2017 and 2016 had the same terms. The Notes were subordinate to the long-term debt due to Silicon Valley Bank (See Note 8. Borrowing Arrangements) and accrue interest at a rate of 5.0% per annum, which was due with all unpaid principal on the maturity date of September 7, 2017. In connection with the Merger, the holders of the Notes agreed to convert the Notes based on an agreed upon price of \$3.36 per share. As a result, the Company recorded a loss on conversion of notes of \$4.7 million during the three and nine months ended September 30, 2017, since the agreed upon price was below the fair value of the Notes at the time of the Merger.

##### *Takeda Collaboration and Stock Purchase*

In connection with the Takeda Stock Purchase Agreement described in Note 4. Research and Development Collaboration Agreements, Takeda became a related party, following the stock purchase. Refer to Note 4. Research and Development Collaboration Agreements for more details about the Takeda Collaboration Agreement and the Takeda Multi-Target Agreement. Refer to Note 11. Stockholders’ Equity, for more detail about the Takeda Stock Purchase Agreement.

##### *Threshold Promissory Note*

The Company received \$4 million in the aggregate from Threshold during 2017 in the form of a promissory note, that was settled as part of the Merger. Refer to Note 3. Merger with Private Molecular, for more details about the Threshold promissory note.

##### *Other*

The Company incurred expenses to a stockholder for consulting fees which totaled approximately \$15,000 for each of the three months ended September 30, 2017 and 2016 included in general and administrative expenses.

**NOTE 6 —MARKETABLE SECURITIES AND FAIR VALUE**

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 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 September 30, 2017 and December 31, 2016 (in thousands):

	Fair Value as of September 30, 2017	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	\$ 12,450	\$ 12,450	\$ —	\$ —

  

	Fair Value as of December 31, 2016	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
Money market funds	\$ 796	\$ 796	\$ —	\$ —

The Company invests in highly-liquid, investment-grade securities. The following is a summary of the Company’s available-for-sale securities at September 30, 2017 and December 31, 2016 (in thousands):

As of September 30, 2017	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	\$ 12,450	\$ —	\$ —	\$ 12,450
Less cash equivalents	(12,450)	—	—	(12,450)
Total marketable securities	\$ —	\$ —	\$ —	\$ —

  

As of December 31, 2016 (in thousands):	Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Money market funds	\$ 796	\$ —	\$ —	\$ 796
Less cash equivalents	(796)	—	—	(796)
Total marketable securities	\$ —	\$ —	\$ —	\$ —

There were no realized gains or losses in the three and nine months ended September 30, 2017 and 2016, respectively.

Fair value of financial liabilities:

As of September 30, 2017 and December 31, 2016, the fair value of the long-term debt, payable in installments through year ended 2019, approximated its carrying value of \$4.1 million and \$5.6 million, respectively, because it is carried at a market observable interest rate, which are considered Level 2.

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 11 — Stockholders' Equity.

#### NOTE 7 — BALANCE SHEET COMPONENTS

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

	September 30, 2017	December 31, 2016
Accrued liabilities:		
Clinical costs	\$ 712	\$ 409
Bridge note interest	—	201
Payroll related	627	553
Consulting and professional fees	103	26
Other accrued expenses	58	21
<b>Total accrued liabilities</b>	<b>\$ 1,500</b>	<b>\$ 1,210</b>

Deferred revenue was comprised of the following:

	September 30, 2017	December 31, 2016
Deferred revenue:		
Grant agreement	\$ 2,493	\$ 620
Collaboration agreements	1,092	1,250
<b>Total deferred revenue</b>	<b>\$ 3,585</b>	<b>\$ 1,870</b>

#### NOTE 8 — BORROWING ARRANGEMENTS

In April 2014, the Company entered into a loan and security agreement with Silicon Valley Bank (“SVB”) that was subsequently amended in April 2015, 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 (“Growth Capital Loan”); (3) warrants to purchase 34,620 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 \$345,000 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 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 September 30, 2016, the Company has received \$6 million in the aggregate from this loan and security agreement. The Company is required to repay the outstanding principal in 30 equal installments beginning November 1, 2016 and is due in full on April 30, 2019. Interest accrues at a rate of 1.19% above prime, or 5.44% per annum as of September 30, 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 approximately \$1,800,000 in principal and \$187,000 in interest in the nine months ended September 30, 2017 and \$0 in principal and \$156,000 in interest in the nine months ended September 30, 2016. The final fee of \$345,000 is being accreted to interest expense over the life of the loan using the effective interest method. The Growth Capital Loan matures on April 30, 2019 and is secured by substantially all assets of the Company. The Company does not have any financial loan covenants related to the Growth Capital Loan.

As of September 30, 2017 and December 31, 2016 the Growth Capital Loan balance was \$4,145,000 and \$5,600,000, respectively. As of September 30, 2017 and December 31, 2016, the Company was in compliance with the non-financial covenants of the Growth Capital Loan.

Future required principal payments on the Growth Capital Loan were as follows as of September 30, 2017 (in thousands):

2017	\$	600
2018		2,400
2019		1,145
Total debt		4,145
Debt discount and deferred finance costs		(63)
Total debt, net	\$	<u>4,082</u>

#### NOTE 9 — COMMITMENTS AND CONTINGENCIES

The Company is obligated under operating lease agreements covering the Company's office facilities. Facilities expense under the operating leases was approximately \$182,000 and \$57,000 for the three months ended September 30, 2017 and 2016, respectively and approximately \$387,000 and \$187,000 for the nine months ended September 30, 2017 and 2016, respectively.

In August, 2017, the Company executed new lease amendments and a new lease for facilities in Austin, Texas and Jersey City, New Jersey, respectively.

Future minimum payments due under the operating lease agreements at September 30, 2017 were as follows (in thousands):

2017 (remaining)	\$	177
2018		1,040
2019		1,136
2020		1,049
2021		1,075
2022		718
Thereafter		486
Total	\$	<u>5,681</u>

The Company leases laboratory equipment under non-cancelable capital lease agreements. As of September 30, 2017 and December 31, 2016, laboratory equipment under capital leases included in property and equipment totaled approximately \$171,000 and \$136,000, respectively, net of accumulated amortization of approximately \$66,000 and \$44,000, respectively. Future minimum capital lease payments consisted of the following at September 30, 2017 (in thousands):

2017 (remaining)	\$	12
2018		55
2019		33
2020		21
Total future minimum capital lease payments		121
Less: amount representing interest		(10)
Total capital lease obligations		111
Current portion of lease obligations		(51)
Capital lease obligations, non-current portion	\$	<u>60</u>

#### NOTE 10 — REDEEMABLE CONVERTIBLE PREFERRED STOCK

The following is a summary of the Company's redeemable convertible preferred stock at September 30, 2017 and December 31, 2016 (collectively, the "Preferred Stock"):

	Par Value	Shares Authorized	Shares Issued and Outstanding	
			September 30, 2017	December 31, 2016
Series A Preferred Stock	\$ 0.001	2,500,000	—	2,500,000
Series B Preferred Stock	\$ 0.001	2,273,531	—	2,273,531
Series C Preferred Stock	\$ 0.001	4,391,748	—	4,342,874
Total		<u>9,165,279</u>	<u>—</u>	<u>9,116,405</u>



On August 1, 2017, the Company's preferred stock was converted to common shares as a result of the Merger.

The following table presents changes in the preferred stock:

	Series A Preferred	Series B Preferred	Series C Preferred	Total
Balance at December 31, 2016	\$ 3,889,257	\$ 5,480,130	\$ 16,501,938	\$ 25,871,325
Deemed dividends on preferred stock	119,406	178,129	660,765	958,300
Conversion to common stock in merger	(4,008,663)	(5,658,259)	(17,162,703)	(26,829,625)
Balance at September 30, 2017	\$ —	\$ —	\$ —	\$ —

## NOTE 11 — STOCKHOLDERS' EQUITY

### Equity Financings

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 (the Longitude Securities Purchase Agreement"), pursuant to which the Company sold an aggregate of 5,793,063 units (the "Units") 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 "Warrants") to purchase 2,896,532 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 September 30, 2017, there were warrants outstanding under this agreement to purchase 2,896,532 share of common stock. The value of these warrants is included in additional paid-in capital on the balance sheet.

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 common stock, at a price per share of \$6.84, for an aggregate purchase price of \$20 million.

### Common Stock Warrant Valuation

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. Due to change in control provisions outside of the Company's control in the warrant agreement, 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 other income (expense) in the Company's consolidated statements of operations.

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

	Warrant Liability
Balance at December 31, 2016	\$ 49
Change in fair value through August 1, 2017	(3)
Exercise of warrant put related to 2014 warrants	(46)
Warrant liability related to Merger on August 1, 2017	1,120
Change in fair value during the two months ended September 30, 2017	272
Balance at September 30, 2017	\$ 1,392

At September 30, 2017, the Company had warrants outstanding ("2017 Warrants") to purchase 377,273 shares of common stock, having an exercise price of \$39.82 per share, that were previously issued by Threshold, and which were recorded by Molecular as a liability as part of the Merger transaction.

At December 31, 2016, the Company had warrants outstanding (“2014 Warrants”) to purchase 48,874 shares of preferred stock, having an exercise price of \$3.07 per share, which were issued by Molecular as part of the loan and security agreement with Silicon Valley Bank (“SVB”). These warrants were converted into common stock at the closing of the Merger. Refer to Note 8, Borrowing Arrangements, for further details about the SVB loan and security agreement.

The fair value of these warrants on September 30, 2017 and December 31, 2016 was determined using a Black-Scholes model with the following key level 3 inputs:

	September 30, 2017	December 31, 2016
Risk-free interest rate	1.62%	1.20%
Expected life (in years)	2.39	2.25
Dividend yield	—	—
Volatility	154%	76%
Stock price	\$ 6.97	\$ 3.07

During the three months ended September 30, 2017 the change in fair value of \$272,000 of noncash expense related to the warrants was recorded as Change in fair value of warrant liabilities in the Company’s consolidated statement of operations.

The following table sets forth the Company’s financial liabilities subject to fair value measurements as of September 30, 2017 and December 31, 2016 (in thousands):

	Fair Value as of September 30, 2017	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
2017 warrants	\$ 1,392	\$ —	\$ —	\$ 1,392

  

	Fair Value as of December 31, 2016	Basis of Fair Value Measurements		
		Level 1	Level 2	Level 3
2014 warrants	\$ 49	\$ —	\$ —	\$ 49

#### NOTE 12 — 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 Equity incentive Plan and under 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 for the three and nine months ended September 30, 2017 and 2016 as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Amortization of stock-based compensation:				
Research and development	\$ 312	\$ —	\$ 312	\$ —
General and administrative	1,066	27	1,118	85
	<u>\$ 1,378</u>	<u>\$ 27</u>	<u>\$ 1,430</u>	<u>\$ 85</u>

### 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 and nine months ended September 30, 2017 and 2016:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Employee Stock Options:				
Risk-free interest rate	1.85%	—	1.85%	1.85%
Expected term (in years)	6.09	—	6.05	5.00
Dividend yield	—	—	—	—
Volatility	113%	—	111%	76%
Weighted-average fair value of stock options granted	5.57	\$ —	5.40	\$ 1.14

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 \$1.4 million and \$1.4 million of stock-based compensation expense related to stock options under the Company's equity incentive plans for the three and nine months ended September 30, 2017 and \$27,000 and \$85,000 of stock-based compensation for the three and nine months ended September 30, 2016. Additionally, pursuant to the terms of the Merger Agreement, the 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.

As of September 30, 2017, the total unrecognized compensation cost related to unvested stock-based awards granted to employees under the Company's equity incentive plans was approximately \$1.7 million. This cost will be recorded as compensation expense on a ratable basis over the remaining weighted average requisite service period of approximately 3.8 years.

### Equity Incentive Plans

**Equity Incentive Plans** The Company has a 2009 Equity Incentive Plan and assumed a 2014 Equity Incentive Plan as a result of the merger. 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 thousands)
Outstanding at December 31, 2016	941,682	\$ 0.92	—	—
Options assumed in merger (1)	963,681	\$ 33.62	—	—
Granted	306,627	\$ 6.40	—	—
Exercised	(3,335)	\$ 4.23	—	—
Forfeitures	(3,094)	\$ 1.84	—	—
Outstanding at September 30, 2017	<u>2,205,561</u>	\$ 15.96	4.11	\$ 6,140
Vested and expected to vest September 30, 2017	<u>2,194,308</u>	\$ 16.01	4.08	\$ 6,131
Exercisable at September 30, 2017	<u>1,870,232</u>	\$ 17.75	3.10	\$ 5,773

- (1) In connection with the Merger with Private Molecular on August 1, 2017, the Company assumed stock options covering an aggregate of 963,681 shares of common stock.

The total intrinsic value of stock options exercised during the nine months ended September 30, 2017 and 2016, was \$7,000 and \$0, respectively, as determined at the date of the option exercise. Cash received from stock option exercises was \$14,000 and \$0 for the nine months ended September 30, 2017 and 2016, respectively. The Company issues new shares of common stock upon exercise of options. In connection with these exercises, there was no tax benefit realized by the Company due to the Company's current loss position.

#### **NOTE 13 — INCOME TAXES**

During the three and nine months ended September 30, 2017 and 2016, the Company did not record a provision for income taxes because it expected to generate a net operating loss for the year ending December 31, 2017 and 2016, respectively.

The Company defines the threshold for recognizing the benefits of tax return positions in the financial statements as "more-likely-than-not" to be sustained by the taxing authorities based solely on the technical merits of the position. If the recognition threshold is met, the tax benefit is measured and recognized as the largest amount of tax benefit that, in the Company's judgment, is greater than 50% likely to be realized.

The significant jurisdictions in which the Company files income tax returns are the United States and the states of Texas, California and New Jersey. For jurisdictions in which tax filings are made, the Company is subject to income tax examination for all fiscal years since inception. The Company believes that it maintains adequate reserves for uncertain tax positions.

In general, under Section 382 of the Internal Revenue Code ("Section 382"), a corporation that undergoes an 'ownership change' is subject to limitations on its ability to utilize its pre-change net operating losses ("NOLs") and tax credits to offset future taxable income. A portion of the Company's existing NOLs and tax credits are subject to limitations arising from previous ownership changes, including those obtained during the Merger with Private Molecular. Future changes in the Company's stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 and result in additional limitations.

## 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 "Risk Factors" section of this Quarterly Report on Form 10-Q. Other than statements of historical fact, statements made in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of Section 21E of the Exchange Act, and Section 27A of the Act. When used in this report or elsewhere by management from time to time, the words "believe," "will," "may," "anticipate," "intend," "plan," "estimate," "expect," and similar expressions are forward-looking statements. Such forward-looking statements are based on current expectations. Forward-looking statements made in this report include, for example, statements about:

- the implementation of our business strategies, including our ability to pursue development pathways and regulatory strategies for MT-3724 and other engineered toxin body (ETB) 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
- our projected financial performance.

Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual events or results may differ materially from those discussed in the forward-looking statements as a result of various factors. For a more detailed discussion of the potential risks and uncertainties that may impact their accuracy, see the "Risk Factors" section in Part II, Item 1A of this Quarterly Report on Form 10-Q. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements reflect our view only as of the date of this report. You should read this report completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by our cautionary statements. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons that actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

## Overview

We are a clinical-stage oncology company focused on the discovery and development of engineered toxin bodies (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

### *The Merger*

On August 1, 2017, we completed our business combination with what was then known as “Molecular Templates, Inc.” (“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 us (formerly known as Threshold Pharmaceuticals, Inc. (NASDAQ: THLD) (“Threshold”), Trojan Merger Sub, Inc. (“Merger Sub”), our wholly owned subsidiary, and Private Molecular, pursuant to which Merger Sub merged with and into Private Molecular, with Private Molecular surviving as our wholly owned subsidiary (the “Merger”). On August 1, 2017, in connection with and prior to the consummation of the Merger, we effected an 11-for-1 reverse stock split of the shares of our common stock. Each outstanding share of Private Molecular common stock was converted into 7.7844 shares of common stock of the post-Merger combined company. As a result, we issued approximately 11.7 million shares of our common stock to the stockholders of Private Molecular in exchange for shares of common stock of Private Molecular. Upon the consummation of the Merger, we changed our name to “Molecular Templates, Inc.” For accounting purposes, Private Molecular is considered to have acquired Threshold in the Merger.

### *Concurrent Financing*

On August 1, 2017, we entered into a Securities Purchase Agreement with Longitude Venture Partners III, L.P. and certain other accredited investors (the “Longitude Securities Purchase Agreement”), pursuant to which we sold an aggregate of 5,793,063 units (the “Units”) 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 “Warrants”) to purchase 0.50 shares of our common stock (the “Private Placement”). The Private Placement was pursuant to equity commitment letter agreements entered into by and between us and certain investors in March and June 2017 (the “Equity Commitment Letters”). 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.

### *Subsequent Financing*

In connection with the execution on June 23, 2017 of the Multi-Target Takeda Agreement, as described below, we entered into a stock purchase agreement with Takeda (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 our common stock, at a price per share of \$6.8423, for an aggregate purchase price of \$20.0 million.

## Business After the Merger

We are developing a pipeline of ETBs that we believe will provide a meaningful benefit to cancer patients. We plan to develop each of these as single agents and/or in combination with other therapies, as applicable.

MT-3724 is a first-generation ETB specific to the B-cell marker CD20 protein. We developed MT-3724 to directly target and kill cancer cells expressing CD20, a not normally internalizing cell surface receptor, for the treatment of NHL. The differentiated mechanism of action of MT-3724 involves binding to the surface protein CD20, forcing internalization into the target cell, retrograde transport to the cytosol and subsequent enzymatic and permanent ribosome-inactivation. We are currently conducting a Phase I study of MT-3724 in patients with relapsed/refractory NHL.

In February 2015, we commenced a Phase I clinical trial of our lead ETB candidate, MT-3724, targeting the cell surface antigen CD20 for the treatment of non-Hodgkin's lymphoma. The primary objective of the study was to determine the MTD of MT-3724. The secondary endpoint was to explore the early efficacy profile of MT-3724. In October 2017, we announced the first patient dosed in a Phase I expansion study, at the identified MTD of 75 mcg/kg, focused on DLBCL patients. We expect to begin reporting top-line results from this expansion trial starting in early 2018. If results from this study are compelling, we intend to initiate a monotherapy Phase II study of MT-3724 in the relapsed or refractory DLBCL setting. We also expect to initiate up to two other Phase I/II clinical trials exploring the use of MT-3724 in various treatments settings in DLBCL patients with high unmet medical need. We expect to begin reporting top-line results from one of these trials starting in mid-2018.

We are also developing MT-4019, an ETB candidate that is designed to target CD38-expressing myeloma cancer cells, and plan to submit an IND application to the FDA in mid-2018 to initiate a Phase I clinical trial in the United States.

Additionally, we have several other ETB candidates in pre-clinical development targeting both solid and hematological cancers where we believe the differentiated mechanism of action innate to ETBs, ribosome inactivation, could play a significant role in treating cancer.

As part of the Merger, Private Molecular agreed to use its commercially reasonable efforts to continue a Threshold evofosfamide Phase I clinical trial for a combination therapy until completion of such study, subject to the determination from time to time by the post-Merger board of directors of the Company that such continuation is in the best interests of the Company. In December 2015, Threshold announced that neither of two pivotal Phase III clinical trials of evofosfamide met its primary endpoint of demonstrating a statistically significant improvement in overall survival. Based on a meaningful improvement in overall survival that was reported for a subgroup of 123 Asian patients, we will continue to engage in discussions with Japan's Pharmaceuticals and Medical Devices Agency, or PMDA, regarding potential registration pathways and additional clinical trials that would be required to bring evofosfamide to market. In the meantime, our current evofosfamide development strategy is limited to a company-sponsored Phase I clinical trial of evofosfamide in combination with an immune checkpoint antibody in collaboration with researchers and clinicians at The University of Texas MD Anderson Cancer Center, initiated March 1, 2017, and an investigator-sponsored clinical trial of evofosfamide in combination with antiangiogenic therapies in a variety of tumor types.

We are a clinical-stage company and have not generated revenue from product sales. Our ability to generate revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our ETB candidates. Since inception, we have incurred significant operating losses. For the three months ended September 30, 2017 and 2016, we incurred net losses of \$11.1 million and \$3.6 million, respectively. As of September 30, 2017, we had an accumulated deficit of \$57.6 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 Private Molecular 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. To date, 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. To date, we have received \$1.0 million under the Takeda Collaboration 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.

We may receive 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 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 revenue from collaboration revenue and government grants. Grant revenue relates to our CPRIT grant for MT-3724. For the three months ending September 30, 2017 and 2016, we did not recognize any CPRIT grant revenues related to the pre-clinical and clinical development of MT-3724. For the nine months ended September 30, 2017 and 2016, we recognized \$0.2 million and \$1.5 million in CPRIT grant revenues related to the pre-clinical and clinical development of 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. Collaboration 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. We will recognize revenue from these agreements in accordance with FASB ASC Topic 605, Revenue Recognition ("ASC 605"). Under ASC 605, revenue is recognized when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) the seller's price to the buyer is fixed or determinable; and (iv) collectability is reasonably assured. Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in our balance sheet. For the three and nine months ended September 30, 2017, we recognized \$0.6 million and \$1.9 million in collaboration revenue related to research collaboration agreements. For the three months ended September 30, 2016, no revenue was recognized in collaboration 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 commercializes 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 (“cGMP”) manufacturing of drug substances and drug products by contract manufacturers;
- fees and other costs paid to clinical trials sites and clinical research organizations (“CROs”) in connection with the performance of clinical trials and preclinical testing;
- costs of laboratory supplies and small equipment, including maintenance; and
- depreciation of long-lived assets.

For the three months ended September 30, 2017 and 2016, we incurred research and development costs of \$2.5 million and \$2.3 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 advances 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 FDA, the EMA or other regulatory authority were to require us to conduct pre-clinical and clinical studies beyond those which we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of our clinical development programs.

### ***General and Administrative Expenses***

Our general and administrative expenses consist principally of:

- salaries for employees other than research and development staff, including stock-based compensation expenses;
- professional fees for auditors and other consulting expenses not related to research and development activities;
- professional fees for legal services not related to the protection and maintenance of our intellectual property;
- 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) primarily consists of loss on conversion of notes and change in fair value of warrant liabilities.

### **Results of Operations**

The table below summarizes our results of operations for the three and nine months ended September 30, 2017 and 2016 (in thousands).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Grant revenue	\$ —	\$ —	\$ 167	\$ 1,526
Collaboration revenue	648	—	2,408	—
Research and development expenses	(2,522)	(2,271)	(4,829)	(7,178)
General and administrative expenses	(3,996)	(810)	(8,233)	(2,553)
Loss from operations	(5,870)	(3,081)	(10,487)	(8,205)
Other income (expense), net	(5,098)	(117)	(5,740)	(277)
Interest income (expense), net	1	6	2	18
Net loss	<u>\$ (10,967)</u>	<u>\$ (3,192)</u>	<u>\$ (16,225)</u>	<u>\$ (8,464)</u>

### ***Grant Revenue***

There was no Grant revenue during the three months ended September 30, 2017 or 2016. Grant revenue decreased \$1.4 million during the nine months ended September 30, 2017 compared to nine months ended September 30, 2016. The decrease was primarily attributable to the decrease in CPRIT grant revenues recognized due to higher drug manufacturing related costs for MT-3724 in 2016.

### ***Collaboration Revenue***

Collaborations revenue increased \$0.6 million and \$2.4 million during the three and nine months ended September 30, 2017 compared to the three and nine months ended September 30, 2016. The increase was mainly attributed to the recognition of collaboration revenue from our collaboration with Takeda on a proportional performance model as research and development services are performed.

### ***Research and Development Expenses***

The table below summarizes our research and development expenses for the three and nine months ended September 30, 2017 and 2016 (in thousands).

Research and development expenses by cost type:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Employee compensation	\$ 983	\$ 512	\$ 1,780	\$ 1,460
Program costs	1,226	1,483	2,449	5,114
Laboratory costs	222	140	434	357
Other research and development costs	91	136	166	247
Total research and development expenses	<u>\$ 2,522</u>	<u>\$ 2,271</u>	<u>\$ 4,829</u>	<u>\$ 7,178</u>

Research and development costs increased \$0.2 million during the three months ended September 30, 2017 as compared to the three months ended three months ended September 30, 2016. The increase was primarily due to costs related to the merger.

Research and development costs decreased \$2.4 million during the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016. The decrease was primarily due to a decrease of \$2.7 million in outsourced costs related to our MT-3724 program.

From a program perspective, all of our research and development expenses relate to the discovery and development of ETBs.

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 \$3.2 million and \$5.6 million during the three and nine months ended September 30, 2017 compared to the three and nine months ended September 30, 2016, respectively. The increase was primarily attributable to increased legal and accounting fees related to the Merger and being a publicly traded company.

#### ***Other income (expense).***

The increase in Other expenses for the three and nine months ended September 30, 2017 was primarily due to a \$4.7 million loss recording as part of the Merger, related to the conversion of convertible notes to common stock.

### **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 \$57.6 million through September 30, 2017. 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 September 30, 2017 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, reverse merger, 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 our inception, we raised gross proceeds of \$78.2 million from private placements of equity securities, including \$40 million from the equity financing in August 2017, and \$20 million from the Takeda Common Stock Purchase in August 2017. Since our inception, we have also received aggregate gross proceeds of \$3.5 million from our collaborators, received \$18.2 million in grants from governmental bodies, 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 received \$15.4 million from Threshold.

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.

We entered into a loan and security agreement with SVB (the “SVB Loan Agreement”) on April 30, 2015, which allows for aggregate borrowings of up to \$6.0 million, subject to our achievement of certain milestones. We borrowed an aggregate of \$6.0 million under the SVB Loan Agreement through September 30, 2017. We paid \$1.8 million in principal and approximately \$187,000 in interest for the nine months ended September 30, 2017. The loan matures on April 30, 2019 and is secured by substantially all our assets.

As of September 30, 2017, we had cash and cash equivalents of \$68.2 million. As of December 31, 2016, we had cash and cash equivalents of \$1.7 million.

## Cash Flows

(in thousands)	Nine Months Ended September 30,	
	2017	2016
Net cash used in operating activities	\$ (6,354)	\$ (8,197)
Net cash provided by / (used in) investing activities	10,447	(396)
Net cash provided by financing activities	62,372	5,980
Net increase (decrease) in cash and cash equivalents	<u>\$ 66,465</u>	<u>\$ (2,613)</u>

The decrease in net cash used in operating activities to \$6.6 million for the nine months ended September 30, 2017 from \$8.2 million for the nine months ended September 30, 2016 was primarily due to an increase in accounts payable.

The increase in net cash provided by investing activities to \$10.4 million for the nine months ended September 30, 2017 from \$0.4 million for the nine months ended September 30, 2016 was primarily due to the cash received from the merger transaction.

The increase in net cash provided by financing activities to \$62.3 million for the nine months ended September 30, 2017 from \$6.0 million for the nine months ended September 30, 2016 was primarily due to the receipt in August 2017 of \$57.8 million in proceeds from the issuance of common stock and warrants.

## Operating and Capital Expenditure Requirements

Other than for one year, we have not achieved profitability since our inception and had an accumulated deficit of \$57.7 million as of September 30, 2017. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seeks 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 expands 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;
- initiate other Phase Ib and 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;
- potentially establish a sales, marketing and distribution infrastructure and scales 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 encounters 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.

The table below summarizes our contractual obligations at September 30, 2017 (in thousands).

	Payments due by period				
	Total	2017	2018-2020	2021-2022	2023-
Operating lease obligations	\$ 5,681	\$ 177	\$ 3,224	\$ 1,793	\$ 486
Capital lease obligations	121	13	109	0	0
Debt obligations	4,145	600	3,545	0	0
Total	<u>\$ 9,947</u>	<u>\$ 790</u>	<u>\$ 6,878</u>	<u>\$ 1,793</u>	<u>\$ 486</u>

### ***Critical Accounting Policies and Use of Estimates***

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires management to make estimates and assumptions that affect reported amounts of assets and liabilities as of the date of the balance sheet and reported amounts of revenues and expenses for the periods presented. Management makes estimates and exercises judgment in income taxes, revenue recognition, research and development expenses, stock-based compensation and preferred stock. Judgments must also be made about the disclosure of contingent liabilities. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We periodically evaluate our estimates and judgments, including those described in greater detail below, in light of changes in circumstances, facts and experience.

We have identified the following accounting policies that we believe require application of management's most subjective judgments, often requiring the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Our actual results could differ from these estimates and such differences could be material.

#### ***Income Taxes***

We record income taxes in accordance with ASC 740, Accounting for Income Taxes ("ASC 740"). Since inception, we have not recorded a provision for income taxes due to reported net losses in each year. However, we have accumulated net operating loss carryforwards during this time. For further information regarding our accounting for income taxes, please see Note 13 ("Income Taxes") to our unaudited condensed financial statements for the three and nine months ended September 30, 2017, included in this Quarterly Report on form 10-Q.

#### ***Revenue Recognition***

The grants we have received from governmental bodies, such as CPRIT, are conditional cost reimbursement grants, and we recognize revenue as allowable costs are paid. Amounts collected in excess of revenue recognized are recorded as deferred revenue.

The collaboration and option agreements with certain of our customers are multiple-element arrangements under ASC 605-25. As such, contract elements which do not have stand-alone value are combined into those contract deliverables with value. Thus, revenue is recognized for each deliverable under the contract according to the method appropriate for each deliverable. For further information regarding our revenue recognition, please see Note 1 ("Organization and summary of significant accounting policies") to our unaudited condensed financial statements for the three and nine months ended September 30, 2017, included in this Quarterly Report on form 10-Q.

#### ***Research and Development Expenses***

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our staff to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors and clinical trial sites in connection with research and development activities for which we have not yet been invoiced.

We record our expenses related to research and development activities based on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expenses. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in our reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

#### ***Stock-Based Compensation***

Our accounts for stock-based compensation expense related to stock options granted to employees, non-employees, and members of our board of directors under our 2014 Equity Incentive Plan, as amended, and our 2009 Equity Incentive Plan, by estimating the fair value of each stock option or award on the date of grant using the Black-Scholes model. We recognize stock-based compensation expense on a straight-line basis over the vesting term.

#### ***Recent Accounting Pronouncements Not Yet Adopted***

For a discussion of recently issued accounting pronouncements and interpretations not yet adopted by us, please see Note 1 (“Organization and Summary of Significant Accounting Policies”) to our unaudited condensed financial statements for the three and nine months ended September 30, 2017, included in this Quarterly Report on form 10-Q.

#### ***Off-Balance Sheet Arrangements***

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

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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 September 30, 2017. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, 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 September 30, 2017, 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 material weaknesses in Private Molecular's internal controls 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. Specifically, Private Molecular did not appropriately design and implement controls over the review and approval of manual journal entries and the related supporting journal entry calculations.

Following the close of the Merger, 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 implementing a more robust review, and increasing the supervision and monitoring of 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 the fiscal quarter ended September 30, 2017 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

As we previously disclosed, on June 20, 2017, a purported stockholder of Threshold filed a putative class action complaint against Threshold and members of its Board in the United States District Court for the Northern District of California. The lawsuit was settled pursuant to a Settlement Agreement entered into on September 14, 2017, between Victor Pariso and Ron Welk, as Plaintiffs, and the Company.

### ITEM 1A. RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and all information contained in this report before you decide to purchase our common stock. If any of the possible adverse events described below actually occurs, we may be unable to conduct our business as currently planned and our financial condition and operating results could be harmed. In addition, the trading price of our common stock could decline due to the occurrence of any of the events described below, and you may lose all or part of your investment.*

#### 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.

***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 after legal restrictions on resale discussed in our proxy statement/prospectus/information statement lapse, the trading price of our common stock could decline. We have outstanding a total of approximately 26,895,230 shares of common stock. Of the 26,895,230 shares of common stock, 12,006,553 shares will be available for sale in the public market beginning 180 days after the closing of the merger as a result of the expiration of lock-up or similar agreements between us and certain stockholders. All other outstanding shares of common stock will be freely tradable, without restriction, in the public market. In addition, shares of common stock that are subject to outstanding options of Private Molecular have become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act. If these shares are sold, the trading price of our common stock could decline.

***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 consists of the 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 and our stockholders may not be able to resell their shares of common stock for a profit, if at all.***

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 never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

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

Following the completion of the merger, the concurrent financing and Takeda equity financing, as of November 1, 2017, our principal stockholders beneficially own, in the aggregate, approximately 70.0% 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 32.6% of our shares, and Longitude Venture Partners III, L.P. and its affiliates and Millennium Pharmaceuticals, Inc. own approximately 15.3% and 10.9%, 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 proceeds from the concurrent financing and Takeda equity financing and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.***

We have broad discretion over the use of proceeds from the concurrent financing and Takeda equity financing. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply the net proceeds of the concurrent financing and Takeda equity financing effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use the net proceeds from the concurrent financing or Takeda equity financing.

#### **Risks Related to Our Financial Condition and Capital Requirements**

***We have incurred losses since its inception, has a limited operating history on which to assess our business, and anticipates 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 \$17.2 million for the nine months ended September 30, 2017. As of September 30, 2017, we had an accumulated deficit of \$50.3 million.

As of September 30, 2017, we had cash and cash equivalents of \$68.2 million. In August 2017, we raised \$60 million through private placements of 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 its 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 candidate;
- continue efforts to discover new product candidates;
- undertake the manufacturing of our product candidates or increases 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 material weaknesses 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 material weaknesses in our internal controls 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.

The material weaknesses related to our inability to prepare accurate financial statements, resulting from a lack of adequate accounting personnel to timely and appropriately account for and disclose the impact of complex, non-routine transactions in accordance with U.S. GAAP. These non-routine transactions impacted the recording of equity-based compensation, cash-flow presentations, revenue, and related disclosures. In response to these material weaknesses, we evaluated our historical financial and operations data for further deficiencies and instituted additional control procedures around the research and recording of non-recurring transactions. Additionally, we are currently working to remediate these material weaknesses through the reallocation of existing internal resources and retaining third-party consultants to help enhance its internal controls over financial reporting. There can be no assurance that these efforts will remediate the material weaknesses or avoid future weaknesses or deficiencies. Any failure to remediate the material weaknesses 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 will be required to assess 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 weaknesses, 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 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 its 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, meet regulatory requirements and our supply needs in sufficient quantities to meet market demand for our product candidates, if approved;
- 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;
- 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 its 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, including the issuance of shares of capital stock by the combined company in the contemplated financing concurrent with the completion of the merger, 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 its 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 Investigational New Drug, or 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 its product candidates for use in clinical trials.

Any inability to successfully complete clinical development and obtain regulatory approval for one or more of its 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 its 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 technologies may encounter setbacks and difficulties that regulators and investors may attribute to our product candidates, whether appropriate or not.



***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. To date, no ETB therapeutics have been approved in the United States.***

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. Our future success depends on our successful development of one or more viable product candidates. Currently, only one of our product candidates, MT-3724, is in clinical development, and the remainder of our product candidates are in preclinical development. 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, 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 its 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.

***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. 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. Serious adverse events, or 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.

***We are heavily dependent on the success of our product candidates, the most advanced of which is in the early stages of clinical development. 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.***

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 in Phase I clinical trials. 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. 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.

In addition, 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.

***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 its 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 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 prevalence of non-Hodgkin's lymphoma in the United States is that an estimated 72,580 new cases and 20,150 deaths will be 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.

***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 plans 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 its 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 timeframe. 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 we believe that 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, its 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.

### **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, products 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, products, product candidates and their uses from unauthorized use by third parties to the extent that valid and enforceable patents, effectively protected trade secrets, or other regulatory exclusivities, 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 future collaboration partners may not have been the first to make the inventions covered by pending patent applications or issued patents;
- we or our 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 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 future collaboration partners' pending patent applications may not result in issued patents;
- we or our 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 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 future collaboration partners' products, compositions and methods may not be patentable;
- others may design around our or our 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 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 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 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 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, 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 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 exclusivity, for our product candidates, we may not be able to compete effectively and our business and results of operations would be harmed.

***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 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 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 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 will be 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. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, 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-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 future collaboration partners’ patents do successfully issue and even if such patents cover 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 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 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 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 establish infringement, 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 our 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 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 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 our competitors or 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 any 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.

***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.

**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 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.

In addition, we do not currently have the capability to manufacture product candidates for use in the conduct of our clinical trials, and we 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. We plan to rely on third-party manufacturers, and their responsibilities will include purchasing from third-party suppliers the materials necessary to produce our product candidates for our clinical trials and regulatory approval. We expect there to be a limited number of suppliers for some of the raw materials that we expect to use to manufacture our product candidates, and we may not be able to identify alternative suppliers to prevent a possible disruption of the manufacture of our product candidates for our clinical trials, and, if approved, ultimately for commercial sale. Although we generally do not expect to begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the trial, any significant delay or discontinuity in the supply of a product candidate, or the raw materials or other material components in the manufacture of the product candidate, could delay completion of our clinical trials and potential timing for regulatory approval of our product candidates, which would harm our business and results of operations.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates and our current costs to manufacture our drug products may not be commercially feasible, and the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, 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 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.***

Even if we are successful in entering into a collaboration with respect to the development and/or commercialization of one or more product candidates, there is no guarantee that the collaboration 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 periodically 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 the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, 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, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right owned by a third party. With respect to consultants, we 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 prevalence of non-Hodgkin's B-cell lymphoma is that an estimated 72,580 new cases and 20,150 deaths will be attributable to the disease in the United States in 2016, 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, Mentrisk Biotech, Merrimack Pharmaceuticals, Spectrum Pharmaceuticals 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. 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 December 31, 2016, we had 24 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, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business. 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.**

On August 1, 2017, we closed on a private placement for the sale of an aggregate of 5,793,063 units (the "Units") having an aggregate purchase price of \$40.0 million, each such Unit consisting of (i) one (1) share of our common stock and (ii) a warrant to purchase 0.50 shares of our common stock (the "Private Placement"). Following the consummation of the Merger and Private Placement, in connection with the execution of the Takeda Multi-Target Agreement, Takeda purchased 2,922,993 shares of our common stock, at a price per share of \$6.84, for an aggregate purchase price of \$20 million (the "Takeda Financing"). We intend to use the proceeds from the Private Placement and the Takeda Financing for general corporate purposes and to fund our working capital needs.

## **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## **ITEM 5. OTHER INFORMATION**

None.

## ITEM 6. EXHIBITS

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.

<b>Exhibit Number</b>	<b>Description</b>
2.1	Agreement and Plan of Merger and Reorganization, dated March 16, 2017, by and among the Threshold, Private Molecular and Trojan Merger Sub, Inc. (incorporated by reference to Annex A to the Company's Registration Statement on Form S-4/A, as filed with the SEC on June 27, 2017)
3.1	Amended and Restated Certificate of Incorporation of the Company, as subsequently amended (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K filed on March 6, 2014)
3.2	Certificate of Amendment (Name Change) of Amended and Restated Certificate of Incorporation of the Company, dated August 1, 2017 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 7, 2017)
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Company, dated August 1, 2017 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 1, 2017)
3.4	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed on November 7, 2016.)
10.1†	Multi-License Collaboration and License Agreement, dated June 23, 2017, between Private Molecular and Millennium Pharmaceuticals, Inc. (a wholly owned subsidiary of Takeda Pharmaceutical Company Ltd.) (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K/A, as filed with the SEC on October 17, 2017)
10.2+	Form of Indemnification Agreement between the Company and each of its directors and executive officers (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 7, 2017)
10.3	Securities Purchase Agreement, dated August 1, 2017, among the Company and the investors named therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on August 7, 2017)
10.4	Registration Rights Agreement, dated August 1, 2017, among the Company and the investors named therein (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed with the SEC on August 7, 2017)
10.5	Form of Warrant issued in the Private Placement (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, as filed with the SEC on August 7, 2017)
10.6+	Amended and Restated Executive Employment Agreement, dated April 22, 2016, between Private Molecular and Eric E. Poma, Ph.D. (incorporated by reference to Exhibit 10.43 to the Company's Registration Statement on Form S-4/A, as filed with the SEC on May 15, 2017)
10.7+	Amended and Restated Executive Employment Agreement, dated April 22, 2016, between Private Molecular and Jason Kim (incorporated by reference to Exhibit 10.44 to the Company's Registration Statement on Form S-4/A, as filed with the SEC on May 15, 2017)
10.8†	Research Collaboration and Option Agreement, dated as of October 31, 2016, by and between Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company, Ltd. and Molecular Templates, Inc. (incorporated by reference to Exhibit 10.31 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017)
10.9†	Cancer Research Grant Contract, dated as of November 7, 2012, by and between the Cancer Prevention & Research Institute of Texas and Private Molecular (incorporated by reference to Exhibit 10.33 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017)
10.10	Note Purchase Agreement, dated as of March 16, 2017, by and between Threshold and Private Molecular (incorporated by reference to Exhibit 10.39 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017)

Exhibit Number	Description
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934 as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934 as amended.
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350.
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
*	Furnished herewith. This certification is not deemed filed for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and is not deemed to be incorporated by reference into any filing under the Securities the Exchange Act.
†	Confidential treatment has been requested or granted as to certain portions, which portions have been omitted and filed separately with the SEC.
+	Management contract or compensatory plans or arrangements.

## EXHIBIT INDEX

Exhibit Number	Description
2.1	<a href="#"><u>Agreement and Plan of Merger and Reorganization, dated March 16, 2017, by and among the Threshold, Private Molecular and Trojan Merger Sub, Inc. (incorporated by reference to Annex A to the Company's Registration Statement on Form S-4/A, as filed with the SEC on June 27, 2017)</u></a>
3.1	<a href="#"><u>Amended and Restated Certificate of Incorporation of the Company, as subsequently amended (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K filed on March 6, 2014)</u></a>
3.2	<a href="#"><u>Certificate of Amendment (Name Change) of Amended and Restated Certificate of Incorporation of the Company, dated August 1, 2017 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 7, 2017)</u></a>
3.3	<a href="#"><u>Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Company, dated August 1, 2017 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 1, 2017)</u></a>
3.4	<a href="#"><u>Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed on November 7, 2016.)</u></a>
10.1†	<a href="#"><u>Multi-License Collaboration and License Agreement, dated June 23, 2017, between Private Molecular and Millennium Pharmaceuticals, Inc. (a wholly owned subsidiary of Takeda Pharmaceutical Company Ltd.) (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K/A, as filed with the SEC on October 17, 2017)</u></a>
10.2+	<a href="#"><u>Form of Indemnification Agreement between the Company and each of its directors and executive officers (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, as filed with the SEC on August 7, 2017)</u></a>
10.3	<a href="#"><u>Securities Purchase Agreement, dated August 1, 2017, among the Company and the investors named therein (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, as filed with the SEC on August 7, 2017)</u></a>
10.4	<a href="#"><u>Registration Rights Agreement, dated August 1, 2017, among the Company and the investors named therein (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, as filed with the SEC on August 7, 2017)</u></a>
10.5	<a href="#"><u>Form of Warrant issued in the Private Placement (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K, as filed with the SEC on August 7, 2017)</u></a>
10.6+	<a href="#"><u>Amended and Restated Executive Employment Agreement, dated April 22, 2016, between Private Molecular and Eric E. Poma, Ph.D. (incorporated by reference to Exhibit 10.43 to the Company's Registration Statement on Form S-4/A, as filed with the SEC on May 15, 2017)</u></a>
10.7+	<a href="#"><u>Amended and Restated Executive Employment Agreement, dated April 22, 2016, between Private Molecular and Jason Kim (incorporated by reference to Exhibit 10.44 to the Company's Registration Statement on Form S-4/A, as filed with the SEC on May 15, 2017)</u></a>
10.8†	<a href="#"><u>Research Collaboration and Option Agreement, dated as of October 31, 2016, by and between Millennium Pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company, Ltd. and Molecular Templates, Inc. (incorporated by reference to Exhibit 10.31 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017)</u></a>
10.9†	<a href="#"><u>Cancer Research Grant Contract, dated as of November 7, 2012, by and between the Cancer Prevention &amp; Research Institute of Texas and Private Molecular (incorporated by reference to Exhibit 10.33 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017)</u></a>
10.10	<a href="#"><u>Note Purchase Agreement, dated as of March 16, 2017, by and between Threshold and Private Molecular (incorporated by reference to Exhibit 10.39 to the Company's Registration Statement on Form S-4, as filed with the SEC on May 15, 2017)</u></a>
31.1	<a href="#"><u>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934 as amended.</u></a>



Exhibit Number	Description
31.2	<a href="#">Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934 as amended.</a>
32.1*	<a href="#">Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350.</a>
32.2*	<a href="#">Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350.</a>
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 Act or the Exchange Act.

† Confidential treatment has been requested or granted as to certain portions, which portions have been omitted and filed separately with the SEC.

+ Management contract or compensatory plans or arrangements.

## SIGNATURES

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

Molecular Templates, Inc.

Date: November 14, 2017

/s/ Eric E. Poma

Eric E. Poma, Ph.D.

Chief Executive Officer and Chief Scientific Officer

(Principal Executive Officer)

Date: November 14, 2017

/s/ Jason S. Kim

Jason S. Kim

President and Chief Operating Officer

(Principal Financial and Accounting Officer)

CERTIFICATION

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: November 14, 2017

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

Eric E. Poma, Ph.D.

Chief Executive Officer and Chief Scientific Officer  
(Principal Executive Officer)

CERTIFICATION

I, Jason S. Kim, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Molecular Templates, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer (s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2017

/s/ Jason S. Kim  
Jason S. Kim  
President and Chief Operating Officer  
(Principal 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 September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Eric E. Poma, Ph.D., Chief Executive Officer and Chief Scientific Officer of the Company, 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: November 14, 2017

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

Eric E. Poma, Ph.D.  
Chief Executive Officer and Chief Scientific Officer  
(Principal 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 September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jason S. Kim, President and Chief Operating Officer and Acting Chief Financial Officer of the Company, 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: November 14, 2017

/s/ Jason S. Kim  
Jason S. Kim  
President and Chief Operating Officer and Acting Chief Financial Officer  
(Principal Financial Officer)

